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COMPILATION OF DOMESTIC DRUG CONTROL LAWS

(As Amended Through the End of 2004)

PREPARED FOR THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

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LETTER OF SUBMITTAL

CONGRESSIONAL RESEARCH SERVICE,
THE LIBRARY OF CONGRESS,
Washington, DC, May 2, 2005.

Hon. MARK E. SOUDER,
Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Government Reform Committee, U.S. House of Representatives

DEAR MR. CHAIRMAN: In response to your request, I am submitting the attached compilation of Federal domestic drug control laws. The volume contains the principal public laws relating to the control, within the United States, of narcotics and other illicit drugs. Related provisions of law, drawn from 23 separate titles of the U.S. Code, are also included, in the order that they appear in the Code. An appendix contains relevant Executive orders.

The compilation was prepared by Mark Eddy, Specialist in Drug Control Policy of the Domestic Social Policy Division, with the assistance of Suzanne Kayne. Charles Doyle, Senior Specialist of the American Law Division, provided legal advice, and Angela Napili, Information Research Specialist of the Knowledge Services Group, performed the electronic retrieval of documents.

We hope this compilation of laws meets the needs of your subcommittee and that it is useful to other committees and Members of Congress by bringing together in one volume the many provisions of law that address the problem of drug abuse in American society.

Sincerely,

DANIEL P. MULHOLLAN,
Director.

NOTE ON THE CONTENTS OF THIS COMPILATION

This volume contains the Federal laws currently in force, as amended through the end of 2004, that were passed by the U.S. Congress to control the use and abuse of controlled substances within the United States and its outlying areas. By agreement with the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the House Committee on Government Reform, which asked the Congressional Research Service (CRS) to prepare this volume, Federal grant programs to States and localities are beyond the scope of this compilation. Also omitted are Federal laws and treaties relating to international drug trafficking, which CRS compiles separately for the Senate Caucus on International Narcotics Control and the House Committee on International Relations.

This volume begins with the principal Federal domestic drug control laws in public law format, along with *Reorganization Plan No. 2 of 1973*, which created the Drug Enforcement Administration. Titles 21 and 42 of the U.S. Code, where these principal drug control laws are codified, have not been enacted into positive law, so amendments and additions to these laws must be drafted in public law format and style.

Additional provisions of law, as shown in the table of contents, are presented in the order they appear in the U.S. Code. Titles 7, 8, 12, 16, 19, 20, 25, 26, 29, 41, 47, and 48 have also not been enacted into positive law. Accordingly, the headers for provisions of law codified to these titles show, for the convenience of lawmakers, the corresponding public law names and numbers. The remaining titles have been enacted into positive law. In these cases, amendments or new provisions of law codified to these sections would be drafted in the language and format of the U.S. Code. The headers to these provisions of law, both in the table of contents and in the body of the compilation, therefore omit the corresponding public law names and numbers.

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OFFICE OF NATIONAL DRUG CONTROL POLICY REAUTHORIZATION ACT OF 1998[1]

SEC. 701. [21 U.S.C. 1701 note] SHORT TITLE.

This title may be cited as the "Office of National Drug Control Policy Reauthorization Act of 1998".

SEC. 702. [21 U.S.C. 1701] DEFINITIONS.

In this title:

(1) DEMAND REDUCTION.—The term "demand reduction" means any activity conducted by a National Drug Control Program agency, other than an enforcement activity, that is intended to reduce the use of drugs, including—

(A) drug abuse education;
(B) drug abuse prevention;
(C) drug abuse treatment;
(D) drug abuse research;
(E) drug abuse rehabilitation;
(F) drug-free workplace programs; and
(G) drug testing.

(2) DIRECTOR.—The term "Director" means the Director of National Drug Control Policy.

(3) DRUG.—The term "drug" has the meaning given the term "controlled substance" in section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6)).

(4) DRUG CONTROL.—The term "drug control" means any activity conducted by a National Drug Control Program agency involving supply reduction or demand reduction.

(5) FUND.—The term "Fund" means the fund established under section 703(d).

(6) NATIONAL DRUG CONTROL PROGRAM.—The term "National Drug Control Program" means programs, policies, and activities undertaken by National Drug Control Program agencies pursuant to the responsibilities of such agencies under the National Drug Control Strategy.

(7) NATIONAL DRUG CONTROL PROGRAM AGENCY.—The term "National Drug Control Program agency" means any agency that is responsible for implementing any aspect of the National Drug Control Strategy, including any agency that receives Federal funds to implement any aspect of the National Drug Control Strategy, but does not include any agency that receives funds for drug control activity solely under the National Foreign Intelligence Program, the Joint Military Intelligence Program or Tactical Intelligence and Related Activities, unless such agency has been designated—

(A) by the President; or

[1] Public Law 105–277 (Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999), Div. C, Title VII, Oct. 21, 1998, 112 Stat. 2681–670, 21 U.S.C. 1701 et seq.

(B) jointly by the Director and the head of the agency.

(8) NATIONAL DRUG CONTROL STRATEGY.—The term "National Drug Control Strategy" means the strategy developed and submitted to Congress under section 706.

(9) OFFICE.—Unless the context clearly implicates otherwise, the term "Office" means the Office of National Drug Control Policy established under section 703(a).

(10) STATE AND LOCAL AFFAIRS.—The term "State and local affairs" means domestic activities conducted by a National Drug Control Program agency that are intended to reduce the availability and use of drugs, including—

(A) coordination and facilitation of Federal, State, and local law enforcement drug control efforts;

(B) promotion of coordination and cooperation among the drug supply reduction and demand reduction agencies of the various States, territories, and units of local government; and

(C) such other cooperative governmental activities which promote a comprehensive approach to drug control at the national, State, territory, and local levels.

(11) SUPPLY REDUCTION.—The term "supply reduction" means any activity of a program conducted by a National Drug Control Program agency that is intended to reduce the availability or use of drugs in the United States and abroad, including—

(A) international drug control;

(B) foreign and domestic drug intelligence;

(C) interdiction; and

(D) domestic drug law enforcement, including law enforcement directed at drug users.

SEC. 703. [21 U.S.C. 1702] OFFICE OF NATIONAL DRUG CONTROL POLICY.

(a) ESTABLISHMENT OF OFFICE.—There is established in the Executive Office of the President an Office of National Drug Control Policy, which shall—

(1) develop national drug control policy;

(2) coordinate and oversee the implementation of that national drug control policy;

(3) assess and certify the adequacy of national drug control programs and the budget for those programs; and

(4) evaluate the effectiveness of the national drug control programs.

(b) DIRECTOR AND DEPUTY DIRECTORS.—

(1) DIRECTOR.—There shall be at the head of the Office a Director of National Drug Control Policy.

(2) DEPUTY DIRECTOR OF NATIONAL DRUG CONTROL POLICY.—There shall be in the Office a Deputy Director of National Drug Control Policy, who shall assist the Director in carrying out the responsibilities of the Director under this title.

(3) OTHER DEPUTY DIRECTORS.—There shall be in the Office—

(A) a Deputy Director for Demand Reduction, who shall be responsible for the activities described in subparagraphs (A) through (G) of section 702(1);

(B) a Deputy Director for Supply Reduction, who shall be responsible for the activities described in subparagraphs (A) through (C) of section 702(11); and

(C) a Deputy Director for State and Local Affairs, who shall be responsible for the activities described in subparagraphs (A) through (C) of section 702(10) and subparagraph (D) of section 702(11).

(c) ACCESS BY CONGRESS.—The location of the Office in the Executive Office of the President shall not be construed as affecting access by Congress, or any committee of the House of Representatives or the Senate, to any—

(1) information, document, or study in the possession of, or conducted by or at the direction of the Director; or

(2) personnel of the Office.

(d) OFFICE OF NATIONAL DRUG CONTROL POLICY GIFT FUND.—

(1) ESTABLISHMENT.—There is established in the Treasury of the United States a fund for the receipt of gifts, both real and personal, for the purpose of aiding or facilitating the work of the Office under section 704(c).

(2) CONTRIBUTIONS.—The Office may accept, hold, and administer contributions to the Fund.

(3) USE OF AMOUNTS DEPOSITED.—Amounts deposited in the Fund are authorized to be appropriated, to remain available until expended for authorized purposes at the discretion of the Director.

SEC. 704. [21 U.S.C. 1703] APPOINTMENT AND DUTIES OF DIRECTOR AND DEPUTY DIRECTORS.

(a) APPOINTMENT.—

(1) IN GENERAL.—The Director, the Deputy Director of National Drug Control Policy, the Deputy Director for Demand Reduction, the Deputy Director for Supply Reduction, and the Deputy Director for State and Local Affairs, shall each be appointed by the President, by and with the advice and consent of the Senate, and shall serve at the pleasure of the President. In appointing the Deputy Director for Demand Reduction under this paragraph, the President shall take into consideration the scientific, educational or professional background of the individual, and whether the individual has experience in the fields of substance abuse prevention, education, or treatment.

(2) DUTIES OF DEPUTY DIRECTOR OF NATIONAL DRUG CONTROL POLICY.—The Deputy Director of National Drug Control Policy shall—

(A) carry out the duties and powers prescribed by the Director; and

(B) serve as the Director in the absence of the Director or during any period in which the office of the Director is vacant.

(3) DESIGNATION OF OTHER OFFICERS.—In the absence of the Deputy Director, or if the Office of the Deputy Director is vacant, the Director shall designate such other permanent employee of the Office to serve as the Director, if the Director is absent or unable to serve.

(4) PROHIBITION.—No person shall serve as Director or a Deputy Director while serving in any other position in the Federal Government.

(5) PROHIBITION ON POLITICAL CAMPAIGNING.—Any officer or employee of the Office who is appointed to that position by the President, by and with the advice and consent of the Senate, may not participate in Federal election campaign activities, except that such official is not prohibited by this paragraph from making contributions to individual candidates.

(b) RESPONSIBILITIES.—The Director—

(1) shall assist the President in the establishment of policies, goals, objectives, and priorities for the National Drug Control Program;

(2) shall promulgate the National Drug Control Strategy under section 706(a) and each report under section 706(b) in accordance with section 706;

(3) shall coordinate and oversee the implementation by the National Drug Control Program agencies of the policies, goals, objectives, and priorities established under paragraph (1) and the fulfillment of the responsibilities of such agencies under the National Drug Control Strategy and make recommendations to National Drug Control Program agency heads with respect to implementation of Federal counter-drug programs;

(4) shall make such recommendations to the President as the Director determines are appropriate regarding changes in the organization, management, and budgets of Federal departments and agencies engaged in drug enforcement, and changes in the allocation of personnel to and within those departments and agencies, to implement the policies, goals, priorities, and objectives established under paragraph (1) and the National Drug Control Strategy;

(5) shall consult with and assist State and local governments with respect to the formulation and implementation of National Drug Control Policy and their relations with the National Drug Control Program agencies;

(6) shall appear before duly constituted committees and subcommittees of the House of Representatives and of the Senate to represent the drug policies of the executive branch;

(7) shall notify any National Drug Control Program agency if its policies are not in compliance with the responsibilities of the agency under the National Drug Control Strategy, transmit a copy of each such notification to the President, and maintain a copy of each such notification;

(8) shall provide, by July 1 of each year, budget recommendations, including requests for specific initiatives that are consistent with the priorities of the President under the National Drug Control Strategy, to the heads of departments and agencies with responsibilities under the National Drug Control Program, which recommendations shall—

(A) apply to the next budget year scheduled for formulation under the Budget and Accounting Act of 1921, and each of the 4 subsequent fiscal years; and

(B) address funding priorities developed in the National Drug Control Strategy;

(9) may serve as representative of the President in appearing before Congress on all issues relating to the National Drug Control Program;

(10) shall, in any matter affecting national security interests, work in conjunction with the Assistant to the President for National Security Affairs;

(11) may serve as spokesperson of the Administration on drug issues;

(12) shall ensure that no Federal funds appropriated to the Office of National Drug Control Policy shall be expended for any study or contract relating to the legalization (for a medical use or any other use) of a substance listed in schedule I of section 202 of the Controlled Substances Act (21 U.S.C. 812) and take such actions as necessary to oppose any attempt to legalize the use of a substance (in any form) that—

(A) is listed in schedule I of section 202 of the Controlled Substances Act (21 U.S.C. 812); and

(B) has not been approved for use for medical purposes by the Food and Drug Administration;

(13) shall require each National Drug Control Program agency to submit to the Director on an annual basis (beginning in 1999) an evaluation of progress by the agency with respect to drug control program goals using the performance measures for the agency developed under section 706(c), including progress with respect to—

(A) success in reducing domestic and foreign sources of illegal drugs;

(B) success in protecting the borders of the United States (and in particular the Southwestern border of the United States) from penetration by illegal narcotics;

(C) success in reducing violent crime associated with drug use in the United States;

(D) success in reducing the negative health and social consequences of drug use in the United States; and

(E) implementation of drug treatment and prevention programs in the United States and improvements in the adequacy and effectiveness of such programs;

(14) shall submit to the Appropriations committees and the authorizing committees of jurisdiction of the House of Representatives and the Senate on an annual basis, not later than 60 days after the date of the last day of the applicable period, a summary of—

(A) each of the evaluations received by the Director under paragraph (13); and

(B) the progress of each National Drug Control Program agency toward the drug control program goals of the agency using the performance measures for the agency developed under section 706(c); and

(15) shall ensure that drug prevention and drug treatment research and information is effectively disseminated by National Drug Control Program agencies to State and local governments and nongovernmental entities involved in demand reduction by—

(A) encouraging formal consultation between any such agency that conducts or sponsors research, and any such agency that disseminates information in developing research and information product development agendas;

(B) encouraging such agencies (as appropriate) to develop and implement dissemination plans that specifically target State and local governments and nongovernmental entities involved in demand reduction; and

(C) developing a single interagency clearinghouse for the dissemination of research and information by such agencies to State and local governments and nongovernmental agencies involved in demand reduction.

(c) NATIONAL DRUG CONTROL PROGRAM BUDGET.—

(1) RESPONSIBILITIES OF NATIONAL DRUG CONTROL PROGRAM AGENCIES.—

(A) IN GENERAL.—For each fiscal year, the head of each department, agency, or program of the Federal Government with responsibilities under the National Drug Control Program Strategy shall transmit to the Director a copy of the proposed drug control budget request of the department, agency, or program at the same time as that budget request is submitted to their superiors (and before submission to the Office of Management and Budget) in the preparation of the budget of the President submitted to Congress under section 1105(a) of title 31, United States Code.

(B) SUBMISSION OF DRUG CONTROL BUDGET REQUESTS.—The head of each National Drug Control Program agency shall ensure timely development and submission to the Director of each proposed drug control budget request transmitted pursuant to this paragraph, in such format as may be designated by the Director with the concurrence of the Director of the Office of Management and Budget.

(2) NATIONAL DRUG CONTROL PROGRAM BUDGET PROPOSAL.—For each fiscal year, following the transmission of proposed drug control budget requests to the Director under paragraph (1), the Director shall, in consultation with the head of each National Drug Control Program agency—

(A) develop a consolidated National Drug Control Program budget proposal designed to implement the National Drug Control Strategy;

(B) submit the consolidated budget proposal to the President; and

(C) after submission under subparagraph (B), submit the consolidated budget proposal to Congress.

(3) REVIEW AND CERTIFICATION OF BUDGET REQUESTS AND BUDGET SUBMISSIONS OF NATIONAL DRUG CONTROL PROGRAM AGENCIES.—

(A) IN GENERAL.—The Director shall review each drug control budget request submitted to the Director under paragraph (1).

(B) REVIEW OF BUDGET REQUESTS.—

(i) INADEQUATE REQUESTS.—If the Director concludes that a budget request submitted under paragraph (1) is inadequate, in whole or in part, to implement the

objectives of the National Drug Control Strategy with respect to the department, agency, or program at issue for the year for which the request is submitted, the Director shall submit to the head of the applicable National Drug Control Program agency a written description of funding levels and specific initiatives that would, in the determination of the Director, make the request adequate to implement those objectives.

(ii) ADEQUATE REQUESTS.—If the Director concludes that a budget request submitted under paragraph (1) is adequate to implement the objectives of the National Drug Control Strategy with respect to the department, agency, or program at issue for the year for which the request is submitted, the Director shall submit to the head of the applicable National Drug Control Program agency a written statement confirming the adequacy of the request.

(iii) RECORD.—The Director shall maintain a record of each description submitted under clause (i) and each statement submitted under clause (ii).

(C) AGENCY RESPONSE.—

(i) IN GENERAL.—The head of a National Drug Control Program agency that receives a description under subparagraph (B)(i) shall include the funding levels and initiatives described by the Director in the budget submission for that agency to the Office of Management and Budget.

(ii) IMPACT STATEMENT.—The head of a National Drug Control Program agency that has altered its budget submission under this subparagraph shall include as an appendix to the budget submission for that agency to the Office of Management and Budget an impact statement that summarizes—

(I) the changes made to the budget under this subparagraph; and

(II) the impact of those changes on the ability of that agency to perform its other responsibilities, including any impact on specific missions or programs of the agency.

(iii) CONGRESSIONAL NOTIFICATION.—The head of a National Drug Control Program agency shall submit a copy of any impact statement under clause (ii) to the Senate and the House of Representatives at the time the budget for that agency is submitted to Congress under section 1105(a) of title 31, United States Code.

(D) CERTIFICATION OF BUDGET SUBMISSIONS.—

(i) IN GENERAL.—At the time a National Drug Control Program agency submits its budget request to the Office of Management and Budget, the head of the National Drug Control Program agency shall submit a copy of the budget request to the Director.

(ii) CERTIFICATION.—The Director—

(I) shall review each budget submission submitted under clause (i); and

(II) based on the review under subclause (I), if the Director concludes that the budget submission of a National Drug Control Program agency does not include the funding levels and initiatives described under subparagraph (B)—

(aa) may issue a written decertification of that agency's budget; and

(bb) in the case of a decertification issued under item (aa), shall submit to the Senate and the House of Representatives a copy of—

(aaa) the decertification issued under item (aa);

(bbb) the description made under subparagraph (B); and

(ccc) the budget recommendations made under subsection (b)(8).

(4) REPROGRAMMING AND TRANSFER REQUESTS.—

(A) IN GENERAL.—No National Drug Control Program agency shall submit to Congress a reprogramming or transfer request with respect to any amount of appropriated funds in an amount exceeding $5,000,000 that is included in the National Drug Control Program budget unless the request has been approved by the Director.

(B) APPEAL.—The head of any National Drug Control Program agency may appeal to the President any disapproval by the Director of a reprogramming or transfer request under this paragraph.

(d) POWERS OF THE DIRECTOR.—In carrying out subsection (b), the Director may—

(1) select, appoint, employ, and fix compensation of such officers and employees of the Office as may be necessary to carry out the functions of the Office under this title;

(2) subject to subsection (e)(3), request the head of a department or agency, or program of the Federal Government to place department, agency, or program personnel who are engaged in drug control activities on temporary detail to another department, agency, or program in order to implement the National Drug Control Strategy, and the head of the department or agency shall comply with such a request;

(3) use for administrative purposes, on a reimbursable basis, the available services, equipment, personnel, and facilities of Federal, State, and local agencies;

(4) procure the services of experts and consultants in accordance with section 3109 of title 5, United States Code, relating to appointments in the Federal Service, at rates of compensation for individuals not to exceed the daily equivalent of the rate of pay payable under level IV of the Executive Schedule under section 5311 of title 5, United States Code;

(5) accept and use gifts and donations of property from Federal, State, and local government agencies, and from the private sector, as authorized in section 703(d);

(6) use the mails in the same manner as any other department or agency of the executive branch;

(7) monitor implementation of the National Drug Control Program, including—

(A) conducting program and performance audits and evaluations; and

(B) requesting assistance from the Inspector General of the relevant agency in such audits and evaluations;

(8) transfer funds made available to a National Drug Control Program agency for National Drug Control Strategy programs and activities to another account within such agency or to another National Drug Control Program agency for National Drug Control Strategy programs and activities, except that—

(A) the authority under this paragraph may be limited in an annual appropriations Act or other provision of Federal law;

(B) the Director may exercise the authority under this paragraph only with the concurrence of the head of each affected agency;

(C) in the case of an interagency transfer, the total amount of transfers under this paragraph may not exceed 3 percent of the total amount of funds made available for National Drug Control Strategy programs and activities to the agency from which those funds are to be transferred;

(D) funds transferred to an agency under this paragraph may only be used to increase the funding for programs or activities [2] have been authorized by Congress; and

(E) the Director shall—

(i) submit to Congress, including to the Committees on Appropriations of the Senate and the House of Representatives, the authorizing committees for the Office, and any other applicable committees of jurisdiction, a reprogramming or transfer request in advance of any transfer under this paragraph in accordance with the regulations of the affected agency or agencies; and

(ii) annually submit to Congress a report describing the effect of all transfers of funds made pursuant to this paragraph or subsection (c)(4) during the 12-month period preceding the date on which the report is submitted;

(9) issue to the head of a National Drug Control Program agency a fund control notice described in subsection (f) to ensure compliance with the National Drug Control Program Strategy; and

(10) participate in the drug certification process pursuant to section 490 of the Foreign Assistance Act of 1961 (22 U.S.C. 2291j).

(e) PERSONNEL DETAILED TO OFFICE.—

(1) EVALUATIONS.—Notwithstanding any provision of chapter 43 of title 5, United States Code, the Director shall perform the evaluation of the performance of any employee detailed to the

[2] So in original. Probably should be "activities that".

Office for purposes of the applicable performance appraisal system established under such chapter for any rating period, or part thereof, that such employee is detailed to such office.

(2) COMPENSATION.—

(A) BONUS PAYMENTS.—Notwithstanding any other provision of law, the Director may provide periodic bonus payments to any employee detailed to the Office.

(B) RESTRICTIONS.—An amount paid under this paragraph to an employee for any period—

(i) shall not be greater than 20 percent of the basic pay paid or payable to such employee for such period; and

(ii) shall be in addition to the basic pay of such employee.

(C) AGGREGATE AMOUNT.—The aggregate amount paid during any fiscal year to an employee detailed to the Office as basic pay, awards, bonuses, and other compensation shall not exceed the annual rate payable at the end of such fiscal year for positions at level III of the Executive Schedule.

(3) MAXIMUM NUMBER OF DETAILEES.—The maximum number of personnel who may be detailed to another department or agency (including the Office) under subsection (d)(2) during any fiscal year is—

(A) for the Department of Defense, 50; and

(B) for any other department or agency, 10.

(f) FUND CONTROL NOTICES.—

(1) IN GENERAL.—A fund control notice may direct that all or part of an amount appropriated to the National Drug Control Program agency account be obligated by—

(A) months, fiscal year quarters, or other time periods; and

(B) activities, functions, projects, or object classes.

(2) UNAUTHORIZED OBLIGATION OR EXPENDITURE PROHIBITED.—An officer or employee of a National Drug Control Program agency shall not make or authorize an expenditure or obligation contrary to a fund control notice issued by the Director.

(3) DISCIPLINARY ACTION FOR VIOLATION.—In the case of a violation of paragraph (2) by an officer or employee of a National Drug Control Program agency, the head of the agency, upon the request of and in consultation with the Director, may subject the officer or employee to appropriate administrative discipline, including, when circumstances warrant, suspension from duty without pay or removal from office.

(g) INAPPLICABILITY TO CERTAIN PROGRAMS.—The provisions of this section shall not apply to the National Foreign Intelligence Program, the Joint Military Intelligence Program and Tactical Intelligence and Related Activities unless the agency that carries out such program is designated as a National Drug Control Program agency by the President or jointly by the Director and the head of the agency.

(h) CONSTRUCTION.—Nothing in this Act shall be construed as derogating the authorities and responsibilities of the Director of

Central Intelligence contained in sections 104 and 504 of the National Security Act of 1947 or any other law.

SEC. 705. [21 U.S.C. 1704] COORDINATION WITH NATIONAL DRUG CONTROL PROGRAM AGENCIES IN DEMAND REDUCTION, SUPPLY REDUCTION, AND STATE AND LOCAL AFFAIRS.

(a) ACCESS TO INFORMATION.—

(1) IN GENERAL.—Upon the request of the Director, the head of any National Drug Control Program agency shall cooperate with and provide to the Director any statistics, studies, reports, and other information prepared or collected by the agency concerning the responsibilities of the agency under the National Drug Control Strategy that relate to—

(A) drug abuse control; or

(B) the manner in which amounts made available to that agency for drug control are being used by that agency.

(2) PROTECTION OF INTELLIGENCE INFORMATION.—

(A) IN GENERAL.—The authorities conferred on the Office and the Director by this title shall be exercised in a manner consistent with provisions of the National Security Act of 1947 (50 U.S.C. 401 et seq.). The Director of Central Intelligence shall prescribe such regulations as may be necessary to protect information provided pursuant to this title regarding intelligence sources and methods.

(B) DUTIES OF DIRECTOR.—The Director of Central Intelligence shall, to the maximum extent practicable in accordance with subparagraph (A), render full assistance and support to the Office and the Director.

(3) ILLEGAL DRUG CULTIVATION.—The Secretary of Agriculture shall annually submit to the Director an assessment of the acreage of illegal drug cultivation in the United States.

(b) CERTIFICATION OF POLICY CHANGES TO DIRECTOR.—

(1) IN GENERAL.—Subject to paragraph (2), the head of a National Drug Control Program agency shall, unless exigent circumstances require otherwise, notify the Director in writing regarding any proposed change in policies relating to the activities of that agency under the National Drug Control Program prior to implementation of such change. The Director shall promptly review such proposed change and certify to the head of that agency in writing whether such change is consistent with the National Drug Control Strategy.

(2) EXCEPTION.—If prior notice of a proposed change under paragraph (1) is not practicable—

(A) the head of the National Drug Control Program agency shall notify the Director of the proposed change as soon as practicable; and

(B) upon such notification, the Director shall review the change and certify to the head of that agency in writing whether the change is consistent with the National Drug Control Program.

(c) GENERAL SERVICES ADMINISTRATION.—The Administrator of General Services shall provide to the Director, in[3] a reimbursable

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basis, such administrative support services as the Director may request.

(d) ACCOUNTING OF FUNDS EXPENDED.—The Director shall—

(A) require the National Drug Control Program agencies to submit to the Director not later than February 1 of each year a detailed accounting of all funds expended by the agencies for National Drug Control Program activities during the previous fiscal year, and require such accounting to be authenticated by the Inspector General for each agency prior to submission to the Director; and

(B) submit to Congress not later than April 1 of each year the information submitted to the Director under subparagraph (A).

SEC. 706. [21 U.S.C. 1705] DEVELOPMENT, SUBMISSION, IMPLEMENTATION, AND ASSESSMENT OF NATIONAL DRUG CONTROL STRATEGY.

(a) TIMING, CONTENTS, AND PROCESS FOR DEVELOPMENT AND SUBMISSION OF NATIONAL DRUG CONTROL STRATEGY.—

(1) TIMING.—Not later than February 1, 1999, the President shall submit to Congress a National Drug Control Strategy, which shall set forth a comprehensive plan, covering a period of not more than 5 years, for reducing drug abuse and the consequences of drug abuse in the United States, by limiting the availability of and reducing the demand for illegal drugs.

(2) CONTENTS.—

(A) IN GENERAL.—The National Drug Control Strategy submitted under paragraph (1) shall include—

(i) comprehensive, research-based, long-range, quantifiable, goals for reducing drug abuse and the consequences of drug abuse in the United States;

(ii) annual, quantifiable, and measurable objectives and specific targets to accomplish long-term quantifiable goals that the Director determines may be achieved during each year of the period beginning on the date on which the National Drug Control Strategy is submitted;

(iii) 5-year projections for program and budget priorities; and

(iv) a review of international, State, local, and private sector drug control activities to ensure that the United States pursues well-coordinated and effective drug control at all levels of government.

(B) CLASSIFIED INFORMATION.—Any contents of the National Drug Control Strategy that involves information properly classified under criteria established by an Executive order shall be presented to Congress separately from the rest of the National Drug Control Strategy.

(3) PROCESS FOR DEVELOPMENT AND SUBMISSION.—

(A) CONSULTATION.—In developing and effectively implementing the National Drug Control Strategy, the Director—

(i) shall consult with—

(I) the heads of the National Drug Control Program agencies;

(II) Congress;

(III) State and local officials;

(IV) private citizens and organizations with experience and expertise in demand reduction;

(V) private citizens and organizations with experience and expertise in supply reduction; and

(VI) appropriate representatives of foreign governments;

(ii) with the concurrence of the Attorney General, may require the El Paso Intelligence Center to undertake specific tasks or projects to implement the National Drug Control Strategy; and

(iii) with the concurrence of the Director of Central Intelligence and the Attorney General, may request that the National Drug Intelligence Center undertake specific tasks or projects to implement the National Drug Control Strategy.

(B) INCLUSION IN STRATEGY.—The National Drug Control Strategy under this subsection, and each report submitted under subsection (b), shall include a list of each entity consulted under subparagraph (A)(i).

(4) SPECIFIC TARGETS.—The targets in the National Drug Control Strategy shall include the following:

(A) Reduction of unlawful drug use to 3 percent of the population of the United States or less by December 31, 2003 (as measured in terms of overall illicit drug use during the past 30 days by the National Household Survey), and achievement of at least 20 percent of such reduction during each of 1999, 2000, 2001, 2002, and 2003.

(B) Reduction of adolescent unlawful drug use (as measured in terms of illicit drug use during the past 30 days by the Monitoring the Future Survey of the University of Michigan or the National PRIDE Survey conducted by the National Parents' Resource Institute for Drug Education) to 3 percent of the adolescent population of the United States or less by December 31, 2003, and achievement of at least 20 percent of such reduction during each of 1999, 2000, 2001, 2002, and 2003.

(C) Reduction of the availability of cocaine, heroin, marijuana, and methamphetamine in the United States by 80 percent by December 31, 2003.

(D) Reduction of the respective nationwide average street purity levels for cocaine, heroin, marijuana, and methamphetamine (as estimated by the interagency drug flows assessment led by the Office of National Drug Control Policy, and based on statistics collected by the Drug Enforcement Administration and other National Drug Control Program agencies identified as relevant by the Director) by 60 percent by December 31, 2003, and achievement of at least 20 percent of each such reduction during each of 1999, 2000, 2001, 2002, and 2003.

(E) Reduction of drug-related crime in the United States by 50 percent by December 31, 2003, and achievement of

at least 20 percent of such reduction during each of 1999, 2000, 2001, 2002, and 2003, including—

(i) reduction of State and Federal unlawful drug trafficking and distribution;

(ii) reduction of State and Federal crimes committed by persons under the influence of unlawful drugs;

(iii) reduction of State and Federal crimes committed for the purpose of obtaining unlawful drugs or obtaining property that is intended to be used for the purchase of unlawful drugs; and

(iv) reduction of drug-related emergency room incidents in the United States (as measured by data of the Drug Abuse Warning Network on illicit drug abuse), including incidents involving gunshot wounds and automobile accidents in which illicit drugs are identified in the bloodstream of the victim, by 50 percent by December 31, 2003.

(5) FURTHER REDUCTIONS IN DRUG USE, AVAILABILITY, AND CRIME.—Following the submission of a National Drug Control Strategy under this section to achieve the specific targets described in paragraph (4), the Director may formulate a strategy for additional reductions in drug use and availability and drug-related crime beyond the 5-year period covered by the National Drug Control Strategy that has been submitted.

(b) ANNUAL STRATEGY REPORT.—

(1) IN GENERAL.—Not later than February 1, 1999, and on February 1 of each year thereafter, the President shall submit to Congress a report on the progress in implementing the Strategy under subsection (a), which shall include—

(A) an assessment of the Federal effectiveness in achieving the National Drug Control Strategy goals and objectives using the performance measurement system described in subsection (c), including—

(i) an assessment of drug use and availability in the United States; and

(ii) an estimate of the effectiveness of interdiction, treatment, prevention, law enforcement, and international programs under the National Drug Control Strategy in effect during the preceding year, or in effect as of the date on which the report is submitted;

(B) any modifications of the National Drug Control Strategy or the performance measurement system described in subsection (c);

(C) an assessment of the manner in which the budget proposal submitted under section 704(c) is intended to implement the National Drug Control Strategy and whether the funding levels contained in such proposal are sufficient to implement such Strategy;

(D) measurable data evaluating the success or failure in achieving the annual measurable objectives described in subsection (a)(2)(A)(ii);

(E) an assessment of current drug use (including inhalants) and availability, impact of drug use, and treatment availability, which assessment shall include—

(i) estimates of drug prevalence and frequency of use as measured by national, State, and local surveys of illicit drug use and by other special studies of—

(I) casual and chronic drug use;

(II) high-risk populations, including school dropouts, the homeless and transient, arrestees, parolees, probationers, and juvenile delinquents; and

(III) drug use in the workplace and the productivity lost by such use;

(ii) an assessment of the reduction of drug availability against an ascertained baseline, as measured by—

(I) the quantities of cocaine, heroin, marijuana, methamphetamine, and other drugs available for consumption in the United States;

(II) the amount of marijuana, cocaine, heroin, and precursor chemicals entering the United States;

(III) the number of hectares of marijuana, poppy, and coca cultivated and destroyed domestically and in other countries;

(IV) the number of metric tons of marijuana, heroin, cocaine, and methamphetamine seized;

(V) the number of cocaine and methamphetamine processing laboratories destroyed domestically and in other countries;

(VI) changes in the price and purity of heroin and cocaine, changes in the price of methamphetamine, and changes in tetrahydrocannabinol level of marijuana;

(VII) the amount and type of controlled substances diverted from legitimate retail and wholesale sources; and

(VIII) the effectiveness of Federal technology programs at improving drug detection capabilities in interdiction, and at United States ports of entry;

(iii) an assessment of the reduction of the consequences of drug use and availability, which shall include estimation of—

(I) the burden drug users placed on hospital emergency departments in the United States, such as the quantity of drug-related services provided;

(II) the annual national health care costs of drug use, including costs associated with people becoming infected with the human immunodeficiency virus and other infectious diseases as a result of drug use;

(III) the extent of drug-related crime and criminal activity; and

(IV) the contribution of drugs to the underground economy, as measured by the retail value of drugs sold in the United States;

(iv) a determination of the status of drug treatment in the United States, by assessing—

(I) public and private treatment capacity within each State, including information on the treatment capacity available in relation to the capacity actually used;

(II) the extent, within each State, to which treatment is available;

(III) the number of drug users the Director estimates could benefit from treatment; and

(IV) the specific factors that restrict the availability of treatment services to those seeking it and proposed administrative or legislative remedies to make treatment available to those individuals; and

(v) a review of the research agenda of the Counter-Drug Technology Assessment Center to reduce the availability and abuse of drugs; and

(F) an assessment of private sector initiatives and cooperative efforts between the Federal Government and State and local governments for drug control.

(2) SUBMISSION OF REVISED STRATEGY.—The President may submit to Congress a revised National Drug Control Strategy that meets the requirements of this section—

(A) at any time, upon a determination by the President, in consultation with the Director, that the National Drug Control Strategy in effect is not sufficiently effective; and

(B) if a new President or Director takes office.

(3) 1999 STRATEGY REPORT.—With respect to the Strategy report required to be submitted by this subsection on February 1, 1999, the President shall prepare the report using such information as is available for the period covered by the report.

(c) PERFORMANCE MEASUREMENT SYSTEM.—

(1) SENSE OF CONGRESS.—It is the sense of Congress that—

(A) the targets described in subsection (a) are important to the reduction of overall drug use in the United States;

(B) the President should seek to achieve those targets during the 5 years covered by the National Drug Control Strategy required to be submitted under subsection (a);

(C) the purpose of such targets and the annual reports to Congress on the progress towards achieving the targets is to allow for the annual restructuring of appropriations by the Appropriations Committees and authorizing committees of jurisdiction of Congress to meet the goals described in this Act;

(D) the performance measurement system developed by the Director described in this subsection is central to the National Drug Control Program targets, programs, and budget;

(E) the Congress strongly endorses the performance measurement system for establishing clear outcomes for reducing drug use nationwide during the next five years, and the linkage of this system to all agency drug control

programs and budgets receiving funds scored as drug control agency funding.

(2) SUBMISSION TO CONGRESS.—Not later than February 1, 1999, the Director shall submit to Congress a description of the national drug control performance measurement system, designed in consultation with affected National Drug Control Program agencies, that—

(A) develops performance objectives, measures, and targets for each National Drug Control Strategy goal and objective;

(B) revises performance objectives, measures, and targets, to conform with National Drug Control Program Agency budgets;

(C) identifies major programs and activities of the National Drug Control Program agencies that support the goals and objectives of the National Drug Control Strategy;

(D) evaluates in detail the implementation by each National Drug Control Program agency of program activities supporting the National Drug Control Strategy;

(E) monitors consistency between the drug-related goals and objectives of the National Drug Control Program agencies and ensures that drug control agency goals and budgets support and are fully consistent with the National Drug Control Strategy; and

(F) coordinates the development and implementation of national drug control data collection and reporting systems to support policy formulation and performance measurement, including an assessment of—

(i) the quality of current drug use measurement instruments and techniques to measure supply reduction and demand reduction activities;

(ii) the adequacy of the coverage of existing national drug use measurement instruments and techniques to measure the casual drug user population and groups that are at risk for drug use; and

(iii) the actions the Director shall take to correct any deficiencies and limitations identified pursuant to subparagraphs (A) and (B) of subsection (b)(4).

(3) MODIFICATIONS.—A description of any modifications made during the preceding year to the national drug control performance measurement system described in paragraph (2) shall be included in each report submitted under subsection (b).

SEC. 707. [21 U.S.C. 1706] HIGH INTENSITY DRUG TRAFFICKING AREAS PROGRAM.

(a) ESTABLISHMENT.—There is established in the Office a program to be known as the High Intensity Drug Trafficking Areas Program.

(b) DESIGNATION.—The Director, upon consultation with the Attorney General, the Secretary of the Treasury, heads of the National Drug Control Program agencies, and the Governor of each applicable State, may designate any specified area of the United States as a high intensity drug trafficking area. After making such a designation and in order to provide Federal assistance to the area so designated, the Director may—

(1) obligate such sums as appropriated for the High Intensity Drug Trafficking Areas Program;

(2) direct the temporary reassignment of Federal personnel to such area, subject to the approval of the head of the department or agency that employs such personnel;

(3) take any other action authorized under section 704 to provide increased Federal assistance to those areas;

(4) coordinate activities under this subsection (specifically administrative, recordkeeping, and funds management activities) with State and local officials.

(c) FACTORS FOR CONSIDERATION.—In considering whether to designate an area under this section as a high intensity drug trafficking area, the Director shall consider, in addition to such other criteria as the Director considers to be appropriate, the extent to which—

(1) the area is a center of illegal drug production, manufacturing, importation, or distribution;

(2) State and local law enforcement agencies have committed resources to respond to the drug trafficking problem in the area, thereby indicating a determination to respond aggressively to the problem;

(3) drug-related activities in the area are having a harmful impact in other areas of the country; and

(4) a significant increase in allocation of Federal resources is necessary to respond adequately to drug-related activities in the area.

(d) USE OF FUNDS.—The Director shall ensure that no Federal funds appropriated for the High Intensity Drug Trafficking Program are expended for the establishment or expansion of drug treatment programs.

SEC. 708. [21 U.S.C. 1707] COUNTER-DRUG TECHNOLOGY ASSESSMENT CENTER.

(a) ESTABLISHMENT.—There is established within the Office the Counter-Drug Technology Assessment Center (referred to in this section as the "Center"). The Center shall operate under the authority of the Director of National Drug Control Policy and shall serve as the central counter-drug technology research and development organization of the United States Government.

(b) DIRECTOR OF TECHNOLOGY.—There shall be at the head of the Center the Director of Technology, who shall be appointed by the Director of National Drug Control Policy from among individuals qualified and distinguished in the area of science, medicine, engineering, or technology.

(c) ADDITIONAL RESPONSIBILITIES OF THE DIRECTOR OF NATIONAL DRUG CONTROL POLICY.—

(1) IN GENERAL.—The Director, acting through the Director of Technology shall—

(A) identify and define the short-, medium-, and long-term scientific and technological needs of Federal, State, and local drug supply reduction agencies, including—

(i) advanced surveillance, tracking, and radar imaging;

(ii) electronic support measures;

(iii) communications;

(iv) data fusion, advanced computer systems, and artificial intelligence; and

(v) chemical, biological, radiological (including neutron, electron, and graviton), and other means of detection;

(B) identify demand reduction basic and applied research needs and initiatives, in consultation with affected National Drug Control Program agencies, including—

(i) improving treatment through neuroscientific advances;

(ii) improving the transfer of biomedical research to the clinical setting; and

(iii) in consultation with the National Institute on Drug Abuse, and through interagency agreements or grants, examining addiction and rehabilitation research and the application of technology to expanding the effectiveness or availability of drug treatment;

(C) make a priority ranking of such needs identified in subparagraphs (A) and (B) according to fiscal and Drug Enforcement Research and Development Program;

(D) oversee and coordinate counter-drug technology initiatives with related activities of other Federal civilian and military departments;

(E) provide support to the development and implementation of the national drug control performance measurement system; and

(F) pursuant to the authority of the Director of National Drug Control Policy under section 704, submit requests to Congress for the reprogramming or transfer of funds appropriated for counter-drug technology research and development.

(2) LIMITATION ON AUTHORITY.—The authority granted to the Director under this subsection shall not extend to the award of contracts, management of individual projects, or other operational activities.

(d) ASSISTANCE AND SUPPORT TO OFFICE OF NATIONAL DRUG CONTROL POLICY.—The Secretary of Defense and the Secretary of Health and Human Services shall, to the maximum extent practicable, render assistance and support to the Office and to the Director in the conduct of counter-drug technology assessment.

SEC. 709. [21 U.S.C. 1708] PRESIDENT'S COUNCIL ON COUNTER-NARCOTICS.

(a) ESTABLISHMENT.—There is established a council to be known as the President's Council on Counter-Narcotics (referred to in this section as the "Council").

(b) MEMBERSHIP.—

(1) IN GENERAL.—Subject to paragraph (2), the Council shall be composed of 18 members, of whom—

(A) 1 shall be the President, who shall serve as Chairman of the Council;

(B) 1 shall be the Vice President;

(C) 1 shall be the Secretary of State;

(D) 1 shall be the Secretary of the Treasury;

(E) 1 shall be the Secretary of Defense;

(F) 1 shall be the Attorney General;
(G) 1 shall be the Secretary of Transportation;
(H) 1 shall be the Secretary of Health and Human Services;
(I) 1 shall be the Secretary of Education;
(J) 1 shall be the Representative of the United States of America to the United Nations;
(K) 1 shall be the Director of the Office of Management and Budget;
(L) 1 shall be the Chief of Staff to the President;
(M) 1 shall be the Director of the Office, who shall serve as the Executive Director of the Council;
(N) 1 shall be the Director of Central Intelligence;
(O) 1 shall be the Assistant to the President for National Security Affairs;
(P) 1 shall be the Counsel to the President;
(Q) 1 shall be the Chairman of the Joint Chiefs of Staff; and
(R) 1 shall be the National Security Adviser to the Vice President.

(2) ADDITIONAL MEMBERS.—The President may, in the discretion of the President, appoint additional members to the Council.

(c) FUNCTIONS.—The Council shall advise and assist the President in—

(1) providing direction and oversight for the national drug control strategy, including relating drug control policy to other national security interests and establishing priorities; and

(2) ensuring coordination among departments and agencies of the Federal Government concerning implementation of the National Drug Control Strategy.

(d) ADMINISTRATION.—

(1) IN GENERAL.—The Council may utilize established or ad hoc committees, task forces, or interagency groups chaired by the Director (or a representative of the Director) in carrying out the functions of the Council under this section.

(2) STAFF.—The staff of the Office, in coordination with the staffs of the Vice President and the Assistant to the President for National Security Affairs, shall act as staff for the Council.

(3) COOPERATION FROM OTHER AGENCIES.—Each department and agency of the executive branch shall—

(A) cooperate with the Council in carrying out the functions of the Council under this section; and

(B) provide such assistance, information, and advice as the Council may request, to the extent permitted by law.

SEC. 710. [21 U.S.C. 1709] PARENTS ADVISORY COUNCIL ON YOUTH DRUG ABUSE.

(a) IN GENERAL.—

(1) ESTABLISHMENT.—There is established a Council to be known as the Parents Advisory Council on Youth Drug Abuse (referred to in this section as the "Council").

(2) MEMBERSHIP.—

(A) COMPOSITION.—The Council shall be composed of 16 members, of whom—

(i) 4 shall be appointed by the President, each of whom shall be a parent or guardian of a child who is not less than 6 and not more than 18 years of age as of the date on which the appointment is made;

(ii) 4 shall be appointed by the Majority Leader of the Senate, 3 of whom shall be a parent or guardian of a child who is not less than 6 and not more than 18 years of age as of the date on which the appointment is made;

(iii) 2 shall be appointed by the Minority Leader of the Senate, each of whom shall be a parent or guardian of a child who is not less than 6 and not more than 18 years of age as of the date on which the appointment is made;

(iv) 4 shall be appointed by the Speaker of the House of Representatives, 3 of whom shall be a parent or guardian of a child who is not less than 6 and not more than 18 years of age as of the date on which the appointment is made; and

(v) 2 shall be appointed by the Minority Leader of the House of Representatives, each of whom shall be a parent or guardian of a child who is not less than 6 and not more than 18 years of age as of the date on which the appointment is made.

(B) REQUIREMENTS.—

(i) IN GENERAL.—Each member of the Council shall be an individual from the private sector with a demonstrated interest and expertise in research, education, treatment, or prevention activities related to youth drug abuse.

(ii) REPRESENTATIVES OF NONPROFIT ORGANIZATIONS.—Not less than 1 member appointed under each of clauses (i) through (v) of paragraph (2)(A) shall be a representative of a nonprofit organization focused on involving parents in antidrug education and prevention.

(C) DATE.—The appointments of the initial members of the Council shall be made not later than 60 days after the date of enactment of this section.

(D) EXECUTIVE DIRECTOR.—The Director shall appoint the Executive Director of the Council, who shall be an employee of the Office of National Drug Control Policy.

(3) PERIOD OF APPOINTMENT; VACANCIES.—

(A) PERIOD OF APPOINTMENT.—Each member of the Council shall be appointed for a term of 3 years, except that, of the initial members of the Council—

(i) 1 member appointed under each of clauses (i) through (v) of paragraph (2)(A) shall be appointed for a term of 1 year; and

(ii) 1 member appointed under each of clauses (i) through (v) of paragraph (2)(A) shall be appointed for a term of 2 years.

(B) VACANCIES.—Any vacancy in the Council shall not affect its powers, provided that a quorum is present, but

shall be filled in the same manner as the original appointment. Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term.

(C) APPOINTMENT OF SUCCESSOR.—To the extent necessary to prevent a vacancy in the membership of the Council, a member of the Council may serve for not more than 6 months after the expiration of the term of that member, if the successor of that member has not been appointed.

(4) INITIAL MEETING.—Not later than 120 days after the date on which all initial members of the Council have been appointed, the Council shall hold its first meeting.

(5) MEETINGS.—The Council shall meet at the call of the Chairperson.

(6) QUORUM.—Nine members of the Council shall constitute a quorum, but a lesser number of members may hold hearings.

(7) CHAIRPERSON AND VICE CHAIRPERSON.—

(A) IN GENERAL.—The members of the Council shall select a Chairperson and Vice Chairperson from among the members of the Council.

(B) DUTIES OF CHAIRPERSON.—The Chairperson of the Council shall assign committee duties relating to the Council and direct the Executive Director to convene hearings and conduct other necessary business of the Council.

(C) DUTIES OF VICE CHAIRPERSON.—If the Chairperson of the Council is unable to serve, the Vice Chairperson shall serve as the Chairperson.

(b) DUTIES OF THE COUNCIL.—

(1) IN GENERAL.—The Council—

(A) shall advise the Director on drug prevention, education, and treatment and assist the Deputy Director of Demand Reduction in the responsibilities for the coordination of the demand reduction programs of the Federal Government and the analysis and consideration of prevention and treatment alternatives; and

(B) may issue reports and recommendations on drug prevention, education, and treatment, in addition to the reports detailed in paragraph (2), as the Council considers appropriate.

(2) SUBMISSION OF REPORTS.—Any report or recommendation issued by the Council shall be submitted to the Director and subsequently to Congress.

(3) ADVICE ON THE NATIONAL DRUG CONTROL STRATEGY.—Not later than December 1, 1999, and on December 1 of each year thereafter, the Council shall submit to the Director an annual report containing drug control strategy recommendations on drug prevention, education, and treatment. The Director may include any recommendations submitted under this paragraph in the report submitted by the Director under section 706(b).

(c) EXPENSES.—The members of the Council shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter

57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Council.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Council such sums as may be necessary[4] carry out this section.

SEC. 711. [21 U.S.C. 1710] DRUG INTERDICTION.

(a) DEFINITION.—In this section, the term ''Federal drug control agency'' means—

(1) the Office of National Drug Control Policy;
(2) the Department of Defense;
(3) the Drug Enforcement Administration;
(4) the Federal Bureau of Investigation;
(5) the Immigration and Naturalization Service;
(6) the United States Coast Guard;
(7) the United States Customs Service; and
(8) any other department or agency of the Federal Government that the Director determines to be relevant.

(b) REPORT.—In order to assist Congress in determining the personnel, equipment, funding, and other resources that would be required by Federal drug control agencies in order to achieve a level of interdiction success at or above the highest level achieved before the date of enactment of this title, not later than 90 days after the date of enactment of this Act, the Director shall submit to Congress and to each Federal drug control program agency a report, which shall include—

(1) with respect to the southern and western border regions of the United States (including the Pacific coast, the border with Mexico, the Gulf of Mexico coast, and other ports of entry) and in overall totals, data relating to—

(A) the amount of marijuana, heroin, methamphetamine, and cocaine—

(i) seized during the year of highest recorded seizures for each drug in each region and during the year of highest recorded overall seizures; and

(ii) disrupted during the year of highest recorded disruptions for each drug in each region and during the year of highest recorded overall seizures; and

(B) the number of persons arrested for violations of section 1010(a) of the Controlled Substances Import and Export Act (21 U.S.C. 960(a)) and related offenses during the year of the highest number of arrests on record for each region and during the year of highest recorded overall arrests;

(2) the price of cocaine, heroin, methamphetamine, and marijuana during the year of highest price on record during the preceding 10-year period, adjusted for purity where possible; and

(3) a description of the personnel, equipment, funding, and other resources of the Federal drug control agency devoted to drug interdiction and securing the borders of the United States

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against drug trafficking for each of the years identified in paragraphs (1) and (2) for each Federal drug control agency.

(c) BUDGET PROCESS.—

(1) INFORMATION TO DIRECTOR.—Based on the report submitted under subsection (b), each Federal drug control agency shall submit to the Director, at the same time as each annual drug control budget request is submitted by the Federal drug control agency to the Director under section 704(c)(1), a description of the specific personnel, equipment, funding, and other resources that would be required for the Federal drug control agency to meet or exceed the highest level of interdiction success for that agency identified in the report submitted under subsection (b).

(2) INFORMATION TO CONGRESS.—The Director shall include each submission under paragraph (1) in each annual consolidated National Drug Control Program budget proposal submitted by the Director to Congress under section 704(c)(2), which submission shall be accompanied by a description of any additional resources that would be required by the Federal drug control agencies to meet the highest level of interdiction success identified in the report submitted under subsection (b).

SEC. 712. ESTABLISHMENT OF SPECIAL FORFEITURE FUND.

Section 6073 of the Asset Forfeiture Amendments Act of 1988 (21 U.S.C. 1509) is amended—

(1) in subsection (b)—

(A) by striking "section 524(c)(9)" and inserting "section 524(c)(8)"; and

(B) by striking "section 9307(g)" and inserting "section 9703(g)"; and

(2) in subsection (e), by striking "strategy" and inserting "Strategy".

SEC. 713. TECHNICAL AND CONFORMING AMENDMENTS.

(a) TITLE 5, UNITED STATES CODE.—Chapter 53 of title 5, United States Code, is amended—

(1) in section 5312, by adding at the end the following:

"Director of National Drug Control Policy.";

(2) in section 5313, by adding at the end the following:

"Deputy Director of National Drug Control Policy."; and

(3) in section 5314, by adding at the end the following:

"Deputy Director for Demand Reduction, Office of National Drug Control Policy.

"Deputy Director for Supply Reduction, Office of National Drug Control Policy.

"Deputy Director for State and Local Affairs, Office of National Drug Control Policy.".

(b) NATIONAL SECURITY ACT OF 1947.—Section 101 of the National Security Act of 1947 (50 U.S.C. 402) is amended by redesignating subsection (f) as subsection (g) and inserting after subsection (e) the following: "(f) The Director of National Drug Control Policy may, in the role of the Director as principal adviser to the National Security Council on national drug control policy, and subject to the direction of the President, attend and participate in meetings of the National Security Council.".

(c) SUBMISSION OF NATIONAL DRUG CONTROL PROGRAM BUDGET WITH ANNUAL BUDGET REQUEST OF PRESIDENT.—Section 1105(a) of title 31, United States Code, is amended by inserting after paragraph (25) the following:

"(26) a separate statement of the amount of appropriations requested for the Office of National Drug Control Policy and each program of the National Drug Control Program.".

SEC. 714. [21 U.S.C. 1711] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this title, to remain available until expended, such sums as may be necessary for each of fiscal years 1999 through 2003.

SEC. 715. [21 U.S.C. 1712] TERMINATION OF OFFICE OF NATIONAL DRUG CONTROL POLICY.

(a) IN GENERAL.—Except as provided in subsection (b), effective on September 30, 2003, this title and the amendments made by this title are repealed.

(b) EXCEPTION.—Subsection (a) does not apply to section 713 or the amendments made by that section.

ESTABLISHMENT OF THE DRUG ENFORCEMENT ADMINISTRATION

REORGANIZATION PLAN NO. 2 OF 1973, as amended [1]

Prepared by the President and transmitted to the Senate and the House of Representatives in Congress assembled, March 28, 1973, pursuant to the provisions of Chapter 9 of Title 5 of the United States Code.[2]

LAW ENFORCEMENT IN ILLICIT DRUG ACTIVITIES

Section 1. Transfers to the Attorney General. There are hereby transferred from the Secretary of the Treasury, the Department of the Treasury, and any other officer or any agency of the Department of the Treasury, to the Attorney General all intelligence, investigative, and law enforcement functions, vested by law in the Secretary, the Department, officers, or agencies which relate to the suppression of illicit traffic in narcotics, dangerous drugs, or marihuana, except that the Secretary shall retain, and continue to perform, those functions, to the extent that they relate to searches and seizures of illicit narcotics, dangerous drugs, or marihuana or to the apprehension or detention of persons in connection therewith, at regular inspection locations at ports of entry or anywhere along the land or water borders of the United States: *Provided*, that any illicit narcotics, dangerous drugs, marihuana, or related evidence seized, and any person apprehended or detained by the Secretary or any officer of the Department of the Treasury, pursuant to the authority retained in them by virtue of this section, shall be turned over forthwith to the jurisdiction of the Attorney General; *Provided further*, that nothing in this section shall be construed as limiting in any way any authority vested by law in the Secretary of the Treasury, the Department of the Treasury, or any other officer or any agency of that Department on the effective date of this Plan with respect to contraband other than illicit narcotics, dangerous drugs, and marihuana: and *Provided further*, that nothing in this section shall be construed as limiting in any way any authority the Attorney General, the Department of Justice, or any other officer or any agency of that Department may otherwise have to make investigations or engage in law enforcement activities, including activities relating to the suppression of illicit traffic in narcotics, dangerous drugs, and marihuana, at ports of entry or along the land and water borders of the United States.

Sec. 2. [Repealed] [3]

Sec. 3. Abolition. The Bureau of Narcotics and Dangerous Drugs, including the Office of Director thereof, is hereby abolished,

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[1] 5 U.S.C. App.

[2] Effective July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, as amended Public Law 93–253, § 1, Mar. 16, 1974, 88 Stat. 50.

[3] Public Law 93–253, § 1(a)(1), (b), Mar. 16, 1974, 88 Stat. 50, effective July 1, 1973.

and section 3(a) of Reorganization Plan No. 1 of 1968 is hereby repealed. The Attorney General shall make such provision as he may deem necessary with respect to terminating those affairs of the Bureau of Narcotics and Dangerous Drugs not otherwise provided for in this Reorganization Plan.

Sec. 4. Drug Enforcement Administration. There is established in the Department of Justice an agency which shall be known as the Drug Enforcement Administration, hereinafter referred to as "the Administration."

Sec. 5. Officers of the Administration. (a) There shall be at the head of the Administration the Administrator of Drug Enforcement, hereinafter referred to as "the Administrator." The Administrator shall be appointed by the President by and with the advice and consent of the Senate, and shall receive compensation at the rate now or hereafter prescribed by law for positions of level III of the Executive Schedule Pay Rates (5 U.S.C. 5314). He shall perform such functions as the Attorney General shall from time to time direct.

(b) There shall be in the Administration a Deputy Administrator of the Drug Enforcement Administration, hereinafter referred to as "the Deputy Administrator," who shall be appointed by the President by and with the advice and consent of the Senate, shall perform such functions as the Attorney General may from time to time direct, and shall receive compensation at the rate now or hereafter prescribed by law for positions of level V of the Executive Schedule Pay Rates (5 U.S.C. 5316).

(c) The Deputy Administrator or such other official of the Department of Justice as the Attorney General shall from time to time designate shall act as Administrator during the absence or disability of the Administrator or in the event of a vacancy in the office of Administrator.

Sec. 6. Performance of Transferred Functions. The Attorney General may from time to time make such provisions as he shall deem appropriate authorizing the performance of any of the functions transferred to him by the provisions of this Reorganization Plan by any officer, employee, or agency of the Department of Justice.

Sec. 7. Coordination. The Attorney General, acting through the Administrator and such other officials of the Department of Justice as he may designate, shall provide for the coordination of all drug law enforcement functions vested in the Attorney General so as to assure maximum cooperation between and among the Administration, the Federal Bureau of Investigation, and other units of the Department involved in the performance of these and related functions.

Sec. 8. Incidental Transfers. (a) So much of the personnel, property, records, and unexpended balances of appropriations, allocations, and other funds employed, used, held, available or to be made available in connection with the functions transferred to the Attorney General by this Reorganization Plan as the Director of the Office of Management and Budget shall determine shall be transferred to the Department of Justice at such time or times as the Director shall direct.

(b) Such further measures and dispositions as the Director of the Office of Management and Budget shall deem to be necessary in order to effectuate transfers referred to in subsection (a) of this section shall be carried out in such manner as he shall direct and by such Federal agencies as he shall designate.

Sec. 9. Interim Officers. (a) The President may authorize any person who, immediately prior to the effective date of this Reorganization Plan, held a position in the Executive Branch of the Government to act as Administrator until the office of Administrator is for the first time filled pursuant to the provisions of this Reorganization Plan or by recess appointment as the case may be.

(b) The President may similarly authorize any such person to act as Deputy Administrator.

(c) The President may authorize any person who serves in an acting capacity under the foregoing provisions of this section to receive the compensation attached to the office in respect to which he so serves. Such compensation, if authorized, shall be in lieu of, but not in addition to, other compensation from the United States to which such person may be entitled.

Sec. 10. Effective Date. The provisions of this Reorganization Plan shall take effect as provided by section 906(a) of title 5 of the United States Code or on July 1, 1973, whichever is later.

CONTROLLED SUBSTANCES ACT [1], as amended

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[1] Public Law 91–513 (Comprehensive Drug Abuse Prevention and Control Act of 1970), Title II, Oct. 27, 1970, 84 Stat. 1242, 21 U.S.C. 801 et seq.

[2] Section 103 was repealed by section 1(b) of Public Law 95–137 without a corresponding amendment to the table of contents.

[3] See footnote to part C set out below.

[4] So in law. Probably should be preceded by "Sec."

[5] So in law. Probably should be "Penalty for simple possession." See the heading for section 404 set out below.

[6] So in law. Probably should be preceded by "Sec."

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[7] So in law. Probably should be preceded by "Sec.".
[8] So in law. Probably should be preceded by "Sec.".
[9] So in law. Probably should be preceded by "Sec.".
[10] So in law. Probably should be preceded by "Sec.".
[11] So in law. Probably should be "Employment or use of persons under 18 years of age in drug operations." See the heading for section 420 set out below.
[12] So in law. Probably should be preceded by "Sec.".
[13] So in law. Probably should be preceded by "Sec.".
[14] So in law. Probably should be preceded by "Sec.".
[15] Section 2(c)(3) of Public Law 106–185 (114 Stat. 21) repealed section 518, but did not make a conforming amendment to the table of contents.
[16] So in law. Probably should be preceded by "Sec.".
[17] So in law. Probably should be "Controlled substances production control.". See the heading for section 519 set out below.

TITLE II—CONTROL AND ENFORCEMENT [18]

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

SHORT TITLE

SEC. 100. [21 U.S.C. 801 note] This title may be cited as the "Controlled Substances Act".

FINDINGS AND DECLARATIONS

SEC. 101. [21 U.S.C. 801] The Congress makes the following findings and declarations:

(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances, possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

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[18] Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 290bb–2a) provides as follows: "The Secretary of Health, Education, and Welfare, after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and shall report thereon from time to time to the Congress.".

Section 602 of Public Law 89–793 (42 U.S.C. 3402) provides as follows: "The Surgeon General and the Attorney General are authorized to give representatives of States and local subdivisions thereof the benefit of their experience in the care, treatment, and rehabilitation of narcotic addicts so that each State may be encouraged to provide adequate facilities and personnel for the care and treatment of narcotic addicts in its jurisdiction.". Reorganization Plan No. 3 of 1966 transferred all statutory powers and functions of the Surgeon General, and other officers of the Public Health Service, to the Secretary of Health, Education, and Welfare. Section 509(b) of the Department of Education Organization Act (20 U.S.C. 3508(b)) provides that references to the Secretary of Health, Education, and Welfare shall be deemed to refer to the Secretary of Health and Human Services.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

DEFINITIONS

SEC. 102. [21 U.S.C. 802] As used in this title:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this title, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(12) The term "drug" has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "isomer" means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term "isomer" means any optical or geometric isomer.

(15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(16) The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake

made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(20) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term "immediate precursor" means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health, Education, and Welfare.

(25) The term "serious bodily injury" means bodily injury which involves—

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, or organ, or mental faculty.

(26)[19] The term "State" means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

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[19] Indentation so in law. See section 607(j)(1) of Public Law 104–294.

(C) Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(33) The term "listed chemical" means any list I chemical or any list II chemical.

(34) The term "list I chemical" means a chemical specified by regulation to the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) Anthranilic acid, its esters, and its salts.

(B) Benzyl cyanide.

(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.

(D) Ergonovine and its salts.

(E) Ergotamine and its salts.

(F) N-Acetylanthranilic acid, its esters, and its salts.

(G) Norpseudoephedrine, its salts, optical isomers, and salts of

(H) Phenylacetic acid, its esters, and its salts.

(I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(J) Piperidine and its salts.

(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(L) 3,4-Methylenedioxyphenyl-2-propanone.

(M) Methylamine.

(N) Ethylamine.

(O) Propionic anhydride.

(P) Isosafrole.[20]

(Q) Safrole.

(R) Piperonal.

(S) N-Methylephedrine.[21]

(T) N-methylpseudoephedrine.

(U) Hydriodic acid.[22]

(V) Benzaldehyde.

(W) Nitroethane.

(X) Gamma butyrolactone.

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[20] Indentation so in law. See section 209 of Public Law 104–237.
[21] Indentation so in law. See section 209 of Public Law 104–237.
[22] Indentation so in law. See section 209 of Public Law 104–237.

(Y) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term "list II chemical" means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

(A) Acetic anhydride.
(B) Acetone.
(C) Benzyl chloride.
(D) Ethyl ether.
(F)[23] Potassium permanaganate.
(G) 2-Butanone (or Methyl Ethyl Ketone).[24]
(H) Toluene.
(I) Iodine.[25]
(J) Hydrochloric gas.[26]

(36) The term "regular customer" means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term "regular importer" means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term "regulated transaction" means—

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include—

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if

[23] Subparagraph (E) was repealed by section 2301(b) of Public Law 101–647 (104 Stat. 4858).
[24] Indentation so in law. See sections 204(a) and 209 of Public Law 104–237.
[25] Indentation so in law. See sections 204(a) and 209 of Public Law 104–237.
[26] Indentation so in law. See sections 204(a) and 209 of Public Law 104–237.

the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 310;

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this title or title III;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) unless—

(I)(aa) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers, pseudoephedrine or its salts, optical isomers, or salts of optical isomers, or phenylpropanolamine or its salts, optical isomers, or salts of optical isomers unless otherwise provided by regulation of the Attorney General issued pursuant to section 204(e) of this title, except that any sale of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products by retail distributors shall not be a regulated transaction (except as provided in section 401(d) of the Comprehensive Methamphetamine Control Act of 1996[27]); or

(bb) the Attorney General has determined under section 204 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of ephedrine, pseudoephedrine, phenylpropanolamine, or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General, except that the threshold for any sale of products containing pseudoephedrine or phenylpropanolamine products by retail distributors or by distributors required to submit reports by section 310(b)(3) of this title shall be 9 grams of pseudoephedrine or 9 grams of phenylpropanolamine in a single transaction and sold in package sizes of not more than 3 grams of pseudoephedrine base or 3 grams of phenylpropanolamine base; or

(v) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this title and title III based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

[27] Section 401(d) of such act is included in this compilation as 21 U.S.C. 802 note. See the heading "Retail Sales of Pseudoephedrine and Phenylpropanolamine".

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term "chemical mixture" means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41)

(A)[28] The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes—

(i) androstanediol—

(I) 3β,17β-dihydroxy-5α-androstane; and

(II) 3α,17β-dihydroxy-5α-androstane;

(ii) androstanedione (5α-androstan-3,17-dione);

(iii) androstenediol—

(I) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene);

(II) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene);

(III) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene); and

(IV) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene);

(iv) androstenedione—

(I) 1-androstenedione ([5α]-androst-1-en-3,17-dione);

(II) 4-androstenedione (androst-4-en-3,17-dione); and

(III) 5-androstenedione (androst-5-en-3,17-dione);

(v) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(vi) boldenone (17β-hydroxyandrost-1,4,-diene-3-one);

(vii) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(viii) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one);

(ix) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one);

(x) Δ 1-dihydrotestosterone (a.k.a. "1-testosterone") (17β-hydroxy-5α-androst-1-en-3-one);

(xi) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one);

(xii) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one);

(xiii) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene);

(xiv) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one);

(xv) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one);

(xvi) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]-furazan);

(xvii) 13β-ethyl-17α-hydroxygon-4-en-3-one;

(xviii) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one);

[28] Separate indentation of subparagraph (A) is so in law. See section 2(a)(1)(B) of Public Law 108–358 (118 Stat. 1661).

(xix) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one);
(xx) mestanolone (17α-methyl-17β-hydroxy-5α-androstan-3-one);
(xxi) mesterolone (1α-methyl-17β-hydroxy-[5α]-androstan-3-one);
(xxii) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one);
(xxiii) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene);
(xxiv) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one);
(xxv) 17α-methyl-3β, 17β-dihydroxy-5α-androstane;
(xxvi) 17α-methyl-3α,17β-dihydroxy-5α-androstane;
(xxvii) 17α-methyl-3β,17β-dihydroxyandrost-4-ene.
(xxviii) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);
(xxix) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);
(xxx) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9-11-trien-3-one);
(xxxi) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);
(xxxii) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one);
(xxxiii) 17α-methyl-Δ 1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. "17-α-methyl-1-testosterone");
(xxxiv) nandrolone (17β-hydroxyestr-4-en-3-one);
(xxxv) norandrostenediol—
(I) 19-nor-4-androstenediol (3β, 17β-dihydroxyestr-4-ene);
(II) 19-nor-4-androstenediol (3α, 17β-dihydroxyestr-4-ene);
(III) 19-nor-5-androstenediol (3β, 17β-dihydroxyestr-5-ene); and
(IV) 19-nor-5-androstenediol (3α, 17β-dihydroxyestr-5-ene);
(xxxvi) norandrostenedione—
(I) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and
(II) 19-nor-5-androstenedione (estr-5-en-3,17-dione;
(xxxvii) norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one);
(xxxviii) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);
(xxxix) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);
(xl) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);
(xli) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]-androstan-3-one);
(xlii) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);
(xliii) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-[5α]-androstan-3-one);

(xliv) stanozolol (17α-methyl-17α-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole);

(xlv) stenbolone (17β-hydroxy-2-methyl-[5α]-androst-1-en-3-one);

(xlvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);

(xlvii) testosterone (17β-hydroxyandrost-4-en-3-one);

(xlviii) tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one);

(xlix) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one); and

(xlx) any salt, ester, or ether of a drug or substance described in this paragraph.

The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 201.

(B)(i)[29] Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

(42) The term ''international transaction'' means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms ''broker'' and ''trader'' mean a person that assists in arranging an international transaction in a listed chemical by—

(A) negotiating contracts;

(B) serving as an agent or intermediary; or

(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(44) The term ''felony drug offense'' means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, anabolic steroids, or depressant or stimulant substances.

(45)[30] The term ''ordinary over-the-counter pseudoephedrine or phenylpropanolamine product'' means any product containing pseudoephedrine or phenylpropanolamine that is—

(A) regulated pursuant to this title; and

(B)(i) except for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base, and that is packaged in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, that is packaged in unit dose packets or pouches; and

[29] Indentation so in law. See section 1902(b) of Public Law 101–647.
[30] Indentation so in law. See section 401(b)(4) of Public Law 104–237.

(ii) for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base.

(46)(A)[31] The term "retail distributor" means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to pseudoephedrine or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) For purposes of this paragraph, sale for personal use means the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use.

(C) For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

(i) A grocery store is an entity within SIC code 5411.

(ii) A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.

(iii) A drug store is an entity within SIC code 5912.

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. [21 U.S.C. 811] (a) The Attorney General shall apply the provisions of this title to the controlled substances listed in the schedules established by section 202 of this title and to any other drug or other substance added to such schedules under this title. Except as provided in subsections (d) and (e), the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 202 for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5 of the United States Code. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to

[31] Indentation so in law. See section 401(b)(4) of Public Law 104–237.

whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

(c) In making any finding under subsection (a) of this section or under subsection (b) of section 202, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this title.

(d)(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 202(b) and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)[32](A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from

[32] Paragraphs (2) through (5) take effect on the date the Convention on Psychotropic Substances, signed at Vienna, Austria on Feb. 21, 1971, enters into force in respect to the United States. See section 112 of Public Law 95–633. The Convention entered into force in respect to the United States on July 15, 1980.

one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health, Education, and Welfare who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health, Education, and Welfare shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health, Education, and Welfare of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health, Education, and Welfare shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3)[33] When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this title to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health, Education, and Welfare, after consultation with the Attorney General, shall first determine whether existing legal controls under this title applicable to the drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health, Education, and Welfare nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

[33] See footnote for paragraph (2).

(B) If such requirements are not met by such existing controls and the Secretary of Health, Education, and Welfare concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health, Education, and Welfare does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall—

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)(A)[34] If the Attorney General determines, after consultation with the Secretary of Health, Education, and Welfare, that proceedings initiated under recommendations made under paragraph[35] (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this title which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated

[34] See footnote for paragraph (2).
[35] So in law. Probably should be "subparagraph".

under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health, Education, and Welfare and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this title which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)—

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 202(b) and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5)[36] Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health, Education, and Welfare or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

(e) The Attorney General may, without regard to the findings required by subsection (a) of this section or section 202(b) and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g)(1) The Attorney General shall by regulation exclude any nonnarcotic drug which contains a controlled substance from the application of titles II and III of the Comprehensive Drug Abuse Prevention and Control Act (21 U.S.C. 802 et seq.)[37] if such drug may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this title unless controlled after the date of such enactment pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this title if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included there in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as

[36] See footnote for paragraph (2).

[37] So in law. See section 2(b)(1) of Public Law 108–358 (118 Stat. 1663). Probably should be "this title and title III of this Act". Section 201 above is part of title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 201 et seq.). That act contains a title III, which relates to imports and exports of controlled substances. (Title II of the act has a separate short title, the "Controlled Substances Act". Title III of the act also has a separate short title, the "Controlled Substances Import and Export Act".)

packaged it does not present any significant potential for abuse.

(C) Upon the recommendation of the Secretary of Health and Human Services, a compound, mixture, or preparation which contains any anabolic steroid, which is intended for administration to a human being or an animal, and which, because of its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.

(h)(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 202 or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act. Such an order may not be issued before the expiration of thirty days from—

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of one year from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) with respect to the substance, extend the temporary scheduling for up to six months.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c), including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

SCHEDULES OF CONTROLLED SUBSTANCES

SEC. 202. [21 U.S.C. 812] (a) There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances

listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after the date of enactment of this title and shall be updated and republished on an annual basis thereafter.

(b) Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on the effective date of this part, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c)[38] Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.
(2) Allylprodine.
(3) Alphacetylmathadol[39].
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.
(36) Phenomorphan.

[38] For current placement of substances in the schedules, see part 1308 of title 21, Code of Federal Regulations. Note that the schedules as they appear in section 202 may not show all controlled substances, and in some cases a substance may actually be on a different schedule than shown in section 202. This is because the Attorney General has rulemaking authority under section 201(a) to add substances to the schedules, to transfer substances from one schedule to another, and to remove substances from the schedules.

[39] So in law. Probably should be "Alphacetylmethadol".

(37) Phenoperidine.
(38) Piritramide.
(39) Proheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.
(6) Dimethyltryptamine.
(7) 4-methyl-2,5-dimethoxy amphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.

(16) Psilocyn.
(17) Tetrahydrocannabinols.

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca[40] leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.
(13) Moramide-Intermediate, 2-methyl-3 morpholino-1,1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.

[40] So in law. Probably should be "Coca".

(20) Racemethorphan.
(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

(a)[41] Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Phenmetrazine and its salts.
(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
(2) Chorexadol.
(3) Glutethimide.
(4) Lysergic acid.
(5) Lysergic acid amide.
(6) Methyprylon.
(7) Phencyclidine.
(8) Sulfondiethylmethane.
(9) Sulfonethylmethane.
(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.
(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

[41] The substances referred to in schedule III(a) have been administratively moved to schedule II.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

SCHEDULE IV

(1) Barbital.
(2) Chloral betaine.
(3) Chloral hydrate.
(4) Ethchlorvynol.
(5) Ethinamate.
(6) Methohexital.
(7) Meprobamate.
(8) Methylphenobarbital.
(9) Paraldehyde.
(10) Petrichloral.
(11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES

SEC. 203. [21 U.S.C. 813] A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of this title and title III as a controlled substance in schedule I.

REMOVAL OF EXEMPTION OF CERTAIN DRUGS

SEC. 204. [21 U.S.C. 814] (a) REMOVAL OF EXEMPTION.—The Attorney General shall by regulation remove from exemption under section 102(39)(A)(iv) a drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

(b) FACTORS TO BE CONSIDERED.—In removing a drug or group of drugs from exemption under subsection (a), the Attorney General shall consider, with respect to a drug or group of drugs that is proposed to be removed from exemption—

(1) the scope, duration, and significance of the diversion;

(2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) whether the listed chemical can be readily recovered from the drug or group of drugs.

(c) SPECIFICITY OF DESIGNATION.—The Attorney General shall limit the designation of a drug or a group of drugs removed from exemption under subsection (a) to the most particularly identifiable type of drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) REINSTATEMENT OF EXEMPTION WITH RESPECT TO PARTICULAR DRUG PRODUCTS.—

(1) REINSTATEMENT.—On application by a manufacturer of a particular drug product that has been removed from exemption under subsection (a), the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

(2) FACTORS TO BE CONSIDERED.—In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider—

(A) the package sizes and manner of packaging of the drug product;

(B) the manner of distribution and advertising of the drug product;

(C) evidence of diversion of the drug product;

(D) any actions taken by the manufacturer to prevent diversion of the drug product; and

(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) as applied to the drug product.

(3) STATUS PENDING APPLICATION FOR REINSTATEMENT.—A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless—

(A) the Attorney General has evidence that, applying the factors described in subsection (b) to the drug product, the drug product is being diverted; and

(B) the Attorney General so notifies the applicant.

(4) AMENDMENT AND MODIFICATION.—A regulation reinstating an exemption under paragraph (1) may be modified or revoked with respect to a particular drug product upon a finding that—

(A) applying the factors described in subsection (b) to the drug product, the drug product is being diverted; or

(B) there is a significant change in the data that led to the issuance of the regulation.

(e) REINSTATEMENT OF EXEMPTION WITH RESPECT TO EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE DRUG PRODUCTS.—Pursuant to subsection (d)(1), the Attorney General shall by regulation reinstate the exemption with respect to a particular ephedrine, pseudoephedrine, or phenylpropanolamine drug product if the Attorney General determines that the drug product is manufactured and distributed in a manner that prevents diversion. In making this determination the Attorney General shall consider the factors listed in subsection (d)(2). Any regulation issued pursuant to this subsection may be amended or revoked based on the factors listed in subsection (d)(4).

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING [42]

RULES AND REGULATIONS

SEC. 301. [21 U.S.C. 821] The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

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[42] Prior to the enactment of Public Law 100–690, section 310 of this title concerned reporting requirements regarding the distribution, sale, or import of piperidine. Section 6052 of such Public Law (102 Stat. 4312) amended section 310 in its entirety, with the result that the section now concerns reporting requirements related to listed chemicals, tableting machines, and encapsulating machines. Section 6054 of such Public Law (102 Stat. 4316) made amendments to the definitions in section 102 of this title, including establishing definitions for the terms "listed chemical" and "listed precursor chemical". Piperidine and its salts were included as listed precursor chemicals.

Section 2(a) of Public Law 103–200 (107 Stat. 2333) made amendments to the definitions in section 102 of this title, including replacing the term "listed precursor chemical" with the term "list I chemical". Piperidine and its salts are currently included as list I chemicals. See section 102(34)(J).

Section 2(a) of such Public Law also replaced the term "listed essential chemical" with the term "list II chemical".

PERSONS REQUIRED TO REGISTER

SEC. 302. [21 U.S.C. 822] (a)(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event; however, shall such registrations be issued for less than one year nor for more than three years.

(b) Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

(c) The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 102(25).[43]

(d) The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(f) The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

REGISTRATION REQUIREMENTS

SEC. 303. [21 U.S.C. 823] (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the

[43] So in law. Probably should be "102(27)". Former paragraph (25) of section 102 was redesignated as paragraph (26) by section 507(a) of Public Law 98–473 (98 Stat. 2071), and section 1003(b)(2) of Public Law 99–570 (100 Stat. 3207–6) redesignated paragraph (26) as paragraph (27).

public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 306.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in

schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity,

shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Seretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a). Article 7 of the Convention on Psychotrophic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this title.

(g)(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 307) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) In any case in which the practitioner is not in a group practice, the total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number.

(iv) In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve

the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term "group practice" has the meaning given such term in section 1877(h)(4) of the Social Security Act.

(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after the date of the enactment of the Drug Addiction Treatment Act of 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 2000[44], a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs, to patients for maintenance or detoxification treatment in accordance with this paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug.

(J)(i) This paragraph takes effect on the date of the enactment of the Drug Addiction Treatment Act of 2000[45], and remains in effect thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 2000, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of

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[44] Section 2501 of Public Law 107–273 (116 Stat. 1803) attempts to amend subparagraphs (I) and (J)(i), but the amendments cannot be executed because some of the matter to be struck in those subparagraphs does not appear. See the reference in the amendments to "October 17, 2000,". Section 303(g)(2) above was added by section 3502 of the Drug Addiction Treatment Act of 2000 (114 Stat. 1222) (title XXXV of Public Law 106–310). That act was enacted Oct. 17, 2000, but that date is not expressly referred to in subparagraph (I) or (J)(i) of section 303(g)(2). Section 2501 of Public Law 107–273 provides as follows:

Section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) is amended—

(1) in subparagraph (I), by striking "on October 17, 2000," and all that follows through "such drugs," and inserting "on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs,"; and

(2) in subparagraph (J)(i), by striking "October 17, 2000," and inserting "the date referred to in subparagraph (I),".

[45] See footnote for subparagraph (I).

maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this Act; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 102(39)(A)(iv). In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. [21 U.S.C. 824] (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this title or title III;

(2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 303 inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1128(a) of the Social Security Act.

A registration pursuant to section 303(g)(1) to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 303(g)(1).

(b) The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Before taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5 of the United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecution or other proceedings under this title or any other law of the United States.

(d) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 303(g)(1) may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 306.

(f) In the event the Attorney General suspends or revokes a registration granted under section 303, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 511(e). All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substances or list I chemicals seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

LABELING AND PACKAGING REQUIREMENTS

SEC. 305. [21 U.S.C. 825] (a) It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 201(k) of the Federal Food, Drug, and Cosmetic Act) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

(b) It shall be unlawful for the manufacturer of any controlled substance to distribute such substances unless the labeling (as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a).

(c) The Secretary shall prescribe regulations under section 503(b) of the Federal Food, Drug, and Cosmetic Act which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that

it is a crime to transfer the drug to any person other than the patient.

(d) It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

QUOTAS APPLICABLE TO CERTAIN SUBSTANCES

SEC. 306. [21 U.S.C. 826] (a) The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a). The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

(c) On or before October 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall

consider such factors specified in subsection (c) of this section as may be relevant.

(e) At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

(f) Notwithstanding any other provisions of this title, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance with respect to which its manufacturer is duly registered under this title. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances.

RECORDS AND REPORTS OF REGISTRANTS

SEC. 307. [21 U.S.C. 827] (a) Except as provided in subsection (c)—

(1) every registrant under this title shall, on the effective date of this section, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this title manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after the effective date of this section, every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) The foregoing provisions of this section shall not apply—

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(2)(A) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act;

(B) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this title.

Nothing in the Convention on Psychotropic Substances shall be construed as superseding or otherwise affecting the provisions of paragraph (1)(B), (2), or (3) of this subsection.[46]

(d) Every manufacturer registered under section 303 shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number

[46] Sentence at end of subsection (c) was added by title I of Public Law 95–633. Section 112 of such Public Law provided as follows: "This title shall take effect on the date the Convention on Psychotropic Substances, signed at Vienna, Austria on February 21, 1971, enters into force in respect to the United States.". The Convention entered into force in respect to the United States on July 15, 1980.

assigned under this title the person or establishment (unless exempt from registration under section 302(d) to whom such sale, delivery, or other disposal was made.

(e)[47] In addition to the reporting and recordkeeping requirements under any other provision of this title, each manufacturer registered under section 303 shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this title on manufacturers subject to the requirements of this subsection.

(f) Regulations under sections 505(i) and 512(j) of the Federal Food, Drug, and Cosmetic Act, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

(g) Every registrant under this title shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

(h) In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

(1) That every person who is registered as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

(2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

(3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other

[47] Subsection (e) was added by title I of Public Law 95–633. Section 112 of such Public Law provided as follows: "This title shall take effect on the date the Convention on Psychotropic Substances, signed at Vienna, Austria on February 21, 1971, enters into force in respect to the United States.". The Convention entered into force in respect to the United States on July 15, 1980.

material, use in manufacturing other material, and use in manufacturing dosage forms.

(4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

(5) That each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.

(6) That section 310(b)(3) (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.

ORDER FORMS

SEC. 308. [21 U.S.C. 828] (a) It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section.

(b) Nothing in subsection (a) shall apply to—

(1) the exportation of such substances from the United States in conformity with title III;

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a).

(c)(1) Every person who in pursuance of an order required under subsection (a) distributes a controlled substance shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General, and by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under such laws to inspect such orders.

(2) Every person who gives an order required under subsection (a) shall, at or before the time of giving such order, make or cause

to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

(d)(1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) only to persons validly registered under section 303 (or exempted from registration under section 302(d)). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances.

(2) The Attorney General may charge reasonable fees for the issuance of such forms in such amounts as he may prescribe for the purpose of covering the cost to the United States of issuing such forms, and other necessary activities in connection therewith.

(e) It shall be unlawful for any person to obtain by means of order forms issued under this section controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research.

PRESCRIPTIONS

SEC. 309. [21 U.S.C. 829] (a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act. Prescriptions shall be retained in conformity with the requirements of section 307 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

REGULATION OF LISTED CHEMICALS AND CERTAIN MACHINES

SEC. 310. [21 U.S.C. 830] (a)(1) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction for two years after the date of the transaction.

(2) A record under this subsection shall be retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer. Such record shall be available for inspection and copying by the Attorney General.

(3) It is the duty of each regulated person who engages in a regulated transaction to identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The Attorney General shall specify by regulation the types of documents and other evidence that constitute proof of identity for purposes of this paragraph.

(b)(1) Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation—

(A) any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this title;

(B) any proposed regulated transaction with a person whose description or other identifying characteristic the Attorney General furnishes in advance to the regulated person;

(C) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; and

(D) any regulated transaction in a tableting machine or an encapsulating machine.

Each report under subparagraph (A) shall be made at the earliest practicable opportunity after the regulated person becomes aware of the circumstance involved. A regulated person may not complete a transaction with a person whose description or identifying characteristic is furnished to the regulated person under subparagraph (B) unless the transaction is approved by the Attorney General. The Attorney General shall make available to regulated persons guidance documents describing transactions and circumstances for which reports are required under subparagraph (A) and subparagraph (C).

(2) A regulated person that manufactures a listed chemical shall report annually to the Attorney General, in such form and manner and containing such specific data as the Attorney General shall prescribe by regulation, information concerning listed chemicals manufactured by the person. The requirement of the preceding sentence shall not apply to the manufacture of a drug product that is exempted under section 102(39)(A)(iv).

(3) MAIL ORDER REPORTING.—

(A) As used in this paragraph:

(i) The term "drug product" means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act for distribution in the United States.

(ii) The term "valid prescription" means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

(B) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction which—

(i) involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals); and

(ii) uses or attempts to use the Postal Service or any private or commercial carrier;

shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General in such form, containing such data, and at such times as the Attorney General shall establish by regulation.

(C) The data required for such reports shall include—

(i) the name of the purchaser;

(ii) the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; and

(iii) the address to which such ephedrine, pseudoephedrine, or phenylpropanolamine was sent.

(D) Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, shall not be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products when such packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 102(46).

(iii) Distributions of drug products to a resident of a long term care facility (as that term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports which have been reported to the Attorney General pursuant to section 1004 or 1018 or which are subject to a waiver granted under section 1018(e)(2).

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or drug products) or of a group of listed chemicals (including specific formulations or drug products) which the Attorney General has excluded by regulation from such reporting requirement on the basis that such reporting is not necessary for the enforcement of this title or title III.

(E) The Attorney General may revoke any or all of the exemptions listed in subparagraph (D) for an individual regulated person if he finds that drug products distributed by the regulated person are being used in violation of this title or title III. The regulated person shall be notified of the revocation, which will be effective upon receipt by the person of such notice, as provided in section 1018(c)(1), and shall have the right to an expedited hearing as provided in section 1018(c)(2).

(c)(1) Except as provided in paragraph (2), any information obtained by the Attorney General under this section which is exempt from disclosure under section 552(a) of title 5, United States Code, by reason of section 552(b)(4) of such title, is confidential and may not be disclosed to any person.

(2) Information referred to in paragraph (1) may be disclosed only—

(A) to an officer or employee of the United States engaged in carrying out this title, title III, or the customs laws;

(B) when relevant in any investigation or proceeding for the enforcement of this title, title III, or the customs laws;

(C) when necessary to comply with an obligation of the United States under a treaty or other international agreement; or

(D) a State or local official or employee in conjunction with the enforcement of controlled substances laws or chemical control laws.

(3) The Attorney General shall—

(A) take such action as may be necessary to prevent unauthorized disclosure of information by any person to whom such information is disclosed under paragraph (2); and

(B) issue guidelines that limit, to the maximum extent feasible, the disclosure of proprietary business information, including the names or identities of United States exporters of listed chemicals, to any person to whom such information is disclosed under paragraph (2).

(4) Any person who is aggrieved by a disclosure of information in violation of this section may bring a civil action against the violator for appropriate relief.

(5) Notwithstanding paragraph (4), a civil action may not be brought under such paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

PART D—OFFENSES AND PENALTIES

PROHIBITED ACTS A—PENALTIES

SEC. 401. [21 U.S.C. 841] (a) Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) Except as otherwise provided in section 409, 418, 419, or 420 any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) In the case of a violation of subsection (a) of this section involving—

(i) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(ii) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 50 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; or

(viii) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of

title 18, United States Code, or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $8,000,000 if the defendant is an individual or $20,000,000 if the defendant is other than an individual, or both. If any person commits a violation of this subparagraph or of section 418, 419, 420 after two or more prior convictions for a felony drug offense have become final, such person shall be sentenced to a mandatory term of life imprisonment without release and fined in accordance with the preceding sentence. Notwithstanding section 3583 of title 18[48], any sentence under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(B) In the case of a violation of subsection (a) of this section involving—

(i) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) 500 grams or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 5 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-

[48] So in law. Probably should be "title 18, United States Code". This act does not contain a title 18.

piperidinyl] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide; or

(vii) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 100 or more marihuana plants regardless of weight; or

(viii) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[49], any sentence under this subparagraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(C) In the case of a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or 1 gram of flunitrazepam, except as provided in subparagraphs (A), (B), and (D), such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the

[49] So in law. Probably should be "title 18, United States Code". This act does not contain a title 18.

defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[50], any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil or in the case of any controlled substance in schedule III (other than gamma hydroxybutyric acid), or 30 milligrams of flunitrazepam, such person shall, except as provided in paragraphs (4) and (5) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United State Code, or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[51], any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 3 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or

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[50] So in law. Probably should be "title 18, United States Code". This act does not contain a title 18.

[51] So in law. Probably should be "title 18, United States Code". This act does not contain a title 18.

$250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title or title III or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 6 years, a fine not to exceed the greater of twice the authorized in accordance with the provisions of title 18, United States Code, or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than 1 year, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $100,000 if the defendant is an individual or $250,000 if the defendant is other than an individual, or both. If any person commits such a violation after one or more convictions of him for an offense punishable under this paragraph, or for a crime under any other provision of this title or title III or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine not to exceed the provisions of title 18, United States Code, or $200,000 if the defendant is an individual or $500,000 if the defendant is other than an individual, or both.

(4) Notwithstanding paragraph (1)(D) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in section 404 and section 3607 of title 18, United States Code.

(5) Any person who violates subsection (a) of this section by cultivating a controlled substance on Federal property shall be imprisoned as provided in this subsection and shall be fined any amount not to exceed—

(A) the amount authorized in accordance with this section;

(B) the amount authorized in accordance with the provisions of title 18, United States Code;

(C) $500,000 if the defendant is an individual; or

(D) $1,000,000 if the defendant is other than an individual; or both.

(6) Any person who violates subsection (a), or attempts to do so, and knowingly or intentionally uses a poison, chemical, or other hazardous substance on Federal land, and, by such use—

(A) creates a serious hazard to humans, wildlife, or domestic animals,

(B) degrades or harms the environment or natural resources, or

(C) pollutes an aquifer, spring, stream, river, or body of water,

shall be fined in accordance with title 18, United States Code, or imprisoned not more than five years, or both.

(7) PENALTIES FOR DISTRIBUTION.—

(A) IN GENERAL.—Whoever, with intent to commit a crime of violence, as defined in section 16 of title 18, United States Code (including rape), against an individual, violates subsection (a) by distributing a controlled substance or controlled substance analogue to that individual without that individual's knowledge, shall be imprisoned not more than 20 years and fined in accordance with title 18, United States Code.

(B) DEFINITION.—For purposes of this paragraph, the term "without that individual's knowledge" means that the individual is unaware that a substance with the ability to alter that individual's ability to appraise conduct or to decline participation in or communicate unwillingness to participate in conduct is administered to the individual.

(c) Any person who knowingly or intentionally—

(1) possesses a listed chemical with intent to manufacture a controlled substance except as authorized by this title;

(2) possesses or distributes, a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by this title; or

(3) with the intent of causing the evasion of the record-keeping or reporting requirements of section 310, or the regulations issued under that section, receives or distributes a reportable amount of any listed chemical in units small enough soi that the making of records or filing of reports under that section is not required;

shall be fined in accordance with title 18, United States Code, or imprisoned not more than 20 years in the case of a violation of paragraph (1) or (2) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (2) involving a list I chemical, or both.

(d)(1) Any person who assembles, maintains, places, or causes to be placed a boobytrap on Federal property where a controlled substance is being manufactured, distributed, or dispensed shall be sentenced to a term of imprisonment for not more than 10 years or fined under title 18, United States Code, or both.

(2) If any person commits such a violation after 1 or more prior convictions for an offense punishable under this subsection, such person shall be sentenced to a term of imprisonment of not more than 20 years or fined under title 18, United States Code, or both.

(3) For the purposes of this subsection, the term "boobytrap" means any concealed or camouflaged device designed to cause bodily injury when triggered by any action of any unsuspecting person making contact with the device. Such term includes guns, ammunition, or explosive devices attached to trip wires or other triggering mechanisms, sharpened stakes, and lines or wires with hooks attached.

(e) In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, manufacture, exportation, or importation of a listed chemical may be enjoined from engaging in any transaction involving a listed chemical for not more than ten years.

(f)(1) Whoever knowingly distributes a listed chemical in violation of this title (other than in violation of a recordkeeping or reporting requirement of section 310) shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both.

(2) Whoever possesses any listed chemical, with knowledge that the recordkeeping or reporting requirements of section 310 have not been adhered to, if, after such knowledge is acquired, such person does not take immediate steps to remedy the violation shall be fined under title 18, United States Code, or imprisoned not more than one year, or both.

PROHIBITED ACTS B—PENALTIES

SEC. 402. [21 U.S.C. 842] (a) It shall be unlawful for any person—

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 309;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 305 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 305 of this title;

(5) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this title or title III;

(6) to refuse any entry into any premises or inspection authorized by this title or title III;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 304(f) or 511 or to remove or dispose of substances so placed under seal;

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this title or title III, any information acquired in the course of an inspection authorized by this title concerning any method or process which as a trade secret is entitled to protection, or to use to his own advantage or reveal (other than as authorized by section 310) any information that is confidential under such section;

(9) who is a regulated person to engage in a regulated transaction without obtaining the identification required by 310(a)(3);

(10) negligently to fail to keep a record or make a report under section 310; or

(11) to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a

controlled substance or a listed chemical, in violation of this title or title III, with reckless disregard for the illegal uses to which such a laboratory supply will be put.

As used in paragraph (11), the term "laboratory supply" means a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals. For purposes of paragraph (11), there is a rebuttable presumption of reckless disregard at trial if the Attorney General notifies a firm in writing that a laboratory supply sold by the firm, or any other person or firm, has been used by a customer of the notified firm, or distributed further by that customer, for the unlawful production of controlled substances or listed chemicals a firm distributes and 2 weeks or more after the notification the notified firm distributes a laboratory supply to the customer.

(b) It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II which is—

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 306; or

(2) in excess of a quota assigned to him pursuant to section 306.

(c)(1)(A) Except as provided in subparagraph (B) of this paragraph and paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 of the United States Code to enforce this paragraph.

(B) In the case of a violation of paragraph (5) or (10) of subsection (a), the civil penalty shall not exceed $10,000.

(2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine under title 18, United States Code, or both.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine under title 18, United States Code, or both.

(C) In addition to the penalties set forth elsewhere in this title or title III, any business that violates paragraph (11) of subsection (a) shall, with respect to the first such violation, be subject to a civil penalty of not more than $250,000, but shall not be subject to

criminal penalties under this section, and shall, for any succeeding violation, be subject to a civil fine of not more than $250,000 or double the last previously imposed penalty, whichever is greater.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

PROHIBITED ACTS C—PENALTIES

SEC. 403. [21 U.S.C. 843] (a) It shall be unlawful for any person knowingly or intentionally—

(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 308 of this title;

(2) to use in the course of the manufacture, distribution, or dispensing of a controlled substance, or to use for the purpose of acquiring or obtaining a controlled substance, a registration number which is fictitious, revoked, suspended, expired, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4)(A) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this title or title III, or (B) to present false or fraudulent identification where the person is receiving or purchasing a listed chemical and the person is required to present identification under section 310(a);

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance;

(6) to possess any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this title or title III;

(7) to manufacture, distribute, export, or import any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this title or title III or, in the case of an exportation, in violation of this title or title III or of the laws of the country to which it is exported;

(8) to create a chemical mixture for the purpose of evading a requirement of section 310 or to receive a chemical mixture created for that purpose; or

(9) to distribute, import, or export a list I chemical without the registration required by this title or title III.

(b) It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this title or title III. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term "communication facility" means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication.

(c)[52] It shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publications, any written advertisement knowing that it has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule I controlled substance. As used in this section the term "advertisement" includes, in addition to its ordinary meaning, such advertisements as those for a catalog of Schedule I controlled substances and any similar written advertisement that has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule I controlled substance. The term "advertisement" does not include material which merely advocates the use of a similar material, which advocates a position or practice, and does not attempt to propose or facilitate an actual transaction in a Schedule I controlled substance.

(d)(1) Except as provided in paragraph (2), any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine under title 18, United States Code, or both; except that if any person commits such a violation after one or more prior convictions of him for violation of this section, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 8 years, a fine under title 18, United States Code, or both.

(2) Any person who, with the intent to manufacture or to facilitate the manufacture of methamphetamine, violates paragraph (6) or (7) of subsection (a), shall be sentenced to a term of imprisonment of not more than 10 years, a fine under title 18, United States Code, or both; except that if any person commits such a violation after one or more prior convictions of that person—

(A) for a violation of paragraph (6) or (7) of subsection (a);

(B) for a felony under any other provision of this subchapter or subchapter II of this chapter;[53] or

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[52] References in subsection (c) to "Schedule I" probably should be "schedule I".

[53] So in law. See section 203(a) of Public Law 104–237 (110 Stat. 3102). The reference to "this subchapter or subchapter II of this chapter" probably should be a reference to "this title or title III". The Controlled Substances Act does not contain any chapters or subchapters. (The Controlled Substances Act is title II of Public Law 91–513, and the Controlled Substances Import and Export Act is title III of such Public Law.)

(C) under any other law of the United States or any State relating to controlled substances or listed chemicals,

has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years, a fine under title 18, United States Code, or both.

(e) In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, manufacture, exportation, or importation of a listed chemical may be enjoined from engaging in any transaction involving a listed chemical for not more than ten years.

(f) INJUNCTIONS.—(1) In addition to any penalty provided in this section, the Attorney General is authorized to commence a civil action for appropriate declaratory or injunctive relief relating to violations of this section, section 402, or 416.

(2) Any action under this subsection may be brought in the district court of the United States for the district in which the defendant is located or resides or is doing business.

(3) Any order or judgment issued by the court pursuant to this subsection shall be tailored to restrain violations of this section or section 402.

(4) The court shall proceed as soon as practicable to the hearing and determination of such an action. An action under this subsection is governed by the Federal Rules of Civil Procedure except that, if an indictment has been returned against the respondent, discovery is governed by the Federal Rules of Criminal Procedure.

PENALTY FOR SIMPLE POSSESSION

SEC. 404. [21 U.S.C. 844] (a) It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this title or title III. It shall be unlawful for any person knowingly or intentionally to possess any list I chemical obtained pursuant to or under authority of a registration issued to that person under section 303 of this title or section 1008 of title III if that registration has been revoked or suspended, if that registration has expired, or if the registrant has ceased to do business in the manner contemplated by his registration. Any person who violates this subsection shall be sentenced to a term of imprisonment of not more than 1 year, and be fined a minimum of $1,000, or both, except that if he commits such offense after a prior conviction under this title or title III, or a prior conviction for any drug, narcotic, or chemical offense chargeable under the law of any State, has become final, he shall be sentenced to a term of imprisonment for not less than 15 days but not more than 2 years, and shall be fined a minimum of $2,500, except, further, that if he commits such offense after two or more prior convictions under this title or title III, or two or more prior convictions for any drug, narcotic, or chemical offense chargeable under the law of any State, or a combination of two or more such offenses have become final, he shall be sentenced to a term of imprisonment for not less than 90 days but not more

than 3 years, and shall be fined a minimum of $5,000. Notwithstanding the preceding sentence, a person convicted under this subsection for the possession of a mixture or substance which contains cocaine base shall be imprisoned not less than 5 years and not more than 20 years, and fined a minimum of $1,000, if the conviction is a first conviction under this subsection and the amount of the mixture or substance exceeds 5 grams, if the conviction is after a prior conviction for the possession of such a mixture or substance under this subsection becomes final and the amount of the mixture or substance exceeds 3 grams, or if the conviction is after 2 or more prior convictions for the possession of such a mixture or substance under this subsection become final and the amount of the mixture or substance exceeds 1 gram. Notwithstanding any penalty provided in this subsection, any person convicted under this subsection for the possession of flunitrazepam shall be imprisoned for not more than 3 years, shall be fined as otherwise provided in this section, or both. The imposition or execution of a minimum sentence required to be imposed under this subsection shall not be suspended or deferred. Further, upon conviction, a person who violates this subsection shall be fined the reasonable costs of the investigation and prosecution of the offense, including the costs of prosecution of an offense as defined in sections 1918 and 1920 of title 28, United States Code, except that this sentence shall not apply and a fine under this section need not be imposed if the court determines under the provision of title 18 that the defendant lacks the ability to pay.

(c)[54] As used in this section, the term ''drug, narcotic, or chemical offense'' means any offense which proscribes the possession, distribution, manufacture, cultivation, sale, transfer, or the attempt or conspiracy to possess, distribute, manufacture, cultivate, sell or transfer any substance the possession of which is prohibited under this title.

SEC. 405. [21 U.S.C. 844a] CIVIL PENALTY FOR POSSESSION OF SMALL AMOUNTS OF CERTAIN CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Any individual who knowingly possesses a controlled substance that is listed in section 401(b)(1)(A) in violation of section 404 in an amount that, as specified by regulation of the Attorney General, is a personal use amount shall be liable to the United States for a civil penalty in an amount not to exceed $10,000 for each such violation.

(b) INCOME AND NET ASSETS.—The income and net assets of an individual shall not be relevant to the determination whether to assess a civil penalty under this section or to prosecute the individual criminally. However, in determining the amount of a penalty under this section, the income and net assets of an individual shall be considered.

(c) PRIOR CONVICTION.—A civil penalty may not be assessed under this section if the individual previously was convicted of a Federal or State offense relating to a controlled substance.

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[54] So in law. Section 404 does not contain a subsection (b). See sections 219 and 235 of Public Law 98–473 (98 Stat. 2027, 2031) and section 1052 of Public Law 99–570 (100 Stat. 3207–8).

(d) LIMITATION ON NUMBER OF ASSESSMENTS.—A civil penalty may not be assessed on an individual under this section on more than two separate occasions.

(e) ASSESSMENT.—A civil penalty under this section may be assessed by the Attorney General only by an order made on the record after opportunity for a hearing in accordance with section 554 of title 5, United States Code. The Attorney General shall provide written notice to the individual who is the subject of the proposed order informing the individual of the opportunity to receive such a hearing with respect to the proposed order. The hearing may be held only if the individual makes a request for the hearing before the expiration of the 30-day period beginning on the date such notice is issued.

(f) COMPROMISE.—The Attorney General may compromise, modify, or remit, with or without conditions, any civil penalty imposed under this section.

(g) JUDICIAL REVIEW.—If the Attorney General issues an order pursuant to subsection (e) after a hearing described in such subsection, the individual who is the subject of the order may, before the expiration of the 30-day period beginning on the date the order is issued, bring a civil action in the appropriate district court of the United States. In such action, the law and the facts of the violation and the assessment of the civil penalty shall be determined de novo, and shall include the right of a trial by jury, the right to counsel, and the right to confront witnesses. The facts of the violation shall be proved beyond a reasonable doubt.

(h) CIVIL ACTION.—If an individual does not request a hearing pursuant to subsection (e) and the Attorney General issues an order pursuant to such subsection, or if an individual does not under subsection (g) seek judicial review of such an order, the Attorney General may commence a civil action in any appropriate district court of the United States for the purpose of recovering the amount assessed and an amount representing interest at a rate computed in accordance with section 1961 of title 28, United States Code. Such interest shall accrue from the expiration of the 30-day period described in subsection (g). In such an action, the decision of the Attorney General to issue the order, and the amount of the penalty assessed by the Attorney General, shall not be subject to review.

(i) LIMITATION.—The Attorney General may not under this subsection [55] commence proceeding against an individual after the expiration of the 5-year period beginning on the date on which the individual allegedly violated subsection (a).

(j) EXPUNGEMENT PROCEDURES.—The Attorney General shall dismiss the proceedings under this section against an individual upon application of such individual at any time after the expiration of 3 years if—

(1) the individual has not previously been assessed a civil penalty under this section;

(2) the individual has paid the assessment;

[55] So in law. See section 6486(i) of Public Law 100–690 (102 Stat. 4384). Probably should be "section". (Section 6486(i) of such Public Law was transferred to this act and redesignated as section 405 by section 1002(g)(1) of Public Law 101–647 (104 Stat. 4828).)

(3) the individual has complied with any conditions imposed by the Attorney General;

(4) the individual has not been convicted of a Federal or State offense relating to a controlled substance; and

(5) the individual agrees to submit to a drug test, and such test shows the individual to be drug free.

A nonpublic record of a disposition under this subsection shall be retained by the Department of Justice solely for the purpose of determining in any subsequent proceeding whether the person qualified for a civil penalty or expungement under this section. If a record is expunged under this subsection, an individual concerning whom such an expungement has been made shall not be held thereafter under any provision of law to be guilty of perjury, false swearing, or making a false statement by reason of his failure to recite or acknowledge a proceeding under this section or the results thereof in response to an inquiry made of him for any purpose.

ATTEMPT AND CONSPIRACY

SEC. 406. [21 U.S.C. 846] Any person who attempts or conspires to commit any offense defined in this title shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

ADDITIONAL PENALTIES

SEC. 407. [21 U.S.C. 847] Any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

CONTINUING CRIMINAL ENTERPRISE

SEC. 408. [21 U.S.C. 848] (a) Any person who engages in a continuing criminal enterprise shall be sentenced to a term of imprisonment which may not be less than 20 years and which may be up to life imprisonment, to a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, and to the forfeiture prescribed in section 413 of this title; except that if any person engages in such activity after one or more prior convictions of him under this section have become final, he shall be sentenced to a term of imprisonment which may not be less than 30 years and which may be up to life imprisonment, to a fine not to exceed the greater of twice the amount authorized in accordance with the provisions of title 18, United States Code, or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, and to the forfeiture prescribed in section 413 of this title.

(b) Any person who engages in a continuing criminal enterprise shall be imprisoned for life and fined in accordance with subsection (a), if—

(1) such person is the principal administrator, organizer, or leader of the enterprise or is one of several such principal administrators, organizers, or leaders; and

(2)(A) the violation referred to in subsection (c)(1) involved at least 300 times the quantity of a substance described in subsection 401(b)(1)(B) of this Act, or

(B) the enterprise, or any other enterprise in which the defendant was the principal or one of several principal administrators, organizers, or leaders, received $10 million dollars in gross receipts during any twelve-month period of its existence for the manufacture, importation, or distribution of a substance described in section 401(b)(1)(B) of this Act.

(c) For purposes of subsection (a), a person is engaged in a continuing criminal enterprise if—

(1) he violates any provision of this title or title III the punishment for which is a felony, and

(2) such violation is a part of a continuing series of violations of this title or title III—

(A) which are undertaken by such person in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and

(B) from which such person obtains substantial income or resources.

(d) In the case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended, probation shall not be granted, and the Act of July 15, 1932 (D.C. Code, secs. 24–203—24–207), shall not apply.

Death Penalty

(e)(1) In addition to the other penalties set forth in this section—

(A) any person engaging in or working in furtherance of a continuing criminal enterprise, or any person engaging in an offense punishable under section 841(b)(1)(A) or section 960(b)(1) who intentionally kills or counsels, commands, induces, procures, or causes the intentional killing of an individual and such killing results, shall be sentenced to any term of imprisonment, which shall not be less than 20 years, and which may be up to life imprisonment, or may be sentenced to death; and

(B) any person, during the commission of, in furtherance of, or while attempting to avoid apprehension, prosecution or service of a prison sentence for, a felony violation of this title or title III who intentionally kills or counsels, commands, induces, procures, or causes the intentional killing of any Federal, State, or local law enforcement officer engaged in, or on account of, the performance of such officer's official duties and such killing results, shall be sentenced to any term of imprisonment, which shall not be less than 20 years, and which may be up to life imprisonment, or may be sentenced to death; and

(2) As used in paragraph (1)(b)[56], the term "law enforcement officer" means a public servant authorized by law or by a Government

[56] So in law. Probably should be "(1)(B)".

agency or Congress to conduct or engage in the prevention, investigation, prosecution or adjudication of an offense, and includes those engaged in corrections, probation, or parole functions.

Hearing Required With Respect to the Death Penalty

(g)[57] A person shall be subjected to the penalty of death for any offense under this section only if a hearing is held in accordance with this section.

Notice by the Government in Death Penalty Cases

(h)(1) Whenever the Government intends to seek the death penalty for an offense under this section for which one of the sentences provided is death, the attorney for the Government, a reasonable time before trial or acceptance by the court of a plea of guilty, shall sign and file with the court, and serve upon the defendant, a notice—

(A) that the Government in the event of conviction will seek the sentence of death; and

(B) setting forth the aggravating factors enumerated in subsection (n) and any other aggravating factors which the Government will seek to prove as the basis for the death penalty.

(2) The court may permit the attorney for the Government to amend this notice for good cause shown.

Hearing Before Court or Jury

(i)(1) When the attorney for the Government has filed a notice as required under subsection (h) and the defendant is found guilty of or pleads guilty to an offense under subsection (e), the judge who presided at the trial or before whom the guilty plea was entered, or any other judge if the judge who presided at the trial or before whom the guilty plea was entered is unavailable, shall conduct a separate sentencing hearing to determine the punishment to be imposed. The hearing shall be conducted—

(A) before the jury which determined the defendant's guilt;

(B) before a jury impaneled for the purpose of the hearing if—

(i) the defendant was convicted upon a plea of guilty;

(ii) the defendant was convicted after a trial before the court sitting without a jury;

(iii) the jury which determined the defendant's guilt has been discharged for good cause; or

(iv) after initial imposition of a sentence under this section, redetermination of the sentence under this section is necessary; or

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[57] So in law. Section 408 does not contain a subsection (f). See subsections (a) and (b) of section 7001 of Public Law 100-690 (102 Stat. 4387, 4388). Section 7001(a) provided for the redesignation of former subsection (e) as subsection (f), and then inserted subsection (e) above. Section 7001(b) added subsections (g) through (r). The redesignating amendment described by section 7001(a) could not be made, however, because there no longer was a subsection (e) as a result of a redesignating amendment made by section 6481(b) of such Public Law (102 Stat. 4382).

(The amendment made by section 6481(b) concerned the fact that there was no subsection (c) in section 408 as a result of an amendment made by section 1253 of Public Law 99–570. Section 6481(b) redesignated subsections (d) and (e) as subsections (c) and (d). Section 7001(a) did not take into account that redesignating amendment.)

(C) before the court alone, upon the motion of the defendant and with the approval of the Government.

(2) A jury impaneled under paragraph (1)(B) shall consist of 12 members, unless, at any time before the conclusion of the hearing, the parties stipulate with the approval of the court that it shall consist of any number less than 12.

Proof of Aggravating and Mitigating Factors

(j) Notwithstanding rule 32(c) of the Federal Rules of Criminal Procedure, when a defendant is found guilty of or pleads guilty to an offense under subsection (e), no presentence report shall be prepared. In the sentencing hearing, information may be presented as to matters relating to any of the aggravating or mitigating factors set forth in subsections (m) and (n), or any other mitigating factor or any other aggravating factor for which notice has been provided under subsection (h)(1)(B). Where information is presented relating to any of the aggravating factors set forth in subsection (n), information may be presented relating to any other aggravating factor for which notice has been provided under subsection (h)(1)(B). Information presented may include the trial transcript and exhibits if the hearing is held before a jury or judge not present during the trial, or at the trial judge's discretion. Any other information relevant to such mitigating or aggravating factors may be presented by either the Government or the defendant, regardless of its admissibility under the rules governing admission of evidence at criminal trials, except that information may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. The Government and the defendant shall be permitted to rebut any information received at the hearing and shall be given fair opportunity to present argument as to the adequacy of the information to establish the existence of any of the aggravating or mitigating factors and as to appropriateness in that case of imposing a sentence of death. The Government shall open the argument. The defendant shall be permitted to reply. The Government shall then be permitted to reply in rebuttal. The burden of establishing the existence of any aggravating factor is on the Government, and is not satisfied unless established beyond a reasonable doubt. The burden of establishing the existence of any mitigating factor is on the defendant, and is not satisfied unless established by a preponderance of the evidence.

Return of Findings

(k) The jury, or if there is no jury, the court, shall consider all the information received during the hearing. It shall return special findings identifying any aggravating factors set forth in subsection (n), found to exist. If one of the aggravating factors set forth in subsection (n)(1) and another of the aggravating factors set forth in paragraphs (2) through (12) of subsection (n) is found to exist, a special finding identifying any other aggravating factor for which notice has been provided under subsection (h)(1)(B), may be returned. A finding with respect to a mitigating factor may be made by one or more of the members of the jury, and any member of the jury who finds the existence of a mitigating factor may consider

such a factor established for purposes of this subsection, regardless of the number of jurors who concur that the factor has been established. A finding with respect to any aggravating factor must be unanimous. If an aggravating factor set forth in subsection (n)(1) is not found to exist or an aggravating factor set forth in subsection (n)(1) is found to exist but no other aggravating factor set forth in subsection (n) is found to exist, the court shall impose a sentence, other than death, authorized by law. If an aggravating factor set forth in subsection (n)(1) and one or more of the other aggravating factors set forth in subsection (n) are found to exist, the jury, or if there is no jury, the court, shall then consider whether the aggravating factors found to exist sufficiently outweigh any mitigating factor or factors found to exist, or in the absence of mitigating factors, whether aggravating factors are themselves sufficient to justify a sentence of death. Based upon this consideration, the jury by unanimous vote, or if there is no jury, the court, shall recommend that a sentence of death shall be imposed rather than a sentence of life imprisonment without possibility of release or some other lesser sentence. The jury or the court, regardless of its findings with respect to aggravating and mitigating factors, is never required to impose a death sentence and the jury shall be so instructed.

Imposition of Sentence

(l) Upon the recommendation that the sentence of death be imposed, the court shall sentence the defendant to death. Otherwise the court shall impose a sentence, other than death, authorized by law. A sentence of death shall not be carried out upon a person who is under 18 years of age at the time the crime was committed. A sentence of death shall not be carried out upon a person who is mentally retarded. A sentence of death shall not be carried out upon a person who, as a result of mental disability—

(1) cannot understand the nature of the pending proceedings, what such person was tried for, the reason for the punishment, or the nature of the punishment; or

(2) lacks the capacity to recognize or understand facts which would make the punishment unjust or unlawful, or lacks the ability to convey such information to counsel or to the court.

Mitigating Factors

(m) In determining whether a sentence of death is to be imposed on a defendant, the finder of fact shall consider mitigating factors, including the following:

(1) The defendant's capacity to appreciate the wrongfulness of the defendant's conduct or to conform conduct to the requirements of law was significantly impaired, regardless of whether the capacity was so impaired as to constitute a defense to the charge.

(2) The defendant was under unusual and substantial duress, regardless of whether the duress was of such a degree as to constitute a defense to the charge.

(3) The defendant is punishable as a principal (as defined in section 2 of title 18 of the United States Code) in the offense,

which was committed by another, but the defendant's participation was relatively minor, regardless of whether the participation was so minor as to constitute a defense to the charge.

(4) The defendant could not reasonably have foreseen that the defendant's conduct in the course of the commission of murder, or other offense resulting in death for which the defendant was convicted, would cause, or would create a grave risk of causing, death to any person.

(5) The defendant was youthful, although not under the age of 18.

(6) The defendant did not have a significant prior criminal record.

(7) The defendant committed the offense under severe mental or emotional disturbance.

(8) Another defendant or defendants, equally culpable in the crime, will not be punished by death.

(9) The victim consented to the criminal conduct that resulted in the victim's death.

(10) That other factors in the defendant's background or character mitigate against imposition of the death sentence.

Aggravating Factors for Homicide

(n) If the defendant is found guilty of or pleads guilty to an offense under subsection (e), the following aggravating factors are the only aggravating factors that shall be considered, unless notice of additional aggravating factors is provided under subsection (h)(1)(B):

(1) The defendant—

(A) intentionally killed the victim;

(B) intentionally inflicted serious bodily injury which resulted in the death of the victim;

(C) intentionally engaged in conduct intending that the victim be killed or that lethal force be employed against the victim, which resulted in the death of the victim;

(D) intentionally engaged in conduct which—

(i) the defendant knew would create a grave risk of death to a person, other than one of the participants in the offense; and

(ii) resulted in the death of the victim.

(2) The defendant has been convicted of another Federal offense, or a State offense resulting in the death of a person, for which a sentence of life imprisonment or a sentence of death was authorized by statute.

(3) The defendant has previously been convicted of two or more State or Federal offenses punishable by a term of imprisonment of more than one year, committed on a different occasions, involving the infliction of, or attempted infliction of, serious bodily injury upon another person.

(4) The defendant has previously been convicted of two or more State or Federal offenses punishable by a term of imprisonment of more than one year, committed on different occasions, involving the distribution of a controlled substance.

(5) In the commission of the offense or in escaping apprehension for a violation of subsection (e), the defendant knowingly created a grave risk of death to one or more persons in addition to the victims of the offense.

(6) The defendant procured the commission of the offense by payment, or promise of payment, of anything of pecuniary value.

(7) The defendant committed the offense as consideration for the receipt, or in the expectation of the receipt, of anything of pecuniary value.

(8) The defendant committed the offense after substantial planning and premeditation.

(9) The victim was particularly vulnerable due to old age, youth, or infirmity.

(10) The defendant had previously been convicted of violating this title or title III for which a sentence of five or more years may be imposed or had previously been convicted of engaging in a continuing criminal enterprise.

(11) The violation of this title in relation to which the conduct described in subsection (e) occurred was a violation of section 418.

(12) The defendant committed the offense in an especially heinous, cruel, or depraved manner in that it involved torture or serious physical abuse to the victim.

Right of the Defendant to Justice Without Discrimination

(o)(1) In any hearing held before a jury under this section, the court shall instruct the jury that in its consideration of whether the sentence of death is justified it shall not consider the race, color, religious beliefs, national origin, or sex of the defendant or the victim, and that the jury is not to recommend a sentence of death unless it has concluded that it would recommend a sentence of death for the crime in question no matter what the race, color, religious beliefs, national origin, or sex of the defendant, or the victim, may be. The jury shall return to the court a certificate signed by each juror that consideration of the race, color, religious beliefs, national origin, or sex of the defendant or the victim was not involved in reaching his or her individual decision, and that the individual juror would have made the same recommendation regarding a sentence for the crime in question no matter what the race, color, religious beliefs, national origin, or sex of the defendant, or the victim, may be.

(2) Not later than one year from the date of enactment of the Anti-Drug Abuse Amendments Act of 1988, the Comptroller General shall conduct a study of the various procedures used by the several States for determining whether or not to impose the death penalty in particular cases, and shall report to the Congress on whether or not any or all of the various procedures create a significant risk that the race of a defendant, or the race of a victim against whom a crime was committed, influence the likelihood that defendants in those States will be sentenced to death. In conducting the study required by this paragraph, the General Accounting Office shall—

(A) use ordinary methods of statistical analysis, including methods comparable to those ruled admissible by the courts in race discrimination cases under title VII of the Civil Rights Act of 1964;

(B) study only crimes occurring after January 1, 1976; and

(C) determine what, if any, other factors, including any relation between any aggravating or mitigating factors and the race of the victim or the defendant, may account for any evidence that the race of the defendant, or the race of the victim, influences the likelihood that defendants will be sentenced to death. In addition, the General Accounting Office shall examine separately and include in the report, death penalty cases involving crimes similar to those covered under this section.

Sentencing in Capital Cases in Which Death Penalty is not Sought or Imposed

(p) If a person is convicted for an offense under subsection (e) and the court does not impose the penalty of death, the court may impose a sentence of life imprisonment without the possibility of parole.

Appeal in Capital Cases; Counsel for Financially Unable Defendants

(q)(1) In any case in which the sentence of death is imposed under this section, the sentence of death shall be subject to review by the court of appeals upon appeal by the defendant. Notice of appeal must be filed within the time prescribed for appeal of judgment in section 2107 of title 28, United States Code. An appeal under this section may be consolidated with an appeal of the judgment of conviction. Such review shall have priority over all other cases.

(2) On review of the sentence, the court of appeals shall consider the record, the evidence submitted during the trial, the information submitted during the sentencing hearing, the procedures employed in the sentencing hearing, and the special findings returned under this section.

(3) The court shall affirm the sentence if it determines that—

(A) the sentence of death was not imposed under the influence of passion, prejudice, or any other arbitrary factor; and

(B) the information supports the special finding of the existence of every aggravating factor upon which the sentence was based, together with, or the failure to find, any mitigating factors as set forth or allowed in this section.

In all other cases the court shall remand the case for reconsideration under this section. The court of appeals shall state in writing the reasons for its disposition of the review of the sentence.

(4)(A) Notwithstanding any other provision of law to the contrary, in every criminal action in which a defendant is charged with a crime which may be punishable by death, a defendant who is or becomes financially unable to obtain adequate representation or investigative, expert, or other reasonably necessary services at any time either—

(i) before judgment; or

(ii) after the entry of a judgment imposing a sentence of death but before the execution of that judgment;

shall be entitled to the appointment of one or more attorneys and the furnishing of such other services in accordance with paragraphs (5), (6), (7), (8), and (9).

(B) In any post conviction proceeding under section 2254 or 2255 of title 28, United States Code, seeking to vacate or set aside a death sentence, any defendant who is or becomes financially unable to obtain adequate representation or investigative, expert, or other reasonably necessary services shall be entitled to the appointment of one or more attorneys and the furnishing of such other services in accordance with paragraphs (5), (6), (7), (8), and (9).

(5) If the appointment is made before judgment, at least one attorney so appointed must have been admitted to practice in the court in which the prosecution is to be tried for less than five years, and must have had not less than three years experience in the actual trial of felony prosecutions in that court.

(6) If the appointment is made after judgment, at least one attorney so appointed must have been admitted to practice in the court of appeals for not less than five years, and must have had not less than three years experience in the handling of appeals in that court in felony cases.

(7) With respect to paragraphs (5) and (6), the court, for good cause, may appoint another attorney whose background, knowledge, or experience would otherwise enable him or her to properly represent the defendant, with due consideration to the seriousness of the possible penalty and to the unique and complex nature of the litigation.

(8) Unless replaced by similarly qualified counsel upon the attorney's own motion or upon motion of the defendant, each attorney so appointed shall represent the defendant throughout every subsequent stage of available judicial proceedings, including pretrial proceedings, trial, sentencing, motions for new trial, appeals, applications for writ of certiorari to the Supreme Court of the United States, and all available post-conviction process, together with applications for stays of execution and other appropriate motions and procedures, and shall also represent the defendant in such competency proceedings and proceedings for executive or other clemency as may be available to the defendant.

(9) Upon a finding that investigative, expert, or other services are reasonably necessary for the representation of the defendant, whether in connection with issues relating to guilt or the sentence, the court may authorize the defendant's attorneys to obtain such services on behalf of the defendant and, if so authorized, shall order the payment of fees and expenses therefor under paragraph (10). No ex parte proceeding, communication, or request may be considered pursuant to this section unless a proper showing is made concerning the need for confidentiality. Any such proceeding, communication, or request shall be transcribed and made a part of the record available for appellate review.

(10)(A) Compensation shall be paid to attorneys appointed under this subsection at a rate of not more than $125 per hour for in-court and out-of-court time. Not less than 3 years after the date of the enactment of the Antiterrorism and Effective Death Penalty

Act of 1996, the Judicial Conference is authorized to raise the maximum for hourly payment specified in the paragraph up to the aggregate of the overall average percentages of the adjustments in the rates of pay for the General Schedule made pursuant to section 5305 of title 5[58] on or after such date. After the rates are raised under the preceding sentence, such hourly range may be raised at intervals of not less than one year, up to the aggregate of the overall average percentages of such adjustments made since the last raise under this paragraph.

(B) Fees and expenses paid for investigative, expert, and other reasonably necessary services authorized under paragraph (9) shall not exceed $7,500 in any case, unless payment in excess of that limit is certified by the court, or by the United States magistrate judge, if the services were rendered in connection with the case disposed of entirely before such magistrate judge, as necessary to provide fair compensation for services of an unusual character or duration, and the amount of the excess payment is approved by the chief judge of the circuit. The chief judge of the circuit may delegate such approval authority to an active circuit judge.

(C) The amounts paid under this paragraph for services in any case shall be disclosed to the public, after the disposition of the petition.

Refusal to Participate by State and Federal Correctional Employees

(r) No employee of any State department of corrections or the Federal Bureau of Prisons and no employee providing services to that department or bureau under contract shall be required, as a condition of that employment, or contractual obligation to be in attendance at or to participate in any execution carried out under this section if such participation is contrary to the moral or religious convictions of the employee. For purposes of this subsection, the term "participation in executions" includes personal preparation of the condemned individual and the apparatus used for execution and supervision of the activities of other personnel in carrying out such activities.

TRANSPORTATION SAFETY OFFENSES

SEC. 409. [21 U.S.C. 849] (a) DEFINITIONS.—In this section—

"safety rest area" means a roadside facility with parking facilities for the rest or other needs of motorists.

"truck stop" means a facility (including any parking lot appurtenant thereto) that—

(A) has the capacity to provide fuel or service, or both, to any commercial motor vehicle (as defined in section 31301 of title 49, United States Code), operating in commerce (as defined in that section); and

(B) is located within 2,500 feet of the National System of Interstate and Defense Highways or the Federal-Aid Primary System.

(b) FIRST OFFENSE.—A person who violates section 401(a)(1) or section 416 by distributing or possessing with intent to distribute

[58] So in law. Probably should read "section 5305 of title 5, United States Code,".

a controlled substance in or on, or within 1,000 feet of, a truck stop or safety rest area is (except as provided in subsection (b)[59]) subject to—

(1) twice the maximum punishment authorized by section 401(b); and

(2) twice any term of supervised release authorized by section 401(b) for a first offense.

(c) SUBSEQUENT OFFENSE.—A person who violates section 401(a)(1) or section 416 by distributing or possessing with intent to distribute a controlled substance in or on, or within 1,000 feet of, a truck stop or a safety rest area after a prior conviction or convictions under subsection (a)[60] have become final is subject to—

(1) 3 times the maximum punishment authorized by section 401(b); and

(2) 3 times any term of supervised release authorized by section 401(b) for a first offense.

INFORMATION FOR SENTENCING

SEC. 410. [21 U.S.C. 850] Except as otherwise provided in this title or section 303(a) of the Public Health Service Act[61], no limitation shall be placed on the information concerning the background, character, and conduct of a person convicted of an offense which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence under this title or title III.

PROCEEDINGS TO ESTABLISH PRIOR CONVICTIONS

SEC. 411. [21 U.S.C. 851] (a)(1) No person who stands convicted of an offense under this part shall be sentenced to increased punishment by reason of one or more prior convictions, unless before trial, or before entry of a plea of guilty, the United States attorney files an information with the court (and serves a copy of such information on the person or counsel for the person) stating in writing the previous convictions to be relied upon. Upon a showing by the United States attorney that facts regarding prior convictions could not with due diligence be obtained prior to trial or before entry of a plea of guilty, the court may postpone the trial or the taking of the plea of guilty for a reasonable period for the purpose of obtaining such facts. Clerical mistakes in the information may be amended at any time prior to the pronouncement of sentence.

(2) An information may not be filed under this section if the increased punishment which may be imposed is imprisonment for a term in excess of three years unless the person either waived or was afforded prosecution by indictment for the offense for which such increased punishment may be imposed.

(b) If the United States attorney files an information under this section, the court shall after conviction but before pronouncement of sentence inquire of the person with respect to whom the information was filed whether he affirms or denies that he has been previously convicted as alleged in the information, and shall inform

[59] So in law. Probably should be "subsection (c)".
[60] So in law. Probably should be "subsection (b)".
[61] Section 303 of the Public Health Service Act was repealed by section 3201(b)(1) of Public Law 106–310 (114 Stat. 1190).

him that any challenge to a prior conviction which is not made before sentence is imposed may not thereafter be raised to attack the sentence.

(c)(1) If the person denies any allegation of the information of prior conviction, or claims that any conviction alleged is invalid, he shall file a written response to the information. A copy of the response shall be served upon the United States attorney. The court shall hold a hearing to determine any issues raised by the response which would except the person from increased punishment. The failure of the United States attorney to include in the information the complete criminal record of the person or any facts in addition to the convictions to be relied upon shall not constitute grounds for invalidating the notice given in the information required by subsection (a)(1). The hearing shall be before the court without a jury and either party may introduce evidence. Except as otherwise provided in paragraph (2) of this subsection, the United States attorney shall have the burden of proof beyond a reasonable doubt on any issue of fact. At the request of either party, the court shall enter findings of fact and conclusions of law.

(2) A person claiming that a conviction alleged in the information was obtained in violation of the Constitution of the United States shall set forth his claim, and the factual basis therefor, with particularity in his response to the information. The person shall have the burden of proof by a preponderance of the evidence on any issue of fact raised by the response. Any challenge to a prior conviction, not raised by response to the information before an increased sentence is imposed in reliance thereon, shall be waived unless good cause be shown for failure to make a timely challenge.

(d)(1) If the person files no response to the information, or if the court determines, after hearing, that the person is subject to increased punishment by reason of prior convictions, the court shall proceed to impose sentence upon him as provided by this part.

(2) If the court determines that the person has not been convicted as alleged in the information, that a conviction alleged in the information is invalid, or that the person is otherwise not subject to an increased sentence as a matter of law, the court shall, at the request of the United States attorney, postpone sentence to allow an appeal from that determination. If no such request is made, the court shall impose sentence as provided by this part. The person may appeal from an order postponing sentence as if sentence had been pronounced and a final judgment of conviction entered.

(e) No person who stands convicted of an offense under this part may challenge the validity of any prior conviction alleged under this section which occurred more than five years before the date of the information alleging such prior conviction.

APPLICATION OF TREATIES AND OTHER INTERNATIONAL AGREEMENTS

SEC. 412. [21 U.S.C. 852] Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit the provision of treatment, education, or rehabilitation as alternatives to conviction or criminal penalty for offenses involving

any drug or other substance subject to control under any such treaty or agreement.

CRIMINAL FORFEITURES

PROPERTY SUBJECT TO CRIMINAL FORFEITURE

SEC. 413. [21 U.S.C. 853] (a) Any person convicted of a violation of this title or title III punishable by imprisonment for more than one year shall forfeit to the United States, irrespective of any provision of State law—

(1) any property constituting, or derived from, any proceeds the person obtained, directly or indirectly, as the result of such violation;

(2) any of the person's property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, such violation; and

(3) in the case of a person convicted of engaging in a continuing criminal enterprise in violation of section 408 of this title (21 U.S.C. 848), the person shall forfeit, in addition to any property described in paragraph (1) or (2), any of his interest in, claims against, and property or contractual rights affording a source of control over, the continuing criminal enterprise.

The court, in imposing sentence on such person, shall order, in addition to any other sentence imposed pursuant to this title or title III, that the person forfeit to the United States all property described in this subsection. In lieu of a fine otherwise authorized by this part, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.

MEANING OF TERM "PROPERTY"

(b) Property subject to criminal forfeiture under this section includes—

(1) real property, including things growing on, affixed to, and found in land; and

(2) tangible and intangible personal property, including rights, privileges, interests, claims, and securities.

THIRD PARTY TRANSFERS

(c) All right, title, and interest in property described in subsection (a) vests in the United States upon the commission of the act giving rise to forfeiture under this section. Any such property that is subsequently transferred to a person other than the defendant may be the subject of a special verdict of forfeiture and thereafter shall be ordered forfeited to the United States, unless the transferee establishes in a hearing pursuant to subsection (n) that he is a bona fide purchaser for value of such property who at the time of purchase was reasonably without cause to believe that the property was subject to forfeiture under this section.

REBUTTABLE PRESUMPTION

(d) There is a rebuttable presumption at trial that any property of a person convicted of a felony under this title or title III is subject to forfeiture under this section if the United States establishes by a preponderance of the evidence that—

(1) such property was acquired by such person during the period of the violation of this title or title III or within a reasonable time after such period; and

(2) there was no likely source for such property other than the violation of this title or title III.

PROTECTIVE ORDERS

(e)(1) Upon application of the United States, the court may enter a restraining order or injunction, require the execution of a satisfactory performance bond, or take any other action to preserve the availability of property described in subsection (a) for forfeiture under this section—

(A) upon the filing of an indictment or information charging a violation of this title or title III for which criminal forfeiture may be ordered under this section and alleging that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section; or

(B) prior to the filing of such an indictment or information, if, after notice to persons appearing to have an interest in the property and opportunity for a hearing, the court determines that—

(i) there is a substantial probability that the United States will prevail on the issue of forfeiture and that failure to enter the order will result in the property being destroyed, removed from the jurisdiction of the court, or otherwise made unavailable for forfeiture; and

(ii) the need to preserve the availability of the property through the entry of the requested order outweighs the hardship on any party against whom the order is to be entered:

Provided, *however*, That an order entered pursuant to subparagraph (B) shall be effective for not more than ninety days, unless extended by the court for good cause shown or unless an indictment or information described in subparagraph (A) has been filed.

(2) A temporary restraining order under this subsection may be entered upon application of the United States without notice or opportunity for a hearing when an information or indictment has not yet been filed with respect to the property, if the United States demonstrates that there is probable cause to believe that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section and that provision of notice will jeopardize the availability of the property for forfeiture. Such a temporary order shall expire not more than ten days after the date on which it is entered, unless extended for good cause shown or unless the party against whom it is entered consents to an extension for a longer period. A hearing requested concerning an order entered under this paragraph shall be held at

the earliest possible time and prior to the expiration of the temporary order.

(3) The court may receive and consider, at a hearing held pursuant to this subsection, evidence and information that would be inadmissible under the Federal Rules of Evidence.

(4)[62] ORDER TO REPATRIATE AND DEPOSIT.—

(A) IN GENERAL.—Pursuant to its authority to enter a pretrial restraining order under this section, the court may order a defendant to repatriate any property that may be seized and forfeited, and to deposit that property pending trial in the registry of the court, or with the United States Marshals Service or the Secretary of the Treasury, in an interest-bearing account, if appropriate.

(B) FAILURE TO COMPLY.—Failure to comply with an order under this subsection, or an order to repatriate property under subsection (p), shall be punishable as a civil or criminal contempt of court, and may also result in an enhancement of the sentence of the defendant under the obstruction of justice provision of the Federal Sentencing Guidelines.

WARRANT OF SEIZURE

(f) The Government may request the issuance of a warrant authorizing the seizure of property subject to forfeiture under this section in the same manner as provided for a search warrant. If the court determines that there is probable cause to believe that the property to be seized would, in the event of conviction, be subject to forfeiture and that an order under subsection (e) may not be sufficient to assure the availability of the property for forfeiture, the court shall issue a warrant authorizing the seizure of such property.

EXECUTION

(g) Upon entry of an order of forfeiture under this section, the court shall authorize the Attorney General to seize all property ordered forfeited upon such terms and conditions as the court shall deem proper. Following entry of an order declaring the property forfeited, the court may, upon application of the United States, enter such appropriate restraining orders or injunctions, require the execution of satisfactory performance bonds, appoint receivers, conservators, appraisers, accountants, or trustees, or take any other action to protect the interest of the United States in the property ordered forfeited. Any income accruing to or derived from property ordered forfeited under this section may be used to offset ordinary and necessary expenses to the property which are required by law, or which are necessary to protect the interests of the United States or third parties.

DISPOSITION OF PROPERTY

(h) Following the seizure of property ordered forfeited under this section, the Attorney General shall direct the disposition of the

[62] Indentation is so in law. See section 319(d)(2) of Public Law 107–56 (115 Stat. 314).

property by sale of any other any other commercially feasible means, making due provision for the rights of any innocent persons. Any property right or interest not exercisable by, or transferable for value to, the United States shall expire and shall not revert to the defendant, nor shall the defendant or any person acting in concert with him or on his behalf be eligible to purchase forfeited property at any sale held by the United States. Upon application of a person, other than the defendant or a person acting in concert with him or on his behalf, the court may restrain or stay the sale or disposition of the property pending the conclusion of any appeal of the criminal case giving rise to the forefeiture, if the applicant demonstrates that proceeding with the sale or disposition of the property will result in irreparable injury, harm, or loss to him.

AUTHORITY OF THE ATTORNEY GENERAL

(i) With respect to property ordered forfeited under this section, the Attorney General is authorized to—

(1) grant petitions for mitigation or remission of forfeiture, restore forfeited property to victims of a violation of this title, or take any other action to protect the rights of innocent persons which is in the interest of justice and which is not inconsistent with the provisions of this section;

(2) compromise claims arising under this section;

(3) award compensation to persons providing information resulting in a forfeiture under this section;

(4) direct the disposition by the United States, in accordance with the provisions of section 511(e) of this title (21 U.S.C. 881(e)), of all property ordered forfeited under this section by public sale or any other commercially feasible means, making due provision for the rights of innocent persons; and

(5) take appropriate measures necessary to safeguard and maintain property ordered forfeited under this section pending its disposition.

APPLICABILITY OF CIVIL FORFEITURE PROVISIONS

(j) Except to the extent that they are inconsistent with the provisions of this section, the provisions of section 511(d) of this title (21 U.S.C. 881(d)) shall apply to a criminal forfeiture under this section.

BAR ON INTERVENTION

(k) Except as provided in subsection (n), no party claiming an interest in property subject to forfeiture under this section may—

(1) intervene in a trial or appeal of a criminal case involving the forfeiture of such property under this section; or

(2) commence an action at law or equity against the United States concerning the validity of his alleged interest in the property subsequent to the filing of an indictment or information alleging that the property in subject to forfeiture under this section.

JURISDICTION TO ENTER ORDERS

(l) The district courts of the United States shall have jurisdiction to enter orders as provided in this section without regard to the location of any property which may be subject to forfeiture under this section or which has been ordered forfeited under this section.

DEPOSITIONS

(m) In order to facilitate the identification and location of property declared forfeited and to facilitate the disposition of petitions for remission or mitigation of forfeiture, after the entry of an order declaring property forfeited to the United States, the court may, upon application of the United States, order that the testimony of any witness relating to the property forfeited be taken by deposition and that any designated book, paper, document, record, recording, or other material not privileged be produced at the same time any place, in the same manner as provided for the taking of depositions under Rule 15 of the Federal Rules of Criminal Procedure.

THIRD PARTY INTERESTS

(n)(1) Following the entry of an order of forfeiture under this section, the United States shall publish notice of the order and of its intent to dispose of the property in such manner as the Attorney General may direct. The Government may also, to the extent practicable, provide direct written notice to any person known to have alleged an interest in the property that is the subject of the order of forfeiture as a substitute for published notice as to those persons so notified.

(2) Any person, other than the defendant, asserting a legal interest in property which has been ordered forfeited to the United States pursuant to this section may, within thirty days of the final publication of notice or his receipt of notice under paragraph (1), whichever is earlier, petition the court for a hearing to adjudicate the validity of his alleged interest in the property. The hearing shall be held before the court alone, without a jury.

(3) The petition shall be signed by the petitioner under penalty of perjury and shall set forth the nature and extent of the petitioner's right, title, or interest in the property, the time and circumstances of the petitioner's acquisition of the right, title, or interest in the property, and additional facts supporting the petitioner's claim, and the relief sought.

(4) The hearing on the petition shall, to the extent practicable and consistent with the interests of justice, be held within thirty days of the filing of the petition. The court may consolidate the hearing on the petition with a hearing on any other petition filed by a person other than the defendant under this subsection.

(5) At the hearing, the petitioner may testify and present evidence and witnesses on his own behalf, and cross-examine witnesses who appear at the hearing. The United States may present evidence and witnesses in rebuttal and in defense of this claim to the property and cross-examine witnesses who appear at the hearing, the court shall consider the relevant portions of the record of the criminal case which resulted in the order of forfeiture.

(6) If, after the hearing, the court determines that the petitioner has established by a preponderance of the evidence that—

(A) the petitioner has a legal right, title, or interest in the property, and such right, title, or interest renders the order of forfeiture invalid in whole or in part because the right, title, or interest was vested in the petitioner rather than the defendant or was superior to any right, title, or interest of the defendant at the time of the commission of the acts which gave rise to the forfeiture of the property under the section; or

(B) the petitioner is a bona fide purchaser for value of the right, title, or interest in the property and was at the time of purchase reasonably without cause to believe that the property was subject to forfeiture under this section;

the court shall amend the order of forfeiture in accordance with its determination.

(7) Following the court's disposition of all petitions filed under this subsection, or if no such petitions are filed following the expiration of the period provided in paragraph (2) for the filing of such petitions, the United States shall have clear title to property that is the subject of the order of forfeiture and may warrant good title to any subsequent purchaser or transferee.

(o) The provisions of this section shall be liberally construed to effectuate its remedial purposes.

(p) FORFEITURE OF SUBSTITUTE PROPERTY.—

(1) IN GENERAL.—Paragraph (2) of this subsection shall apply, if any property described in subsection (a), as a result of any act or omission of the defendant—

(A) cannot be located upon the exercise of due diligence;

(B) has been transferred or sold to, or deposited with, a third party;

(C) has been placed beyond the jurisdiction of the court;

(D) has been substantially diminished in value; or

(E) has been commingled with other property which cannot be divided without difficulty.

(2) SUBSTITUTE PROPERTY.—In any case described in any of subparagraphs (A) through (E) of paragraph (1), the court shall order the forfeiture of any other property of the defendant, up to the value of any property described in subparagraphs (A) through (E) of paragraph (1), as applicable.

(3) RETURN OF PROPERTY TO JURISDICTION.—In the case of property described in paragraph (1)(C), the court may, in addition to any other action authorized by this subsection, order the defendant to return the property to the jurisdiction of the court so that the property may be seized and forfeited.

(q) The court, when sentencing a defendant convicted of an offense under this title or title III involving the manufacture of amphetamine or methamphetamine, shall—

(1) order restitution as provided in sections 3612 and 3664 of title 18, United States Code;

(2) order the defendant to reimburse the United States, the State or local government concerned, or both the United States and the State or local government concerned for the costs incurred by the United States or the State or local government concerned, as the case may be, for the cleanup associated with

the manufacture of amphetamine or methamphetamine by the defendant; and

(3) order restitution to any person injured as a result of the offense as provided in section 3663A of title 18, United States Code.

INVESTMENT OF ILLICIT DRUG PROFITS

SEC. 414. [21 U.S.C. 854] (a) It shall be unlawful for any person who has received any income derived, directly or indirectly, from a violation of this title of title III punishable by imprisonment for more than one year in which such person has participated as a principal within the meaning of section 2 of title 18, United States Code, to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect interstate or foreign commerce. A purchase of securities on the open market for purposes of investment, and without the intention of controlling or participating in the control of the issuer, or of assisting another to do so, shall not be unlawful under this section if the securities of the issuer held by the purchaser, the members of his immediate family, and his or their accomplices in any violation of this title or title III after such purchases do not amount in the aggregate to 1 per centum of the outstanding securities of any one class, and do not confer, either in law or in fact, the power to elect one or more directors of this issuer.

(b) Whoever violates this section shall be fined not more than $50,000 or imprisoned not more than ten years, or both.

(c) As used in this section, the term "enterprise" includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.

(d) The provisions of this section shall be liberally construed to effectuate its remedial purposes.

ALTERNATIVE FINE

SEC. 415. [21 U.S.C. 855] In lieu of a fine otherwise authorized by this part, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.

SEC. 416. [21 U.S.C. 856] MAINTAINING DRUG-INVOLVED PREMISES.

(a) Except as authorized by this title, it shall be unlawful to—

(1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance;

(2) manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance.

(b) Any person who violates subsection (a) of this section shall be sentenced to a term of imprisonment of not more than 20 years or

a fine of not more than $500,000, or both, or a fine of $2,000,000 for a person other than an individual.

(c) A violation of subsection (a) shall be considered an offense against property for purposes of section 3663A(c)(1)(A)(ii) of title 18, United States Code.

(d)(1) Any person who violates subsection (a) shall be subject to a civil penalty of not more than the greater of—

(A) $250,000; or

(B) 2 times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person.

(2) If a civil penalty is calculated under paragraph (1)(B), and there is more than 1 defendant, the court may apportion the penalty between multiple violators, but each violator shall be jointly and severally liable for the civil penalty under this subsection.

(e) Any person who violates subsection (a) shall be subject to declaratory and injunctive remedies as set forth in section 403(f).

ENDANGERING HUMAN LIFE WHILE ILLEGALLY MANUFACTURING A CONTROLLED SUBSTANCE

SEC. 417. [21 U.S.C. 858] Whoever, while manufacturing a controlled substance in violation of this title, or attempting to do so, or transporting or causing to be transported materials, including chemicals, to do so, creates a substantial risk of harm to human life shall be fined in accordance with title 18, United States Code, or imprisoned not more than 10 years, or both.

DISTRIBUTION TO PERSONS UNDER AGE TWENTY-ONE

SEC. 418. [21 U.S.C. 859] (a) Except as provided in section 419, any person at least eighteen years of age who violates section 401(a)(1) by distributing a controlled substance to a person under twenty-one years of age is (except as provided in subsection (b)) subject to (1) twice the maximum punishment authorized by section 401(b), and (2) at least twice any term of supervised release authorized by section 401(b), for a first offense involving the same controlled substance and schedule. Except to the extent a greater minimum sentence is otherwise provided by section 401(b), a term of imprisonment under this subsection shall be not less than one year. The mandatory minimum sentencing provisions of this subsection shall not apply to offenses involving 5 grams or less of marihuana.

(b) Except as provided in section 419, any person at least eighteen years of age who violates section 401(a)(1) by distributing a controlled substance to a person under twenty-one years of age after a prior conviction under subsection (a) of this section (or under section 303(b)(2) of the Federal Food, Drug, and Cosmetic Act as in effect prior to the effective date of section 701(b) of this Act) has become final, is subject to (1) three times the maximum punishment authorized by section 401(b), and (2) at least three times any term of supervised release authorized by section 401(b), for a second offense or subsequent offense involving the same controlled substance and schedule. Except to the extent a greater minimum sentence is otherwise provided by section 401(b), a term of

imprisonment under this subsection shall be not less than one year. Penalties for third and subsequent convictions shall be governed by section 401(b)(1)(A).

DISTRIBUTION IN OR NEAR SCHOOLS [63]

SEC. 419. [21 U.S.C. 860] (a) Any person who violates section 401(a)(1) or section 416 by distributing, possessing with intent to distribute, or manufacturing a controlled substance in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public housing authority, or within 100 feet of a public or private youth center, public swimming pool, or video arcade facility, is (except as provided in subsection (b)) subject to (1) twice the maximum punishment authorized by section 401(b) of this title; and (2) at least twice any term of supervised release authorized by section 401(b) for a first offense. A fine up to twice that authorized by section 401(b) may be imposed in addition to any term of imprisonment authorized by this subsection. Except to the extent a greater minimum sentence is otherwise provided by section 401(b), a person shall be sentenced under this subsection to a term of imprisonment of not less than one year. The mandatory minimum sentencing provisions of this paragraph shall not apply to offenses involving 5 grams or less of marihuana.

(b) Any person who violates section 401(a)(1) or section 416 by distributing, possessing with intent to distribute, or manufacturing a controlled substance in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public housing authority, or within 100 feet of a public or private youth center, public swimming pool, or video arcade facility, after a prior conviction under subsection (a) has become final is punishable (1) by the greater of (A) a term of imprisonment of not less than three years and not more than life imprisonment or (B) three times the maximum punishment authorized by section 401(b) for a first offense, and (2) at least three times any term of supervised release authorized by section 401(b) of this title for a first offense. A fine up to three times that authorized by section 401(b) may be imposed in addition to any term of imprisonment authorized by this subsection. Except to the extent a greater minimum sentence is otherwise provided by section 401(b), a person shall be sentenced under this subsection to a term of imprisonment of not less than three years. Penalties for third and subsequent convictions shall be governed by section 401(b)(1)(A).

(c) Notwithstanding any other law, any person at least 21 years of age who knowingly and intentionally—

(1) employs, hires, uses, persuades, induces, entices, or coerces a person under 18 years of age to violate this section; or

[63] So in law. Probably should be "DISTRIBUTION OR MANUFACTURING IN OR NEAR SCHOOLS AND COLLEGES". Public Law 99–570 added references to manufacturing and to colleges.

(2) employs, hires, uses, persuades, induces, entices, or coerces a person under 18 years of age to assist in avoiding detection or apprehension for any offense under this section by any Federal, State, or local law enforcement official,

is punishable by a term of imprisonment, a fine, or both, up to triple those authorized by section 401.

(d) In the case of any mandatory minimum sentence imposed under subsection (b)[64], imposition or execution of such sentence shall not be suspended and probation shall not be granted. An individual convicted under this section shall not be eligible for parole until the individual has served the mandatory minimum term of imprisonment as provided by this section.

(e) For the purposes of this section—

(1) The term "playground" means any outdoor facility (including any parking lot appurtenant thereto) intended for recreation, open to the public, and with any portion thereof containing three or more separate apparatus intended for the recreation of children including, but not limited to, sliding boards, swingsets, and teeterboards.

(2) The term "youth center" means any recreational facility and/or gymnasium (including any parking lot appurtenant thereto), intended primarily for use by persons under 18 years of age, which regularly provides athletic, civic, or cultural activities.

(3) The term "video arcade facility" means any facility, legally accessible to persons under 18 years of age, intended primarily for the use of pinball and video machines for amusement containing a minimum of ten pinball and/or video machines.

(4) The term "swimming pool" includes any parking lot appurtenant thereto.

EMPLOYMENT OR USE OF PERSONS UNDER 18 YEARS OF AGE IN DRUG OPERATIONS

SEC. 420. [21 U.S.C. 861] (a) It shall be unlawful for any person at least eighteen years of age to knowingly and intentionally—

(1) employ, hire, use, persuade, induce, entice, or coerce, a person under eighteen years of age to violate any provision of this title or title III;

(2) employ, hire, use persuade, induce, entice, or coerce, a person under eighteen years of age to assist in avoiding detection or apprehension for any offense of this title or title III by any Federal, State, or local law enforcement official; or

(3) receive a controlled substance from a person under 18 years of age, other than an immediate family member, in violation of this title or title III.

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[64] Section 1214(3)(B) of Public Law 101–647 (104 Stat. 4833) attempted to strike "subsection (b) of", with the apparent intent for the language to read "under this section" rather than "under subsection (b)", but the amendment cannot be executed because the phrase "subsection (b) of" does not appear. See section 503(a) of Public Law 98–473 (98 Stat. 2069), which added section 419. (The section was added as section 405A, and was redesignated as section 419 by section 1002(b) of Public Law 101–647 (104 Stat. 4827).) (The amendment described in section 1214(3)(B) of Public Law 101–647 is directed to section "419(c)". Subsection (d) above formerly was subsection (c), and was redesignated as subsection (d) by section 140006 of Public Law 103–322 (108 Stat. 2032).)

(b) Any person who violates subsection (a) is punishable by a term of imprisonment up to twice that otherwise authorized, or up to twice the fine otherwise authorized, or both [65], and at least twice any term of supervised release otherwise authorized for a first offense. Except to the extent a greater minimum sentence is otherwise provided, a term of imprisonment under this subsection shall not be less than one year.

(c) Any person who violates subsection (a) after a prior conviction under subsection (a) of this section has become final, is punishable by a term of imprisonment up to three times that otherwise authorized, or both [66], and at least three times any term of supervised release otherwise authorized for a first offense. Except to the extent a greater minimum sentence is otherwise provided, a term of imprisonment under this subsection shall not be less than one year. Penalties for third and subsequent convictions shall be governed by section 401(b)(1)(A).

(d) Any person who violates section 405B(a) (1) or (2) [67]

(1) by knowingly providing or distributing a controlled substance or a controlled substance analogue to any person under eighteen years of age; or

(2) if the person employed, hired, or used is fourteen years of age or younger.

shall be subject to a term of imprisonment for not more than five years or a fine of not more than $50,000, or both, in addition to any other punishment authorized by this section.

(e) In any case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended and probation shall not be granted. An individual convicted under this section of an offense for which a mandatory minimum term of imprisonment is applicable shall not be eligible for parole under section 4202 of title 18, United States Code,[68] until the individual has served the mandatory term of imprisonment as enhanced by this section.

(f) Except as authorized by this title, it shall be unlawful for any person to knowingly or intentionally provide or distribute any controlled substance to a pregnant individual in violation of any provision of this title. Any person who violates this subsection shall be subject to the provisions of subsections (b), (c), and (e).

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[65] Section 1003(c) of Public Law 101–647 (104 Stat. 4829) attempted in each of subsections (b) and (c) above to strike a certain phrase and insert another, but the amendments cannot be executed because the phrase to be struck did not appear.

In subsection (b), the phrase to be struck was "is punishable by a term of imprisonment up to twice that authorized, or up to twice the fine authorized, or both,", which does not appear. The language to be inserted was "is subject to twice the maximum punishment otherwise authorized".

In subsection (c), the phrase to be struck was "is punishable by a term of imprisonment up to three times that authorized, or up to three times the fine authorized, or both,", which does not appear. The language to be inserted was "is subject to three times the maximum punishment otherwise authorized".

[66] See footnote for subsection (b).

[67] So in law. Probably should be followed by a dash.

[68] Section 4202 of title 18, United States Code, was repealed by section 218(a)(5) of Public Law 98–473 (98 Stat. 2027). For information on effective dates relating to such repeal, see the notes in the United States Code relating to former sections 4201 through 4218 of title 18 (former chapter 311).

SEC. 421. [21 U.S.C. 862] DENIAL OF FEDERAL BENEFITS TO DRUG TRAFFICKERS AND POSSESSORS.

(a) DRUG TRAFFICKERS.—(1) Any individual who is convicted of any Federal or State offense consisting of the distribution of controlled substances shall—

(A) at the discretion of the court, upon the first conviction for such an offense be ineligible for any or all Federal benefits for up to 5 years after such conviction;

(B) at the discretion of the court, upon a second conviction for such an offense be ineligible for any or all Federal benefits for up to 10 years after such conviction; and

(C) upon a third or subsequent conviction for such an offense be permanently ineligible for all Federal benefits.

(2) The benefits which are denied under this subsection shall not include benefits relating to long-term drug treatment programs for addiction for any person who, if there is a reasonable body of evidence to substantiate such declaration, declares himself to be an addict and submits himself to a long-term treatment program for addiction, or is deemed to be rehabilitated pursuant to rules established by the Secretary of Health and Human Services.

(b) DRUG POSSESSORS.—(1) Any individual who is convicted of any Federal or State offense involving the possession of a controlled substance (as such term is defined for purposes of the Controlled Substances Act) shall—

(A) upon the first conviction for such an offense and at the discretion of the court—

(i) be ineligible for any or all Federal benefits for up to one year;

(ii) be required to successfully complete an approved drug treatment program which includes periodic testing to insure that the individual remains drug free;

(iii) be required to perform appropriate community service; or

(iv) any combination of clauses (i), (ii), or (iii); and

(B) upon a second or subsequent conviction for such an offense be ineligible for all Federal benefits for up to 5 years after such conviction as determined by the court. The court shall continue to have the discretion in subparagraph (A) above. In imposing penalties and conditions under subparagraph (A), the court may require that the completion of the conditions imposed by clause (ii) and (iii) be a requirement for the reinstatement of benefits under clause (i).

(2) The penalties and conditions which may be imposed under this subsection shall be waived in the case of a person who, if there is a reasonable body of evidence of substantiate such declaration, declares himself to be an addict and submits himself to a long-term treatment program for addiction, or is deemed to be rehabilitated pursuant to rules established by the Secretary of Health and Human Services.

(c) SUSPENSION OF PERIOD OF INELIGIBILITY.—The period of ineligibility referred to in subsections (a) and (b) shall be suspended if the individual—

(A) completes a supervised drug rehabilitation program after becoming ineligible under this section;

(B) has otherwise been rehabilitated; or

(C) has made a good faith effort to gain admission to a supervised drug rehabilitation program, but is unable to do so because of inaccessibility or unavailability of such a program, or the inability of the individual to pay for such a program.

(d) DEFINITIONS.—As used in this section—

(1) the term "Federal benefit"—

(A) means the issuance of any grant, contract, loan, professional license, or commercial license provided by an agency of the United States or by appropriated funds of the United States; and

(B) does not include any retirement, welfare, Social Security, health, disability, veterans benefit, public housing, or other similar benefit, or any other benefit for which payments or services are required for eligibility; and

(2) the term "veterans benefit" means all benefits provided to veterans, their families, or survivors by virtue of the service of a veteran in the Armed Forces of the United States.

(e) INAPPLICABILITY OF THIS SECTION TO GOVERNMENT WITNESSES.—The penalties provided by this section shall not apply to any individual who cooperates or testifies with the Government in the prosecution of a Federal or State offense or who is in a Government witness protection program.

(f) INDIAN PROVISION.—Nothing in this section shall be construed to affect the obligation of the United States to any Indian or Indian tribe arising out of any treaty, statute, Executive order, or the trust responsibility of the United States owing to such Indian or Indian tribe. Nothing in this subsection shall exempt any individual Indian from the sanctions provided for in this section, provided that no individual Indian shall be denied any benefit under Federal Indian programs comparable to those described in subsection (d)(1)(B) or (d)(2) above.

(g) PRESIDENTIAL REPORT.—(1) On or before May 1, 1989, the President shall transmit to the Congress a report—

(A) delineating the role of State courts in implementing this section;

(B) describing the manner in which Federal agencies will implement and enforce the requirements of this section;

(C) detailing the means by which Federal and State agencies, courts, and law enforcement agencies will exchange and share the data and information necessary to implement and enforce the withholding of Federal benefits; and

(D) recommending any modifications to improve the administration of this section or otherwise achieve the goal of discouraging the trafficking and possession of controlled substances.

(2) No later than September 1, 1989, the Congress shall consider the report of the President and enact such changes as it deems appropriate to further the goals of this section.

(h) EFFECTIVE DATE.—The denial of Federal benefits set forth in this section shall take effect for convictions occurring after September 1, 1989.

DRUG PARAPHERNALIA

SEC. 422. [21 U.S.C. 863] (a) It is unlawful for any person—

(1) to sell or offer for sale drug paraphernalia;

(2) to use the mails or any other facility of interstate commerce to transport drug paraphernalia; or

(3) to import or export drug paraphernalia.

(b) Anyone convicted of an offense under subsection (a) of this section shall be imprisoned for not more than three years and fined under title 18, United States Code.

(c) Any drug paraphernalia involved in any violation of subsection (a) of this section shall be subject to seizure and forfeiture upon the conviction of a person for such violation. Any such paraphernalia shall be delivered to the Administrator of General Services, General Services Administration, who may order such paraphernalia destroyed or may authorize its use for law enforcement or educational purposes by Federal, State, or local authorities.

(d) The term "drug paraphernalia" means any equipment, product, or material of any kind which is primarily intended or designed for use in manufacturing, compounding, converting, concealing, producing, processing, preparing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance, possession of which is unlawful under the Controlled Substances Act (title II of Public Law 91–513). It includes items primarily intended or designed for use in ingesting, inhaling, or otherwise introducing marijuana[69], cocaine, hashish, hashish oil, PCP, methamphetamine, or amphetamines into the human body, such as—

(1) metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;

(2) water pipes;

(3) carburetion tubes and devices;

(4) smoking and carburetion masks;

(5) roach clips: meaning objects used to hold burning material, such as a marihuana cigarette, that has become too small or too short to be held in the hand;

(6) miniature spoons with level capacities of one-tenth cubic centimeter or less;

(7) chamber pipes;

(8) carburetor pipes;

(9) electric pipes;

(10) air-driven pipes;

(11) chillums;

(12) bongs;

(13) ice pipes or chillers;

(14) wired cigarette papers; or

(15) cocaine freebase kits.

(e) In determining whether an item constitutes drug paraphernalia, in addition to all other logically relevant factors, the following may be considered:

(1) instructions, oral or written, provided with the item concerning its use;

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[69] So in law. Probably should be "marihuana". See the list of substances in schedule I under section 202(c).

(2) descriptive materials accompanying the item which explain or depict its use;

(3) national and local advertising concerning its use;

(4) the manner in which the item is displayed for sale;

(5) whether the owner, or anyone in control of the item, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products;

(6) direct or circumstantial evidence of the radio of sales of the item(s) to the total sales of the business enterprise;

(7) the existence and scope of legitimate uses of the item in the community; and

(8) expert testimony concerning its use.

(f) This section shall not apply to—

(1) any person authorized by local, State, or Federal law to manufacture, possess, or distribute such items; or

(2) any item that, in the normal lawful course of business, is imported, exported, transported, or sold through the mail or by any other means, and traditionally intended for use with tobacco products, including any pipe, paper, or accessory.

ANHYDROUS AMMONIA

SEC. 423. [21 U.S.C. 864] (a) It is unlawful for any person—

(1) to steal anhydrous ammonia, or

(2) to transport stolen anhydrous ammonia across State lines,

knowing, intending, or having reasonable cause to believe that such anhydrous ammonia will be used to manufacture a controlled substance in violation of this part.

(b) Any person who violates subsection (a) shall be imprisoned or fined, or both, in accordance with section 403(d) as if such violation were a violation of a provision of section 403.

PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

PROCEDURES

SEC. 501. [21 U.S.C. 871] (a) The Attorney General may delegate any of his functions under this title to any officer or employee of the Department of Justice.

(b) The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this title.

(c) The Attorney General may accept in the name of the Department of Justice any form of devise, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. He may take all appropriate steps to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

EDUCATION AND RESEARCH PROGRAMS OF THE ATTORNEY GENERAL

SEC. 502. [21 U.S.C. 872] (a) The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or

other substances which are or may be subject to control under this title. Such programs may include—

(1) educational and training programs on drug abuse and controlled substances law enforcement for local, State, and Federal personnel;

(2) studies or special projects designed to compare the deterrent effects of various enforcement strategies on drug use and abuse;

(3) studies or special projects designed to assess and detect accurately the presence in the human body of drugs or other substances which are or may be subject to control under this title, including the development of rapid field identification methods which would enable agents to detect microquantities of such drugs or other substances;

(4) studies or special projects designed to evaluate the nature and sources of the supply of illegal drugs throughout the country;

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels; and

(6) studies or special projects to develop information necessary to carry out his functions under section 201 of this title.

(b) The Attorney General may enter into contracts for such educational and research activities without performance bonds and without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

(c) The Attorney General may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of such research. Persons who obtain this authorization may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which such authorization was obtained.

(d)[70] Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit, modify, or prevent the protection of the confidentiality of patient records or of the names and other identifying characteristics of research subjects as provided by any Federal, State, or local law or regulation.

(e) The Attorney General, on his own motion or at the request of the Secretary, may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research. Persons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by the Attorney General.

(f) The Attorney General shall maintain an active program, both domestic and international, to curtail the diversion of precursor

[70] Subsection (d) was added by title I of Public Law 95–633. Section 112 of such Public Law provided as follows: "This title shall take effect on the date the Convention on Psychotropic Substances, signed at Vienna, Austria on February 21, 1971, enters into force in respect to the United States.". The Convention entered into force in respect to the United States on July 15, 1980.

chemicals and essential chemicals used in the illicit manufacture of controlled substances.

COOPERATIVE ARRANGEMENTS

SEC. 503. [21 U.S.C. 873] (a) The Attorney General shall cooperate with local, State, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he is authorized to—

(1) arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;

(2) cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing boards and courts of the several States;

(3) conduct training programs on controlled substance law enforcement for local, State, and Federal personnel;

(4) maintain in the Department of Justice a unit which will accept, catalog, file, and otherwise utilize all information and statistics, including records of controlled substance abusers and other controlled substance law offenders, which may be received from Federal, State, and local agencies, and make such information available for Federal, State, and local law enforcement purposes;

(5) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted;

(6) assist State and local governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels by—

(A) making periodic assessments of the capabilities of State and local governments to adequately control the diversion of controlled substances;

(B) providing advice and counsel to State and local governments on the methods by which such governments may strengthen their controls against diversion; and

(C) establishing cooperative investigative efforts to control diversion; and

(7) notwithstanding any other provision of law, enter into contractual agreements with State and local law enforcement agencies to provide for cooperative enforcement and regulatory activities under this Act.

(b) When requested by the Attorney General, it shall be the duty of any agency or instrumentality of the Federal Government to furnish assistance, including technical advice, to him for carrying out his functions under this title; except that no such agency or instrumentality shall be required to furnish the name of, or other identifying information about, a patient or research subject whose identity it has undertaken to keep confidential.

(c) The Attorney General shall annually (1) select the controlled substance (or controlled substances) contained in schedule II which, in the Attorney General's discretion, is determined to have the

highest rate of abuse, and (2) prepare and make available to regulatory, licensing, and law enforcement agencies of States descriptive and analytic reports on the actual distribution patterns in such States of each such controlled substance.

(d)(1) The Attorney General may make grants, in accordance with paragraph (2), to State and local governments to assist in meeting the costs of—

(A) collecting and analyzing data on the diversion of controlled substances,

(B) conducting investigations and prosecutions of such diversions,

(C) improving regulatory controls and other authorities to control such diversions,

(D) programs to prevent such diversions,

(E) preventing and detecting forged prescriptions, and

(F) training law enforcement and regulatory personnel to improve the control of such diversions.

(2) No grant may be made under paragraph (1) unless an application therefor is submitted to the Attorney General in such form and manner as the Attorney General may prescribe. No grant may exceed 80 per centum of the costs for which the grant is made, and no grant may be made unless the recipient of the grant provides assurances satisfactory to the Attorney General that it will obligate funds to meet the remaining 20 per centum of such costs. The Attorney General shall review the activities carried out with grants under paragraph (1) and shall report annually to Congress on such activities.

(3) To carry out this subsection there is authorized to be appropriated $6,000,000 for fiscal year 1985 and $6,000,000 for fiscal year 1986.

ADVISORY COMMITTEES

SEC. 504. [21 U.S.C. 874] The Attorney General may from time to time appoint committees to advise him with respect to preventing and controlling the abuse of controlled substances. Members of the committees may be entitled to receive compensation at the rate of $100 for each day (including traveltime) during which they are engaged in the actual performance of duties. While traveling on official business in the performance of duties for the committees, members of the committees shall be allowed expenses of travel, including per diem instead of subsistence, in accordance with subchapter I of chapter 57 of title 5, United States Code.

ADMINISTRATIVE HEARINGS

SEC. 505. [21 U.S.C. 875] (a) In carrying out his functions under this title, the Attorney General may hold hearings, sign and issue subpenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

(b) Except as otherwise provided in this title, notice shall be given and hearings shall be conducted under appropriate procedures of subchapter II of chapter 5, title 5, United States Code.

SUBPENAS

SEC. 506. [21 U.S.C. 876] (a) In any investigation relating to his functions under this title with respect to controlled substances, listed chemicals, tableting machines, or encapsulating machines, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in any State or in any territory or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(b) A subpena issued under this section may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

(c) In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

JUDICIAL REVIEW

SEC. 507. [21 U.S.C. 877] All final determinations, findings, and conclusions of the Attorney General under this title shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

POWERS OF ENFORCEMENT PERSONNEL

SEC. 508. [21 U.S.C. 878] (a) Any officer or employee of the Drug Enforcement Administration or any State or local law enforcement officer or (with respect to offenses under this title or title III) any State or local law enforcement officer[71] designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant (A) for any offense against the United States committed in his presence, or (B) for any felony, cognizable under the laws of the United States, if he has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this title; and

(5) perform such other law enforcement duties as the Attorney General may designate.

(b) State and local law enforcement officers performing functions under this section shall not be deemed Federal employees and shall not be subject to provisions of law relating to Federal employees, except that such officers shall be subject to section 3374(c) of title 5, United States Code.

(b)[72] State and local law enforcement officers performing functions under this section shall not be deemed Federal employees and shall not be subject to provisions of law relating to Federal employees, except that such officers shall be subject to section 3374(c) of title 5, United States Code.

SEARCH WARRANTS

SEC. 509. [21 U.S.C. 879] A search warrant relating to offenses involving controlled substances may be served at any time of the day or night if the judge or United States magistrate issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant and for its service at such time.

ADMINISTRATIVE INSPECTIONS AND WARRANTS

SEC. 510. [21 U.S.C. 880] (a) As used in this section, the term "controlled premises" means—

(1) places where original or other records or documents required under this title are kept or required to be kept, and

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[71] Two Public Laws in the 99th Congress amended section 508, and the amendments made by the two were substantially similar. The first set of amendments was made by section 1869 of Public Law 99-570 (100 Stat. 3207–55) and the second by section 86 of Public Law 99–646 (100 Stat. 3620).

Both added a subsection (b), and the two subsections are identical. In adding a subsection (b), both designated the pre-existing text of section 508 as subsection (a).

In the matter preceding paragraph (1) of subsection (a), both inserted a reference to "any State or local law enforcement officer". There was one difference between the two: section 1869 inserted the phrase "(with respect to offenses under this title or title III)", while section 86 did not.

The second set of amendments (section 86) was executed to section 508 as such section appeared after the execution of the first set (section 1869).

[72] See footnote for subsection (a).

(2) places, including factories, warehouses, and other establishments, and conveyances, where persons registered under section 303 (or exempt from registration under section 302(d) or by regulation of the Attorney General) or regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained.

(b)(1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this title and otherwise facilitating the carrying out of his functions under this title, the Attorney General is authorized, in accordance with this section, to enter controlled premises and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as "inspectors") designated by the Attorney General. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) a written notice of his inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of such warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

(3) Except as may otherwise be indicated in an applicable inspection warrant, the inspector shall have the right—

(A) to inspect and copy records, reports, and other documents required to be kept or made under this title;

(B) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs, listed chemicals, and other substances or materials, containers, and labeling found therein, and, except as provided in paragraph (4) of this subsection, all other things therein (including records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, and documents referred to in clause (A) or otherwise bearing on the provisions of this title; and

(C) to inventory any stock of any controlled substance or listed chemical therein and obtain samples of any such substance or chemical.

(4) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to—

(A) financial data;

(B) sales data other than shipment data; or

(C) pricing data.

(c) A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpena issued in accordance with section 506, nor for entries and administrative inspections (including seizures of property)—

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstances where time or opportunity to apply for a warrant is lacking; or

(5) in any other situations where a warrant is not constitutionally required.

(d) Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of the United States or of a State court of record, or any United States magistrate, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this title or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term "probable cause" means a valid public interest in the effective enforcement of this title or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents thereof, in the circumstances specified in the application for the warrant.

(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (b)(2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the

presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

(4) The judge or magistrate who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

FORFEITURES

SEC. 511. [21 U.S.C. 881] (a) The following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) All controlled substances which have been manufactured, distributed, dispensed, or acquired in violation of this title.

(2) All raw materials, products, and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance or listed chemical in violation of this title.

(3) All property which is used, or intended for use, as a container for property described in paragraph (1), (2), or (9).

(4) All conveyances, including aircraft, vehicles, or vessels, which are used, or are intended for use, to transport, or in any manner to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1), (2), or (9).

(5) All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this title.

(6) All moneys, negotiable instruments, securities, or other things of value furnished or intended to be furnished by any person in exchange for a controlled substance or listed chemical in violation of this title, all proceeds traceable to such an exchange, and all moneys, negotiable instruments, and securities used or intended to be used to facilitate any violation of this title.

(7) All real property, including any right, title, and interest (including any leasehold interest) in the whole of any lot or tract of land and any appurtenances or improvements, which is used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, a violation of this title punishable by more than one year's imprisonment.

(8) All controlled substances which have been possessed in violation of this title.

(9) All listed chemicals, all drug manufacturing equipment, all tableting machines, all encapsulating machines, and all

gelatin capsules, which have been imported, exported, manufactured, possessed, distributed, dispensed, acquired,or intended to be distributed, dispensed, acquired, imported, or exported, in violation of this title or title III.

(10) Any drug paraphernalia (as defined in section 422).

(11) Any firearm (as defined in section 921 of title 18, United States Code) used or intended to be used to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1) or (2) and any proceeds traceable to such property.

(b) SEIZURE PROCEDURES.—Any property subject to forfeiture to the United States under this section may be seized by the Attorney General in the manner set forth in section 981(b) of title 18, United States Code.

(c) Property taken or detained under this section shall not be repleviable, but shall be deemed to be in the custody of the Attorney General, subject only to the orders and decrees of the court or the official having jurisdiction thereof. Whenever property is seized under any of the provisions of this title, the Attorney General may—

(1) place the property under seal;

(2) remove the property to a place designated by him; or

(3) require that the General Services Administration take custody of the property and remove it, if practicable, to an appropriate location for disposition in accordance with law.

(d) The provisions of law relating to the seizure, summary and judicial forfeiture, and condemnation of property for violation of the customs laws; the disposition of such property or the proceeds from the sale thereof; the remission or mitigation of such forfeitures; and the compromise of claims shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under any of the provisions of this title, insofar as applicable and not inconsistent with the provisions hereof; except that such duties as are imposed upon the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws shall be performed with respect to seizures and forfeitures of property under this title by such officers, agents, or other persons as may be authorized or designated for that purpose by the Attorney General, except to the extent that such duties arise from seizures and forfeitures effected by any customs officer.

(e)(1) Whenever property is civilly or criminally forfeited under this title the Attorney General may—

(A) retain the property for official use or, in the manner provided with respect to transfers under section 616 of the Tariff Act of 1930, transfer the property to any Federal agency or to any State or local law enforcement agency which participated directly in the seizure or forfeiture of the property;

(B) except as provided in paragraph (4), sell, by public sale or any other commercially feasible means, any forfeited property which is not required to be destroyed by law and which is not harmful to the public;

(C) require that the General Services Administration take custody of the property and dispose of it in accordance with law;

(D) forward it to the Bureau of Narcotics and Dangerous Drugs for disposition (including delivery for medical or scientific use to any Federal or State agency under regulations of the Attorney General); or

(E) transfer the forfeited personal property or the proceeds of the sale of any forfeited personal or real property to any foreign country which participated directly or indirectly in the seizure or forfeiture of the property, if such a transfer—

(i) has been agreed to by the Secretary of State;

(ii) is authorized in an international agreement between the United States and the foreign country; and

(iii) is made to a country which, if applicable, has been certified under section 490(b) of the Foreign Assistance Act of 1961.

(2)(A) The proceeds from any sale under subparagraph (B) of paragraph (1) and any moneys forfeited under this title shall be used to pay—

(i) all proper expenses of the proceedings for forfeiture and sale including expenses of seizure, maintenance of custody, advertising, and court costs; and

(ii) awards of up to $100,000 to any individual who provides original information which leads to the arrest and conviction of a person who kills or kidnaps a Federal drug law enforcement agent.

Any award paid for information concerning the killing or kidnapping of a Federal drug law enforcement agent, as provided in clause (ii), shall be paid at the discretion of the Attorney General.

(B) The Attorney General shall forward to the Treasurer of the United States for deposit in accordance with section 524(c) of title 28, United States Code, any amounts of such moneys and proceeds remaining after payment of the expenses provided in subparagraph (A), except that, with respect to forfeitures conducted by the Postal Service, the Postal Service shall deposit in the Postal Service Fund, under section 2003(b)(7) of title 39, United States Code, such moneys and proceeds.

(3) The Attorney General shall assure that any property transferred to a State or local law enforcement agency under paragraph (1)(A)—

(A) has a value that bears a reasonable relationship to the degree of direct participation of the State or local agency in the law enforcement effort resulting in the forfeiture, taking into account the total value of all property forfeited and the total law enforcement effort with respect to the violation of law on which the forfeiture is based; and

(B) will serve to encourage further cooperation between the recipient State or local agency and Federal law enforcement agencies.

(4)(A) With respect to real property described in subparagraph (B), if the chief executive officer of the State involved submits to the Attorney General a request for purposes of such subparagraph, the authority established in such subparagraph is in lieu of the authority established in paragraph (1)(B).

(B) In the case of property described in paragraph (1)(B) that is civilly or criminally forfeited under this title, if the property is real

property that is appropriate for use as a public area reserved for recreational or historic purposes or for the preservation of natural conditions, the Attorney General, upon the request of the chief executive officer of the State in which the property is located, may transfer title to the property to the State, either without charge or for a nominal charge, through a legal instrument providing that—

(i) such use will be the principal use of the property; and

(ii) title to the property reverts to the United States in the event that the property is used otherwise.

(f)(1) All controlled substances in schedule I or II that are possessed, transferred, sold, or offered for sale in violation of the provisions of this title; all dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2) of this section; and any equipment or container subject to forfeiture under subsection (a)(2) or (3) which cannot be separated safely from such raw materials or products shall be deemed contraband and seized and summarily forfeited to the United States. Similarly, all substances in schedule I or II, which are seized or come into the possession of the United States, the owners of which are unknown, shall be deemed contraband and summarily forfeited to the United States.

(2) The Attorney General may direct the destruction of all controlled substances in schedule I or II seized for violation of this title; all dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2) of this section; and any equipment or container subject to forfeiture under subsection (a)(2) or (3) which cannot be separated safely from such raw materials or products under such circumstances as the Attorney General may deem necessary.

(g)(1) All species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this title, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the United States.

(2) The failure, upon demand by the Attorney General or his duly authorized agent, of the person in occupancy or in control of land or premises upon which such species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, shall constitute authority for the seizure and forfeiture.

(3) The Attorney General, or his duly authorized agent, shall have authority to enter upon any lands, or into any dwelling pursuant to a search warrant, to cut, harvest, carry off, or destroy such plants.

(h) All right, title, and interest in property described in subsection (a) shall vest in the United States upon commission of the act giving rise to forfeiture under this section.

(i) The provisions of section 981(g) of title 18, United States Code, regarding the stay of a civil forfeiture proceeding shall apply to forfeitures under this section.

(j) In addition to the venue provided for in section 1395 of title 28, United States Code, or any other provision of law, in the case of property of a defendant charged with a violation that is the basis for forfeiture of the property under this section, a proceeding for

forfeiture under this section may be brought in the judicial district in which the defendant owning such property is found or in the judicial district in which the criminal prosecution is brought.

(l)[73] The functions of the Attorney General under this section shall be carried out by the Postal Service pursuant to such agreement as may be entered into between the Attorney General and the Postal Service.

INJUNCTIONS

SEC. 512. [21 U.S.C. 882] (a) The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this title.

(b) In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

ENFORCEMENT PROCEEDINGS

SEC. 513. [21 U.S.C. 883] Before any violation of this title is reported by the Administrator of the Drug Enforcement Administration to any United States attorney for institution of a criminal proceeding, the Administrator may require that the person against whom such proceeding is contemplated be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

IMMUNITY AND PRIVILEGE

SEC. 514. [21 U.S.C. 884] (a) Whenever a witness refuses, on the basis of his privilege against self-incrimination, to testify or provide other information in a proceeding before a court or grand jury of the United States, involving a violation of this title, and the person presiding over the proceeding communicates to the witness an order issued under this section, the witness may not refuse to comply with the order on the basis of his privilege against self-incrimination. But no testimony or other information compelled under the order issued under subsection (b) of this section or any information obtained by the exploitation of such testimony or other information, may be used against the witness in any criminal case, including any criminal case brought in a court of a State, except a prosecution for perjury, giving a false statement, or otherwise failing to comply with the order.

(b) In the case of any individual who has been or may be called to testify or provide other information at any proceeding before a court or grand jury of the United States, the United States district court for the judicial district in which the proceeding is or may be held shall issue, upon the request of the United States attorney for

[73] So in law. Probably should be "(k)". See section 6253(a) of Public Law 100–690 (102 Stat. 4363).

such district, an order requiring such individual to give any testimony or provide any other information which he refuses to give or provide on the basis of his privilege against self-incrimination.

(c) A United States attorney may, with the approval of the Attorney General or the Deputy Attorney General, the Associate Attorney General, or any Assistant Attorney General designated by the Attorney General, request an order under subsection (b) when in his judgment—

(1) the testimony or other information from such individual may be necessary to the public interest; and

(2) such individual has refused or is likely to refuse to testify or provide other information on the basis of his privilege against self-incrimination.

BURDEN OF PROOF; LIABILITIES

SEC. 515. [21 U.S.C. 885] (a)(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this title in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this title, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

(2) In the case of a person charged under section 404(a) with the possession of a controlled substance, any label identifying such substance for purposes of section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act shall be admissible in evidence and shall be prima facie evidence that such substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of his professional practice.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this title, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

(c) The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this title shall be on the persons engaged in such use.

(d) Except as provided in sections 2234 and 2235 of title 18, United States Code, no civil or criminal liability shall be imposed by virtue of this title upon any duly authorized Federal officer lawfully engaged in the enforcement of this title, or upon any duly authorized officer of any State, territory, political subdivision thereof, the District of Columbia, or any possession of the United States, who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

PAYMENTS AND ADVANCES

SEC. 516. [21 U.S.C. 886] (a) The Attorney General is authorized to pay any person, from funds appropriated for the Drug Enforcement Administration, for information concerning a violation of this title, such sum or sums of money as he may deem appropriate,

without reference to any moieties or rewards to which such person may otherwise be entitled by law.

(b) Moneys expended from appropriations of the Drug Enforcement Administration for purchase of controlled substances and subsequently recovered shall be reimbursed to the current appropriation for the Bureau [74].

(c) The Attorney General is authorized to direct the advance of funds by the Treasury Department in connection with the enforcement of this title. Section 16 of Public Law 96–132 (93 Stat. 1049) amended this title in several other places by striking references to the Bureau of Narcotics and Dangerous Drugs and inserting references to the Drug Enforcement Administration.

(d)(1) There is established in the Treasury a trust fund to be known as the "Drug Pollution Fund" (hereinafter referred to in this subsection as the "Fund"), consisting of amounts appropriated or credited to such Fund under section 401(b)(6).

(2) There are hereby appropriated to the Fund amounts equivalent to the fines imposed under section 401(b)(6).

(3) Amounts in the Fund shall be available, as provided in appropriations Acts, for the purpose of making payments in accordance with paragraph (4) for the clean up of certain pollution resulting from the actions referred to in section 401(b)(6).

(4)(A) The Secretary of the Treasury, after consultation with the Attorney General, shall make payments under paragraph (3), in such amounts as the Secretary determines appropriate, to the heads of executive agencies or departments that meet the requirements of subparagraph (B).

(B) In order to receive a payment under paragraph (3), the head of an executive agency or department shall submit an application in such form and containing such information as the Secretary of the Treasury shall by regulation require. Such application shall contain a description of the fine imposed under section 401(b)(6), the circumstances surrounding the imposition of such fine, and the type and severity of pollution that resulted from the actions to which such fine applies.

(5) For purposes of subchapter B of chapter 98 of the Internal Revenue Code of 1986, the Fund established under this paragraph shall be treated in the same manner as a trust fund established under subchapter A of such chapter.

COORDINATION AND CONSOLIDATION OF POST-SEIZURE ADMINISTRATION

SEC. 517. [21 U.S.C. 887] The Attorney General and the Secretary of the Treasury shall take such action as may be necessary to develop and maintain a joint plan to coordinate and consolidate post-seizure administration of property seized under this title, title III or provisions of the customs laws relating to controlled substances.

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[74] So in law. Probably should be "Administration". Section 16 of Public Law 96–132 (93 Stat. 1049) amended this title in several other places by striking references to the Bureau of Narcotics and Dangerous Drugs and inserting references to the Drug Enforcement Administration.

CONTROLLED SUBSTANCES PRODUCTION CONTROL

SEC. 519.[75] [21 U.S.C. 889] (a) As used in this section:

(1) The term "controlled substance" has the same meaning given such term in section 102(6) of the Controlled Substances Act (21 U.S.C. 801(6)).

(2) The term "Secretary" means the Secretary of Agriculture.

(3) The term "State" means each of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands of the United States, American Samoa, the Commonwealth of the Northern Mariana Islands, or the Trust Territory of the Pacific Islands.

(b) Notwithstanding any other provision of law, following the date of enactment of this Act, any person who is convicted under Federal or State law of planting, cultivation, growing, producing, harvesting, or storing a controlled substance in any crop year shall be ineligible for—

(1) as to any commodity produced during that crop year, and the four succeeding crop years, by such person—

(A) any price support or payment made available under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.), the Commodity Credit Corporation Charter Act (15 U.S.C. 714 et seq.), or any other Act;

(B) a farm storage facility loan made under section 4(h) of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b(h));

(C) crop insurance under the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.);

(D) a disaster payment made under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.); or

(E) a loan made, insured or guaranteed under the Consolidated Farm and Rural Development Act (7 U.S.C. 1921 et seq.) or any other provision of law administered by the Farmers Home Administration; or

(2) a payment made under section 4 or 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b or 714c) for the storage of an agricultural commodity that is—

(A) produced during that crop year, or any of the four succeeding crop years, by such person; and

(B) acquired by the Commodity Credit Corporation.

(c) Not later than 180 days after the date of enactment of this Act, the Secretary shall issue such regulations as the Secretary determines are necessary to carry out this section, including regulations that—

(1) define the term "person";

(2) govern the determination of persons who shall be ineligible for program benefits under this section; and

(3) protect the interests of tenants and sharecroppers.

SEC. 520. [21 U.S.C. 890] REVIEW OF FEDERAL SALES OF CHEMICALS USABLE TO MANUFACTURE CONTROLLED SUBSTANCES.

A Federal department or agency may not sell from the stocks of the department or agency any chemical which, as determined by

[75] Section 518 was repealed by section 2(c)(3) of Public Law 106–185 (114 Stat. 210).

the Administrator of the Drug Enforcement Administration, could be used in the manufacture of a controlled substance unless the Administrator certifies in writing to the head of the department or agency that there is no reasonable cause to believe that the sale of the chemical would result in the illegal manufacture of a controlled substance.

PART F—ADVISORY COMMISSION

ESTABLISHMENT OF COMMISSION ON MARIHUANA AND DRUG ABUSE

SEC. 601. [21 U.S.C. 801n] (a) There is established a commission to be known as the Commission on Marihuana and Drug Abuse (hereafter in this section referred to as the "Commission"). The Commission shall be composed of—

(1) two Members of the Senate appointed by the President of the Senate;

(2) two Members of the House of Representatives appointed by the Speaker of the House of Representatives; and

(3) nine members appointed by the President of the United States.

At no time shall more than one of the members appointed under paragraph (1), or more than one of the members appointed under paragraph (2), or more than five of the members appointed under paragraph (3) be members of the same political party.

(b)(1) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

(2) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive $100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel, subsistence, and other necessary expenses incurred in the performance of such duties.

(3) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

(c)(1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of $75 per diem, including travel time. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence,

as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

(3) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties under this section. Upon request of the Chairman of the Commission, such department or agency shall furnish such information to the Commission.

(d)(1) The Commission shall conduct a study of marihuana including, but not limited to, the following areas:

(A) the extent of use of marihuana in the United States to include its various sources, the number of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;

(B) an evaluation of the efficacy of existing marihuana laws;

(C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological;

(D) the relationship of marihuana use to aggressive behavior and crime;

(E) the relationship between marihuana and the use of other drugs; and

(F) the international control of marihuana.

(2) Within one year after the date on which funds first become available to carry out this section, the Commission shall submit to the President and the Congress a comprehensive report on its study and investigation under this subsection which shall include its recommendations and such proposals for legislation and administrative action as may be necessary to carry out its recommendations.

(e) The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.

(f) Total expenditures of the Commission shall not exceed $1,000,000.

PART G—CONFORMING, TRANSITIONAL AND EFFECTIVE DATE, AND GENERAL PROVISIONS

REPEALS AND CONFORMING AMENDMENTS

SEC. 701. (a) Sections 201(v), 301(q), and 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(v), 331(q), 360(a)) are repealed.

(b) Subsections (a) and (b) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) are amended to read as follows:

"SEC. 303. (a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

"(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

(c) Section 304(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended (1) by striking out clauses (A) and (D), (2) by striking out "of such depressant or stimulant drug or" in clause (C), (3) by adding "and" after the comma at the end of clause (C), and (4) by redesignating clauses (B), (C), and (E) as clauses (A), (B), and (C), respectively.

(d) Section 304(d)(3)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(d)(3)(iii)) is amended by striking out "depressant or stimulant drugs or".

(e) Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended (1) in subsection (a) by striking out paragraph (2), by inserting "and" at the end of paragraph (1), and by redesignating paragraph (3) as paragraph (2); (2) by striking out "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug" in the first sentence of subsection (b); (3) by striking out the last sentence of subsection (b); (4) by striking out "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug" in the first sentence of subsection (c); (5) by striking out the last sentence of subsection (c); (6) by striking out "(1)" in subsection (d) and by inserting a period after "drug or drugs" in that subsection and deleting the remainder of that subsection; and (7) by striking out "AND CERTAIN WHOLESALERS" in the section heading.

(f) Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by striking out "to depressant or stimulant drugs or" in subsection (e).

(g) Section 201(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)(2)) is amended by inserting a period after "Canal Zone" the first time these words appear and deleting all thereafter in such section 201(a)(2).

(h) The last sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended (1) by striking out "This paragraph" and inserting in lieu thereof "Clause (2) of the third sentence of this paragraph,", and (2) by striking out "section 2 of the Act of May 26, 1922, as amended (U.S.C. 1934, edition, title 21, sec. 173)" and inserting in lieu thereof "the Controlled Substances Import and Export Act".

(i)(1) Section 1114 of title 18, United States Code, is amended by striking out "the Bureau of Narcotics" and inserting in lieu thereof "the Bureau of Narcotics and Dangerous Drugs".

(2) Section 1952 of such title is amended—

(A) by inserting in subsection (b)(1) "or controlled substances (as defined in section 102(6) of the Controlled Substances Act)" immediately following "narcotics"; and

(B) by striking out "or narcotics" in subsection (c).

(j) Subsection (a) of section 302 of the Public Health Service Act (42 U.S.C. 242(a)) is amended to read as follows:

"SEC. 302. (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts."

PENDING PROCEEDINGS

SEC. 702. [21 U.S.C. 321 note] (a) Prosecutions for any violation of law occurring prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs on the date of enactment of this Act shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act, such drug shall automatically be controlled under this title by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has been made prior to the date of enactment of this Act which is not listed in section 202 within schedules I through V shall automatically be controlled under this title by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary.

(d) Notwithstanding subsection (a) of this section or section 1103, section 4202 of title 18, United States Code, shall apply to any individual convicted under any of the laws repealed by this title or title III without regard to the terms of any sentence imposed on such individual under such law.

PROVISIONAL REGISTRATION

SEC. 703. [21 U.S.C. 822 note] (a)(1) Any person who—

(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302, and

(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act or under section 4722 of the Internal Revenue Code of 1954,

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of section 303 of this title.

(b) The provisions of section 304, relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

(1) the date on which such person has registered with the Attorney General under section 303 or has had his registration denied under such section, or

(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first.

EFFECTIVE DATES AND OTHER TRANSITIONAL PROVISIONS

SEC. 704. [21 U.S.C. 801 note] (a) Except as otherwise provided in this section, this title shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment.

(b) Parts A, B, E, and F of this title, section 702, this section, and sections 705 through 709, shall become effective upon enactment.

(c) Sections 305 (relating to labels and labeling), and 306 (relating to manufacturing quotas) shall become effective on the date specified in subsection (a) of this section, except that the Attorney General may by order published in the Federal Register postpone the effective date of either or both of these sections for such period as he may determine to be necessary for the efficient administration of this title.

CONTINUATION OF REGULATIONS

SEC. 705. [21 U.S.C. 801 note] Any orders, rules, and regulations which have been promulgated under any law affected by this title and which are in effect on the day preceding enactment of this title shall continue in effect until modified, superseded, or repealed.

SEVERABILITY

SEC. 706. [21 U.S.C. 901] If a provision of this Act is held invalid, all valid provisions that are severable shall remain in effect. If a provision of this Act is held invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

SAVING PROVISION

SEC. 707. [21 U.S.C. 902] Nothing in this Act, except this part and, to the extent of any inconsistency, sections 307(e) and 309 of this title, shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act.

APPLICATION OF STATE LAW

SEC. 708. [21 U.S.C. 903] No provision of this title shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together.

PAYMENT OF TORT CLAIMS

SEC. 709. [21 U.S.C. 904] Notwithstanding section 2680(k) of title 28, United States Code, the Attorney General, in carrying out the functions of the Department of Justice under this title, is authorized to pay tort claims in the manner authorized by section 2672 of title 28, United States Code, when such claims arise in a foreign country in connection with the operations of the Drug Enforcement Administration abroad.

CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT[1], as amended

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TITLE III—IMPORTATION AND EXPORTATION; AMENDMENTS AND REPEALS OF REVENUE LAWS

SHORT TITLE

SEC. 1000. [21 U.S.C. 951 note] This title may be cited as the "Controlled Substances Import and Export Act".

[1] Public Law 91–513 (Comprehensive Drug Abuse Prevention and Control Act of 1970), Title III, Oct. 27, 1970, 84 Stat. 1285, 21 U.S.C. 951 et seq.

PART A—IMPORTATION AND EXPORTATION

DEFINITIONS

SEC. 1001. [21 U.S.C. 951] (a) For purposes of this part—

(1) The term "import" means, with respect to any article, any bringing in or introduction of such article into any area (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(2) The term "customs territory of the United States" has the meaning assigned to such term by general note 2 of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202).

(b) Each term defined in section 102 of title II shall have the same meaning for purposes of this title as such term has for purposes of title II.

IMPORTATION OF CONTROLLED SUBSTANCES

SEC. 1002. [21 U.S.C. 952] (a) It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of title II, or any narcotic drug in schedule III, IV, or V of title II, except that—

(1) such amounts of crude opium poppy straw, concentrate of poppy straw, and coca leaves as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes, and

(2) such amounts of any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States—

(A) during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate,

(B) in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303, or

(C) in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses,

may be so imported under such regulations as the Attorney General shall prescribe. No crude opium may be so imported for the purpose of manufacturing heroin or smoking opium.

(b) It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, IV, or V, unless such nonnarcotic controlled substance—

(1) is imported for medical, scientific or other legitimate uses, and

(2) is imported pursuant to such notification or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such import permit, notification, or declaration, as the Attorney General may by regulation prescribe, except that if a nonnarcotic control substance in schedule IV or V is also listed in schedule I or II of the Convention on Psychotropic Substances it shall be imported pursuant to such import permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

(c) In addition to the amount of coca leaves authorized to be imported into the United States under subsection (a), the Attorney General may permit the importation of additional amounts of coca leaves. All cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in such additional amounts of coca leaves imported under this subsection shall be destroyed under the supervision of an authorized representative of the Attorney General.

EXPORTATION OF CONTROLLED SUBSTANCES

SEC. 1003. [21 U.S.C. 953] (a) It shall be unlawful to export from the United States any narcotic drug in schedule I, II, III, or IV unless—

(1) it is exported to a country which is a party to—

(A) the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention signed at Geneva on February 19, 1925; or

(B) the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs concluded at Geneva, July 13, 1931, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention of July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946), signed at Paris, November 19, 1948; or

(C) the Single Convention on Narcotic Drugs, 1961, signed at New York, March 30, 1961;

(2) such country has instituted and maintains, in conformity with the conventions to which it is a party, a system for the control of imports of narcotic drugs which the Attorney General deems adequate;

(3) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import, and a permit or license to import such drug has been issued by the country of import;

(4) substantial evidence is furnished to the Attorney General by the exporter that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drug for medical or scientific uses within such country; and

(5) a permit to export the narcotic drug in each instance has been issued by the Attorney General.

(b) Notwithstanding subsection (a), the Attorney General may authorize any narcotic drug (including crude opium and coca leaves) in schedule I, II, III, or IV to be exported from the United States to a country which is a party to any of the international instruments mentioned in subsection (a) if the particular drug is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(c) It shall be unlawful to export from the United States any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country which has instituted and maintains a system which the Attorney General deems adequate for the control of imports of such substances;

(2) the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) substantial evidence is furnished to the Attorney General that (A) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country to which exported, (B) it will not be exported from such country, and (C) there is an actual need for the controlled substance for medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance in each instance has been issued by the Attorney General.

(d) Notwithstanding subsection (c), the Attorney General may authorize any nonnarcotic controlled substance in schedule I or II to be exported from the United States if the particular substance is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(e) It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substances in schedule III or IV or any controlled substances in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination for consumption for medical, scientific, or other legitimate purposes;

(2) it is exported pursuant to such notification or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such export permit, notification, or declaration as the Attorney General may by regulation prescribe; and

(3) in the case of a nonnarcotic controlled substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, it is exported pursuant to such export permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES

SEC. 1004. [21 U.S.C. 954] Notwithstanding sections 1002, 1003, and 1007—

(1) A controlled substance in schedule I may—

(A) be imported into the United States for transshipment to another country, or

(B) be transferred or transshipped from one vessel, vehicle, or aircraft to another vessel, vehicle, or aircraft within the United States for immediate exportation,

if and only if it is so imported, transferred, or transshipped (i) for scientific, medical, or other legitimate purposes in the country of destination, and (ii) with the prior written approval of the Attorney General (which shall be granted or denied within 21 days of the request).

(2) A controlled substance in schedule II, III, or IV may be so imported, transferred, or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General.

POSSESSION ON BOARD VESSELS, ETC., ARRIVING IN OR DEPARTING FROM UNITED STATES

SEC. 1005. [21 U.S.C. 955] It shall be unlawful for any person to bring or possess on board any vessel or aircraft, or on board any vehicle of a carrier, arriving in or departing from the United States or the customs territory of the United States, a controlled substance in schedule I or II or a narcotic drug in schedule III or IV, unless such substance or drug is a part of the cargo entered in the manifest or part of the official supplies of the vessel, aircraft, or vehicle.

EXEMPTION AUTHORITY

SEC. 1006. [21 U.S.C. 956] (a)(1) Subject to paragraph (2), the Attorney General may by regulation exempt from sections 1002 (a) and (b), 1003, 1004, and 1005 any individual who has a controlled substance (except a substance in schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if the lawfully obtained such substance and he makes such declaration (or gives such other notification) as the Attorney General may by regulation require.

(2)[2] Notwithstanding any exemption under paragraph (1), a United States resident who enters the United States through an international land border with a controlled substance (except a substance in schedule I) for which the individual does not possess a valid prescription issued by a practitioner (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) in accordance

[2] Public Law 105–357, § 2(b), (c), Nov. 10, 1998, 112 Stat. 3271, provided that:

"(b) FEDERAL MINIMUM REQUIREMENT.—Section 1006(a)(2) of the Controlled Substances Import and Export Act, as added by this section [subsec. (a)(2) of this section], is a minimum Federal requirement and shall not be construed to limit a State from imposing any additional requirement.

"(c) EXTENT.—The amendment made by subsection (a) [amending this section] shall not be construed to affect the jurisdiction of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.).".

with applicable Federal and State law (or documentation that verifies the issuance of such a prescription to that individual) may not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.

(b) The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance listed in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of this title if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

PERSONS REQUIRED TO REGISTER

SEC. 1007. [21 U.S.C. 957] (a) No person may—

(1) import into the customs territory of the United States from any place outside thereof (but within the United States), or import into the United States from any place outside thereof, any controlled substance or list I chemical, or

(2) export from the United States any controlled substance or list I chemical,

unless there is in effect with respect to such person a registration issued by the Attorney General under section 1008, or unless such person is exempt from registration under subsection (b).

(b)(1) The following persons shall not be required to register under the provisions of this section and may lawfully possess a controlled substance or list I chemical:

(A) An agent or an employee of any importer or exporter registered under section 1008 if such agent or employee is acting in the usual course of his business or employment.

(B) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance or list I chemical is in the usual course of his business or employment.

(C) An ultimate user who possesses such substance for a purpose specified in section 102(25)[3] and in conformity with an exemption granted under section 1006(a).

(2) The Attorney General may, by regulation, waive the requirement for registration of certain importers and exporters if he finds it consistent with the public health and safety; and may authorize any such importer or exporter to possess controlled substances or list I chemicals for purposes of importation and exportation.

REGISTRATION REQUIREMENTS

SEC. 1008. [21 U.S.C. 958] (a) The Attorney General shall register an applicant to import or export a controlled substance in

[3] So in law. Probably should be "102(27)". Former paragraph (25) of section 102 was redesignated as paragraph (26) by section 507(a) of Public Law 98–473 (98 Stat. 2071), and section 1003(b)(2) of Public Law 99–570 (100 Stat. 3207–6) redesignated paragraph (26) as paragraph (27).

schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this section. In determining the public interest, the factors enumerated in paragraph (1) through (6) of section 303(a) shall be considered.

(b) Registration granted under this section shall not entitle a registrant to import or export controlled substances other than specified in the registration.

(c)(1) The Attorney General shall register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the factors enumerated in paragraphs (1) through (6) of section 303(d) shall be considered.

(2)(A) The Attorney General shall register an applicant to import or export a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the import or export of a drug product that is exempted under section 102(39)(A)(iv).

(B) In determining the public interest for the purposes of subparagraph (A), the Attorney General shall consider the factors specified in section 303(h).

(d)(1) The Attorney General may deny an application for registration under subsection (a) if he is unable to determine that such registration is consistent with the public interest (as defined in subsection (a)) and with the United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part.

(2) The Attorney General may deny an application for registration under subsection (c), or revoke or suspend a registration under subsection (a) or (c), if he determines that such registration is inconsistent with the public interest (as defined in subsection (a) or (c)) or with the United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part.

(3) The Attorney General may limit the revocation or suspension of a registration to the particular controlled substance, or substances, or list I chemical or chemicals, with respect to which grounds for revocation or suspension exist.

(4) Before taking action pursuant to this subsection, the Attorney General shall serve upon the applicant or registrant an order to show cause as to why the registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General, or his designee, at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this subsection in accordance with subchapter II of chapter 5 of title 5 of the United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

(5) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this subsection, in cases where he finds that there is an imminent danger to the public health and safety. Such suspension shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(6) In the event that the Attorney General suspends or revokes a registration granted under this section, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be seized or placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded, except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of the sale thereof which have been deposited with the court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 511(e) of the Controlled Substances Act.

(e) No registration shall be issued under this part for a period in excess of one year. Unless the regulations of the Attorney General otherwise provide, sections 302(f), 305, 307, and 310 shall apply to persons registered under this section to the same extent such sections apply to persons registered under section 303.

(f) The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of importers and exporters of controlled substances or listed chemicals.

(g) Persons registered by the Attorney General under this section to import or export controlled substances or list I chemicals may import or export (and, for the purpose of so importing or exporting, may possess) such substances to the extent authorized by their registration and in conformity with the other provisions of this title and title II.

(h) A separate registration shall be required at each principal place of business where the applicant imports or exports controlled substances or list I chemicals.

(i) Except in emergency situations as described in section 1002(a)(2)(A), prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registration for the bulk manufacture of the substance an opportunity for a hearing.

POSSESSION, MANUFACTURE OR DISTRIBUTION FOR PURPOSES OF UNLAWFUL IMPORTATION

SEC. 1009. [21 U.S.C. 959] (a) It shall be unlawful for any person to manufacture or distribute a controlled substance in schedule I or II or flunitrazepam or listed chemical—

(1) intending that such substance or chemical be unlawfully imported into the United States or into waters within a distance of 12 miles of the coast of the United States; or

(2) knowing that such substance or chemical will be unlawfully imported into the United States or into waters within a distance of 12 miles of the coast of the United States.

(b) It shall be unlawful for any United States citizen on board any aircraft, or any person on board an aircraft owned by a United States citizen or registered in United States, to—

(1) manufacture or distribute a controlled substance or listed chemical; or

(2) possess a controlled substance or listed chemical with intent to distribute.

(c) This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States. Any person who violates this section shall be tried in the United States district court at the point of entry where such person enters the United States, or in the United States District Court for the District of Columbia.

PROHIBITED ACTS A—PENALTIES

SEC. 1010. [21 U.S.C. 960] (a) Any person who—

(1) contrary to section 1002, 1003, or 1007, knowingly or intentionally imports or exports a controlled substance,

(2) contrary to section 1005, knowingly or intentionally brings or possesses on board a vessel, aircraft, or vehicle a controlled substance, or

(3) contrary to section 1009, manufactures, possesses with intent to distribute, or distributes a controlled substance,

shall be punished as provided in subsection (b).

(b)(1) In the case of a violation of subsection (a) of this section involving—

(A) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(B) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(i) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(ii) cocaine, its salts, optical and geometric isomers, and salts or isomers;

(iii) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(iv) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in clauses (i) through (iii);

(C) 50 grams or more of a mixture or substance described in subparagraph (B) which contains cocaine base;

(D) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(E) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(F) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(G) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(H) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.[4]

the person committing such violation shall be sentenced to a term of imprisonment of not less than 10 years and not more than life and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than 20 years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $8,000,000 if the defendant is an individual or $20,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[5], any sentence under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this paragraph. No person sentenced under this paragraph shall be eligible for parole during the term of imprisonment imposed therein.

(2) In the case of a violation of subsection (a) of this section involving—

(A) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(B) 500 grams or more of a mixture or substance containing a detectable amount of—

[4] So in law. The period probably should be a semicolon.

[5] So in law. Probably should be "title 18, United States Code". This act does not contain a title 18.

(i) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(ii) cocaine, its salts, optical and geometric isomers, and salts or isomers;

(iii) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(iv) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in clauses (i) through (iii);

(C) 5 grams or more of a mixture or substance described in subparagraph (B) which contains cocaine base;

(D) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(E) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(F) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(G) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(H) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.[6]

the person committing such violation shall be sentenced to a term of imprisonment of not less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[7], any sentence imposed under this paragraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding

[6] So in law. The period probably should be a semicolon.

[7] So in law. Probably should be "title 18, United States Code". This act does not contain a title 18.

any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this paragraph. No person sentenced under this paragraph shall be eligible for parole during the term of imprisonment imposed therein.

(3) In the case of a violation under subsection (a) of this section involving a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or flunitrazepam, the person committing such violation shall, except as provided in paragraphs (1), (2), and (4), be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[8], any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding the prior sentence, and notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this paragraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(4) In the case of a violation under subsection (a) with respect to less than 50 kilograms of marihuana except in the case of 100 or more marihuana plants regardless of weight, less than 10 kilograms of hashish, less than one kilogram of hashish oil, or any quantity of a controlled substance in schedule III, IV, or V,[9] (except a violation involving flunitrazepam and except a violation involving gamma hydroxybutyric acid) the person committing such violation shall be imprisoned not more than five years, or be fined not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $250,000 if the defendant

[8] So in law. Probably should be "title 18, United States Code". This act does not contain a title 18.

[9] So in law. The comma probably should go after the closing parenthesis. See section 2(b)(1)(C) of Public Law 104–305 (110 Stat. 3807).

is an individual or $1,000,000 if the defendant is other than an individual, or both.

(c)[10] A special parole term imposed under this section or section 1012 may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. The special term provided for in this section and in section 1012 is in addition to, and not in lieu of, any other parole provided for by law.

(d) A person who knowingly or intentionally—

(1) imports or exports a listed chemical with intent to manufacture a controlled substance in violation of this title or title II;

(2) exports a listed chemical in violation of the laws of the country to which the chemical is exported or serves as a broker or trader for an international transaction involving a listed chemical, if the transaction is in violation of the laws of the country to which the chemical is exported;

(3) imports or exports a listed chemical knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of this title or title II;

(4) exports a listed chemical, or serves as a broker or trader for an international transaction involving a listed chemical, knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported;

(5) imports or exports a listed chemical, with the intent to evade the reporting or recordkeeping requirements of section 1018 applicable to such importation or exportation by falsely representing to the Attorney General that the importation or exportation qualifies for a waiver of the 15-day notification requirement granted pursuant to section 1018(e) (2) or (3) by misrepresenting the actual country of final destination of the listed chemical or the actual listed chemical being imported or exported;

(6) imports or exports a listed chemical in violation of section 1007 or 1018; or

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[10] The probable intent of the Congress is that subsection (c) not appear in the law. Section 225 of Public Law 98–473 (98 Stat. 2030) provided that section 1010 above is amended "by repealing subsection (c)". That repeal, however, was subject to a delayed effective date (see section 235 of such Public Law), and before that effective date was reached, section 1005(c) of Public Law 99–570 (100 Stat. 3207–6) amended section 225 of Public Law 98–473 so that the text of section 225 provided as follows: "Section 1515 of the Controlled Substances Import and Export Act (21 U.S.C. 960) is amended by repealing subsection (c).". The probable intent of the Congress was that the amended section 225 strike subsection (c) of section 1010, not section 1515, as this act does not contain a section 1515 and as the cite provided to the United States Code is the Code citation for section 1010.

(7) manufactures, possesses with intent to distribute, or distributes a listed chemical in violation of section 959 of this title.[11]

shall be fined in accordance with title 18, imprisoned not more than 20 years in the case of a violation of paragraph (1) or (3) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (3) involving a list I chemical, or both.

PROHIBITED ACTS B—PENALTIES

SEC. 1011. [21 U.S.C. 961] Any person who violates section 1004 or fails to notify the Attorney General of an importation or exportation under section 1018 shall be subject to the following penalties:

(1) Except as provided in paragraph (2), any such person shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. Sections 402(c)(1) and (c)(3) shall apply to any civil penalty assessed under this paragraph.

(2) If such a violation is prosecuted by an information or indictment which alleges that the violation was committed knowingly or intentionally and the trier of fact specifically finds that the violation was so committed, such person shall be sentenced to imprisonment for not more than one year or a fine of not more than $25,000 or both.

SECOND OR SUBSEQUENT OFFENSES

SEC. 1012. [21 U.S.C. 962] (a) Any person convicted of any offense under this part is, if the offense is a second or subsequent offense, punishable by a term of imprisonment twice that otherwise authorized, by twice the fine otherwise authorized, or by both.

(b) For purposes of this section, a person shall be considered convicted of a second or subsequent offense if, prior to the commission of such offense, one or more prior convictions of such person for a felony drug offense have become final.

(c) Section 411 shall apply with respect to any proceeding to sentence a person under this section.

ATTEMPT AND CONSPIRACY

SEC. 1013. [21 U.S.C. 963] Any person who attempts or conspires to commit any offense defined in this title shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

ADDITIONAL PENALTIES

SEC. 1014. [21 U.S.C. 964] Any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

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[11] The reference to section 959 is so in law. See 102(c)(3) of Public Law 104–237 (110 Stat. 3100). Probably should be a reference to section 1009.

APPLICABILITY OF PART E OF TITLE II

SEC. 1015. [21 U.S.C. 965] Part E of title II shall apply with respect to functions of the Attorney General (and of officers and employees of the Bureau of Narcotics and Dangerous Drugs) under this title, to administrative and judicial proceedings under this title, and to violations of this title, to the same extent that such part applies to functions of the Attorney General (and such officers and employees) under title II, to such proceedings under title II, and to violations of title II. For purposes of the application of this section to section 510 or 511, any reference in such section 510 or 511 to "this title" shall be deemed to be a reference to title III, any reference to section 303 shall be deemed to be a reference to section 1008, and any reference to section 302(d) shall be deemed to be a reference to section 1007(b)(2).

AUTHORITY OF SECRETARY OF TREASURY [12]

SEC. 1016. [21 U.S.C. 966] Nothing in this Act shall derogate from the authority of the Secretary of the Treasury under the customs and related laws.

CRIMINAL FORFEITURES

SEC. 1017. [21 U.S.C. 970] Section 413 of title II, relating to criminal forfeitures, shall apply in every respect to a violation of this title punishable by imprisonment for more than one year.

NOTIFICATION, SUSPENSION OF SHIPMENT, AND PENALTIES WITH RESPECT TO IMPORTATION AND EXPORTATION OF LISTED CHEMICALS

SEC. 1018. [21 U.S.C. 971] (a) Each regulated person who imports or exports a listed chemical shall notify the Attorney General of the importation or exportation not later than 15 days before the transaction is to take place.

(b)(1) The Attorney General shall provide by regulation for circumstances in which the requirement of subsection (a) does not apply to a transaction between a regulated person and a regular customer or to an importation by a regular importer. At the time of any importation or exportation constituting a transaction referred to in the preceding sentence, the regulated person shall notify the Attorney General of the transaction.

(2) The regulations under this subsection shall provide that the initial notification under subsection (a) with respect to a customer of a regulated person or to an importer shall, upon the expiration of the 15-day period, qualify the customer as a regular customer or the importer as a regular importer, unless the Attorney General otherwise notifies the regulated person in writing.

(c)(1) The Attorney General may order the suspension of any importation or exportation of a listed chemical (other than a regulated transaction to which the requirement of subsection (a) does not apply by reason of subsection (b)) or may disqualify any regular customer or regular importer on the ground that the chemical may

[12] Additional provisions of law relating to the authority of the Secretary of the Treasury to enforce narcotic laws are codified at 21 U.S.C. 967–969 and can be found later in this compilation in the section titled "Title 21. Food and Drugs."

be diverted to the clandestine manufacture of a controlled substance. From and after the time when the Attorney General provides written notice of the order (including a statement of the legal and factual basis for the order) to the regulated person, the regulated person may not carry out the transaction.

(2) Upon written request to the Attorney General, a regulated person to whom an order applies under paragraph (1) is entitled to an agency hearing on the record in accordance with subchapter II of chapter 5 of title 5, United States Code. The hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time, if so requested by the regulated person.

(d) A person located in the United States who is a broker or trader for an international transaction in a listed chemical that is a regulated transaction solely because of that person's involvement as a broker or trader shall, with respect to that transaction, be subject to all of the notification, reporting, recordkeeping, and other requirements placed upon exporters of listed chemicals by this title and title II.

(e)(1) The Attorney General may by regulation require that the 15-day notification requirement of subsection (a) apply to all exports of a listed chemical to a specified country, regardless of the status of certain customers in such country as regular customers, if the Attorney General finds that such notification is necessary to support effective chemical diversion control programs or is required by treaty or other international agreement to which the United States is a party.

(2) The Attorney General may by regulation waive the 15-day notification requirement for exports of a listed chemical to a specified country if the Attorney General determines that such notification is not required for effective chemical diversion control. If the notification requirement is waived, exporters of the listed chemical shall be required to submit to the Attorney General reports of individual exportations or periodic reports of such exportation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation.

(3) The Attorney General may by regulation waive the 15-day notification requirement for the importation of a listed chemical if the Attorney General determines that such notification is not necessary for effective chemical diversion control. If the notification requirement is waived, importers of the listed chemical shall be required to submit to the Attorney General reports of individual importations or periodic reports of the importation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation.

PART B—AMENDMENTS AND REPEALS, TRANSITIONAL AND EFFECTIVE DATE PROVISIONS

REPEALS

SEC. 1101. (a) The following provisions of law are repealed:

(1) The Act of February 23, 1887 (21 U.S.C. 191–193).

(2) The Narcotic Drugs Import and Export Act (21 U.S.C. 171, 173, 174–184, 185).

(3) The Act of March 28, 1928 (31 U.S.C. 529a).
(4) Sections 2(b), 6, 7, and 8 of the Act of June 14, 1930 (21 U.S.C. 162(b), 173a, 197, 198).
(5) The Act of July 3, 1930 (21 U.S.C. 199).
(6) Section 6 of the Act of March 28, 1928 (31 U.S.C. 529g).
(7) The Opium Poppy Control Act of 1942 (21 U.S.C. 188–188n).
(8) Section 15 of the Act of August 1, 1956 (48 U.S.C. 1421m).
(9) The Act of July 11, 1941 (21 U.S.C. 184a).
(10) The Narcotics Manufacturing Act of 1960 (21 U.S.C. 501–517).

(b)(1)(A) Chapter 68 of title 18 of the United States Code (relating to narcotics) is repealed.
(B) The item relating to such chapter 68 in the analysis of part I of such title 18 is repealed.
(2)(A) Section 3616 of title 18 of the United States Code (relating to use of confiscated motor vehicles) is repealed.
(B) The item relating to such section 3616 in the analysis of chapter 229 of such title 18 is repealed.
(3)(A) Subchapter A of chapter 39 of the Internal Revenue Code of 1954 (relating to narcotic drugs and marihuana) is repealed.
(B) The table of subchapters of such chapter 39 is amended by striking out

"SUBCHAPTER A. Narcotic drugs and marihuana."

(4)(A) Sections 7237 (relating to violation of laws relating to narcotic drugs and to marihuana) and 7238 (relating to violation of laws relating to opium for smoking) of the Internal Revenue Code of 1954 are repealed.
(B) The table of sections of part II of subchapter A of chapter 75 of the Internal Revenue Code of 1954 is amended by striking out the items relating to such sections 7237 and 7238.
(5)(A) Section 7491 of the Internal Revenue Code of 1954 (relating to burden of proof of exemptions in case of marihuana offenses) is repealed.
(B) The table of sections for subchapter E of chapter 76 of the Internal Revenue Code of 1954 is amended by striking out the item relating to such section 7491.

CONFORMING AMENDMENTS

SEC. 1102. [21 U.S.C. 4901(a)] (a) Section 4901(a) of the Internal Revenue Code of 1954 is amended by striking out the comma immediately before "4461" and inserting in lieu thereof "or", and by striking out ", 4721 (narcotic drugs), or 4751 (marihuana)".
(b) Section 4905(b)(1) of the Internal Revenue Code of 1954 (relating to registration) is amended by striking out ", narcotics, marihuana," and ", 4722, 4753,".
(c) Section 6808 of the Internal Revenue Code of 1954 (relating to special provisions relating to stamps) is amended by striking out paragraph (8).
(d) Section 7012 of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out subsections (a) and (b).

(e) Section 7103(d)(3) of the Internal Revenue Code of 1954 (relating to bonds required with respect to certain products) is amended by striking out subparagraph (D).

(f) Section 7326 of the Internal Revenue Code of 1954 (relating to disposal of forfeited or abandoned property in special cases) is amended by striking out subsection (b).

(g)(1) Section 7607 of the Internal Revenue Code of 1954 (relating to additional authority for Bureau of Narcotics and Bureau of Customs) is amended—

(A) by striking out "The Commissioner, Deputy Commissioner, Assistant to the Commissioner, and agents of the Bureau of Narcotics of the Department of the Treasury, and officers" and inserting in lieu thereof "Officers";

(B) by striking out in paragraph (2) "narcotic drugs (as defined in section 4731) or marihuana (as defined in section 4761)" and inserting in lieu thereof "narcotic drugs (as defined in section 102(16) of the Controlled Substances Act) or marihuana (as defined in section 102(15) of the Controlled Substances Act)"; and

(C) by striking out "Bureau of Narcotics and" in the section heading.

(2) The item relating to section 7607 in the table of contents of subchapter A of chapter 78 of the Internal Revenue Code of 1954 is amended by striking out "Bureau of Narcotics and".

(h) Section 7609(a) of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out paragraphs (3) and (4).

(i) Section 7641 of the Internal Revenue Code of 1954 (relating to supervision of operations of certain manufacturers) is amended by striking out "opium suitable for smoking purposes,".

(j) Section 7651 of the Internal Revenue Code of 1954 (relating to administration and collection of taxes in possessions) is amended by striking out "and in sections 4705(b), 4735, and 4762 (relating to taxes on narcotic drugs and marihuana)".

(k) Section 7655(a) of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out paragraphs (3) and (4).

(l) Section 2901(a) of title 28 of the United States Code is amended by striking out "as defined by section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined by section 102(16) of the Controlled Substances Act".

(m) The last sentence of the second paragraph of section 584 of the Act of June 17, 1930 (19 U.S.C. 1584), is amended to read as follows: "As used in this paragraph, the terms 'opiate' and 'marihuana' shall have the same meaning given those terms by sections 102(17) and 102(15), respectively, of the Controlled Substances Act."

(n)(1) The first section of the Act of August 7, 1939 (31 U.S.C. 529a), is repealed.

(2) Section 3 of such Act (31 U.S.C. 529d) is amended by striking out "or the Commissioner of Narcotics, as the case may be,".

(3) Section 4 of such Act (31 U.S.C. 529e) is amended by striking out "or narcotics" each place it appears.

(4) Section 5 of such Act (31 U.S.C. 529f) is amended by striking out "or narcotics" in the first sentence.

[(o) Repealed.]

(p) Paragraph (a) of section 301 of the Narcotic Addict Rehabilitation Act of 1966 (42 U.S.C. 3411) is amended by striking out "as defined in section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined in section 102(16) of the Controlled Substances Act."

[(q) Repealed.]

(r) Paragraph (d) of section 7 of the Act of August 9, 1939 (49 U.S.C. 787) is amended to read as follows:

"(d) The term 'narcotic drug' shall have the meaning given that term by section 102(16) of the Controlled Substances Act and shall also include marihuana as defined by section 102(15) of such Act;".

(s) Paragraph (a) of section 4251 of title 18, United States Code, is amended by striking out "as defined in section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined in section 102(16) of the Controlled Substances Act".

(t) The first section of the Act of August 11, 1955 (21 U.S.C. 198a), is amended to read as follows: "That for the purpose of any investigation which, in the opinion of the Secretary of the Treasury, is necessary and proper to the enforcement of section 545 of title 18 of the United States Code (relating to smuggling goods into the United States) with respect to any controlled substance (as defined in section 102 of the Controlled Substances Act), the Secretary of the Treasury may administer oaths and affirmations, subpena witnesses, compel their attendance, take evidence, and require the production of records (including books, papers, documents, and tangible things which constitute or contain evidence) relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place within the customs territory of the United States, except that a witness shall not be required to appear at any hearing distant more than 100 miles from the place where he was served with subpena. Witnesses summoned by the Secretary shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. Oaths and affirmations may be made at any place subject to the jurisdiction of the United States."

PENDING PROCEEDINGS

SEC. 1103. [21 U.S.C. 171 note] (a) Prosecutions for any violation of law occurring prior to the effective date of section 1101 shall not be affected by the repeals or amendments made by such section or section 1102, or abated by reason thereof.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 1101 shall not be affected by the repeals or amendments made by such section or section 1102, or abated by reason thereof.

PROVISIONAL REGISTRATION

SEC. 1104. [21 U.S.C. 957 note] (a)(1) Any person—

(A) who is engaged in importing or exporting any controlled substance on the day before the effective date of section 1007,

(B) who notifies the Attorney General that he is so engaged, and

(C) who is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act or under section 4722 of the Internal Revenue Code of 1954,

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 1008 for the import or export (as the case may be) of controlled substances.

(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of part A of this title.

(b) The provisions of section 304, relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

(1) the date on which such person has registered with the Attorney General under section 1008 or has had his registration denied under such section, or

(2) such date as may be prescribed by the Attorney General for registration of importers or exporters, as the case may be,

whichever occurs first.

EFFECTIVE DATES AND OTHER TRANSITIONAL PROVISIONS

SEC. 1105. [21 U.S.C. 951 note] (a) Except as otherwise provided in this section, this title shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment.

(b) Sections 1000, 1001, 1006, 1015, 1016, 1103, 1104, and this section shall become effective upon enactment.

(c)(1) If the Attorney General, pursuant to the authority of section 704(c) of title II, postpones the effective date of section 306 (relating to manufacturing quotas) for any period beyond the date specified in section 704(a) and such postponement applies to narcotic drugs, the repeal of the Narcotics Manufacturing Act of 1960 by paragraph (10) of section 1101(a) of this title is hereby postponed for the same period, except that the postponement made by this paragraph shall not apply to the repeal of sections 4, 5, 13, 15, and 16 of that Act.

(2) Effective for any period of postponement, by paragraph (1) of this subsection, of the repeal of provisions of the Narcotics Manufacturing Act of 1960, that Act shall be applied subject to the following modifications:

(A) The term "narcotic drug" shall mean a narcotic drug as defined in section 102(16) of title II, and all references, in the Narcotics Manufacturing Act of 1960, to a narcotic drug as defined by section 4731 of the Internal Revenue Code of 1954 are

amended to refer to a narcotic drug as defined by such section 102(16).

(B) On and after the date prescribed by the Attorney General pursuant to clause (2) of section 703(c) of title II, the requirements of a manufacturer's license with respect to a basic class of narcotic drug under the Narcotics Manufacturing Act of 1960, and of a registration under section 4722 of the Internal Revenue Code of 1954 as a prerequisite to issuance of such a license, shall be superseded by a requirement of actual registration (as distinguished from provisional registration) as a manufacturer of that class of drug under section 303(a) of title II.

(C) On and after the effective date of the repeal of such section 4722 by section 1101(b)(3) of this title, but prior to the date specified in subparagraph (B) of this paragraph, the requirement of registration under such section 4722 as a prerequisite of a manufacturer's license under the Narcotics Manufacturing Act of 1960 shall be superseded by a requirement of either (i) actual registration as a manufacturer under section 303 of title II or (ii) provisional registration (by virtue of a preexisting registration under such section 4722) under section 703 of title II.

(d) Any orders, rules, and regulations which have been promulgated under any law affected by this title and which are in effect on the day preceding enactment of this title shall continue in effect until modified, superseded, or repealed.

PUBLIC HEALTH SERVICE ACT[1,2], as amended [Partial]

TITLE I—SHORT TITLE AND DEFINITIONS

SHORT TITLE

SECTION 1. [42 U.S.C. 201 note] This Act may be cited as the "Public Health Service Act".

DEFINITIONS

SEC. 2. [42 U.S.C. 201] When used in this Act—

(a) The term "Service" means the Public Health Service;

(b) The term "Surgeon General" means the Surgeon General of the Public Health Service;

(c) Unless the context otherwise requires, the term "Secretary" means the Secretary of Health and Human Services;

(d) The term "regulations", except when otherwise specified, means rules and regulations made by the Surgeon General with the approval of the Secretary;

(e) The term "executive department" means any executive department, agency, or independent establishment of the United States or any corporation wholly owned by the United States;

(f) Except as provided in sections 314(g)(4)(B), 318(c)(1), 331(h)(3), 335(5), 361(d), 701(9), 1002(c), 1401(13), 1531(1), and 1633(1), the term "State" includes, in addition to the several States, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(g) The term "possession" includes, among other possessions, Puerto Rico and the Virgin Islands;

(h) [Repealed.]

(i) The term "vessel" includes every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, exclusive of aircraft and amphibious contrivances;

(j) The term "habit-forming narcotic drug" or "narcotic" means opium and coca leaves and the several alkaloids derived therefrom, the best known of these alkaloids being morphia, heroin, and codeine, obtained from opium, and cocaine derived from the coca

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[1] Public Law 78–410, July 1, 1944, 58 Stat. 682, 42 U.S.C. 201 et seq.

[2] Reorganization Plan No. 3 of 1966 transferred all statutory powers and functions of the Surgeon General and other officers of the Public Health Service and of all agencies of or in the Service to the Secretary of Health, Education, and Welfare. The Department of Education Organization Act designated the Secretary of Health, Education, and Welfare as the Secretary of Health and Human Services. References in the act to the Surgeon General, other officers of the Service, the Secretary of Health, Education, and Welfare, and the Department of Health, Education, and Welfare, should be read in the light of the transfer of statutory functions and the redesignation.

plant; all compounds, salts, preparations, or other derivatives obtained either from the raw material or from the various alkaloids; Indian hemp and its various derivatives, compounds, and preparations, and peyote in its various forms; isonipecaine and its derivatives, compounds, salts and preparations; opiates (as defined in section 3228(f) of the Internal Revenue Code);

(k) The term "addict" means any person who habitually uses any habit-forming narcotic drugs so as to endanger the public morals, health, safety, or welfare, or who is or has been so far addicted to the use of such habit-forming narcotic drugs as to have lost the power of self-control with reference to his addiction;

(l) The term "psychiatric disorders" includes diseases of the nervous system which affect mental health;

(m) The term "State mental health authority" means the State health authority, except that, in the case of any State in which there is a single State agency, other than the State health authority, charged with responsibility for administering the mental health program of the State, it means such other State agency;

(n) The term "heart diseases" means diseases of the heart and circulation;

(o) The term "dental diseases and conditions" means diseases and conditions affecting teeth and their supporting structures, and other related diseases of the mouth;

(p) The term "uniformed service" means the Army, Navy, Air Force, Marine Corps, Coast Guard, Public Health Service, or Coast and Geodetic Survey; and

(q) The term "drug dependent person" means a person who is using a controlled substance (as defined in section 102 of the Controlled Substances Act) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

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NARCOTICS

SEC. 302. [42 U.S.C. 242] (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific

requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts.

(b) The Surgeon General shall cooperate with States for the purpose of aiding them to solve their narcotic drug problems and shall give authorized representatives of the States the benefit of his experience in the care, treatment, and rehabilitation of narcotic addicts to the end that each State may be encouraged to provide adequate facilities and methods for the care and treatment of its narcotic addicts.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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Subpart 15—National Institute on Drug Abuse

PURPOSE OF INSTITUTE

SEC. 464L. [42 U.S.C. 285o] (a) IN GENERAL.—The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with respect to pregnant women).

(c) COLLABORATION.—The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(d) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, other than section 464P, there are authorized to be appropriated $440,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year,

the Director shall obligate not less than 15 percent to carry out health services research relating to drug abuse.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 464M. [42 U.S.C. 285o–1] (a) IN GENERAL.—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of drug abuse. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in drug abuse and the prevention of such abuse.

(b) REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

DRUG ABUSE RESEARCH CENTERS

SEC. 464N. [42 U.S.C. 285o–2] (a) AUTHORITY.—The Director of the Institute may designate National Drug Abuse Research Centers for the purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. No entity may be designated as a Center unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on drug abuse and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application;

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of drug abuse;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on drug abuse;

(E) the applicant has the capacity to conduct courses on drug abuse problems and research on drug abuse for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.[3]

[3] So in law. See section 123(b) of Public Law 102–321 (106 Stat. 361). The period probably should be "; and".

(2) the application contains a detailed five-year plan for research relating to drug abuse.

(b) GRANTS.—The Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 701(1).[4]

(c) DRUG ABUSE AND ADDITION RESEARCH.—

(1) GRANTS OR COOPERATIVE AGREEMENTS.—The Director of the Institute may make grants or enter into cooperative agreements to expand the current and ongoing interdisciplinary research and clinical trials with treatment centers of the National Drug Abuse Treatment Clinical Trials Network relating to drug abuse and addiction, including related biomedical, behavioral, and social issues.

(2) USE OF FUNDS.—Amounts made available under a grant or cooperative agreement under paragraph (1) for drug abuse and addiction may be used for research and clinical trials relating to—

(A) the effects of drug abuse on the human body, including the brain;

(B) the addictive nature of drugs and how such effects differ with respect to different individuals;

(C) the connection between drug abuse and mental health;

(D) the identification and evaluation of the most effective methods of prevention of drug abuse and addiction;

(E) the identification and development of the most effective methods of treatment of drug addiction, including pharmacological treatments;

(F) risk factors for drug abuse;

(G) effects of drug abuse and addiction on pregnant women and their fetuses; and

(H) cultural, social, behavioral, neurological, and psychological reasons that individuals abuse drugs, or refrain from abusing drugs.

(3) RESEARCH RESULTS.—The Director shall promptly disseminate research results under this subsection to Federal, State, and local entities involved in combating drug abuse and addiction.

(4) AUTHORIZATION OF APPROPRIATIONS.—

(A) IN GENERAL.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary for each fiscal year.

(B) SUPPLEMENT NOT SUPPLANT.—Amounts appropriated pursuant to the authorization of appropriations in subparagraph (A) for a fiscal year shall supplement and not

[4] So in law. See section 2(a) of Public Law 102–352 (106 Stat. 938). Section 701(1) does not provide a definition for the term "construction", but former section 701(1) did provide such a definition. Public Law 102–408 amended title VII generally; definitions for the title are now provided in section 799, and that section does not define the term "construction".

supplant any other amounts appropriated in such fiscal year for research on drug abuse and addiction.

OFFICE ON AIDS

SEC. 464O. [42 U.S.C. 285o–3] The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via drug abuse;

(2) drug abuse services research; and

(3) other matters determined appropriate by the Director.

MEDICATION DEVELOPMENT PROGRAM

SEC. 464P. [42 U.S.C. 285o–4] (a) ESTABLISHMENT.—There is established in the Institute a Medication Development Program through which the Director of such Institute shall—

(1) conduct periodic meetings with the Commissioner of Food and Drugs to discuss measures that may facilitate the approval process of drug abuse treatments;

(2) encourage and promote (through grants, contracts, international collaboration, or otherwise) expanded research programs, investigations, experiments, community trials, and studies, into the development and use of medications to treat drug addiction;

(3) establish or provide for the establishment of research facilities;

(4) report on the activities of other relevant agencies relating to the development and use of pharmacotherapeutic treatments for drug addiction;

(5) collect, analyze, and disseminate data useful in the development and use of pharmacotherapeutic treatments for drug addiction and collect, catalog, analyze, and disseminate through international channels, the results of such research;

(6) directly or through grants, contracts, or cooperative agreements, support training in the fundamental sciences and clinical disciplines related to the pharmacotherapeutic treatment of drug abuse, including the use of training stipends, fellowships, and awards where appropriate; and

(7) coordinate the activities conducted under this section with related activities conducted within the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and other appropriate institutes and shall consult with the Directors of such Institutes.

(b) DUTIES.—In carrying out the activities described in subsection (a), the Director of the Institute—

(1) shall collect and disseminate through publications and other appropriate means, information pertaining to the research and other activities under this section;

(2) shall make grants to or enter into contracts and cooperative agreements with individuals and public and private entities to further the goals of the program;

(3) may, in accordance with section 496, and in consultation with the National Advisory Council on Drug Abuse, acquire, construct, improve, repair, operate, and maintain pharmacotherapeutic research centers, laboratories, and other necessary facilities and equipment, and such other real or personal property as the Director determines necessary, and may, in consultation with such Advisory Council, make grants for the construction or renovation of facilities to carry out the purposes of this section;

(4) may accept voluntary and uncompensated services;

(5) may accept gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible; and

(6) shall take necessary action to ensure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(c) REPORT.—

(1) IN GENERAL.—Not later than December 31, 1992, and each December 31 thereafter, the Director of the Institute shall submit to the Office of National Drug Control Policy established under section 1002 of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1501) a report, in accordance with paragraph (3), that describes the objectives and activities of the program assisted under this section.

(2) NATIONAL DRUG CONTROL STRATEGY.—The Director of National Drug Control Policy shall incorporate, by reference or otherwise, each report submitted under this subsection in the National Drug Control Strategy submitted the following February 1 under section 1005 of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1504).

(d) DEFINITION.—For purposes of this section, the term ''pharmacotherapeutics'' means medications used to treat the symptoms and disease of drug abuse, including medications to—

(1) block the effects of abused drugs;

(2) reduce the craving for abused drugs;

(3) moderate or eliminate withdrawal symptoms;

(4) block or reverse the toxic effect of abused drugs; or

(5) prevent relapse in persons who have been detoxified from drugs of abuse.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $85,000,000 for fiscal year 1993, and $95,000,000 for fiscal year 1994.

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TITLE V—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

PART A—ORGANIZATION AND GENERAL AUTHORITIES

SEC. 501. [42 U.S.C. 290aa] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

(a) ESTABLISHMENT.—The Substance Abuse and Mental Health Services Administration (hereafter referred to in this title as the "Administration") is an agency of the Service.

(b) AGENCIES.—The following entities are agencies of the Administration:

(1) The Center for Substance Abuse Treatment.

(2) The Center for Substance Abuse Prevention.

(3) The Center for Mental Health Services.

(c) ADMINISTRATOR AND DEPUTY ADMINISTRATOR.—

(1) ADMINISTRATOR.—The Administration shall be headed by an Administrator (hereinafter in this title referred to as the "Administrator") who shall be appointed by the President, by and with the advice and consent of the Senate.

(2) DEPUTY ADMINISTRATOR.—The Administrator, with the approval of the Secretary, may appoint a Deputy Administrator and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.

(d) AUTHORITIES.—The Secretary, acting through the Administrator, shall—

(1) supervise the functions of the agencies of the Administration in order to assure that the programs carried out through each such agency receive appropriate and equitable support and that there is cooperation among the agencies in the implementation of such programs;

(2) establish and implement, through the respective agencies, a comprehensive program to improve the provision of treatment and related services to individuals with respect to substance abuse and mental illness and to improve prevention services, promote mental health and protect the legal rights of individuals with mental illnesses and individuals who are substance abusers;

(3) carry out the administrative and financial management, policy development and planning, evaluation, knowledge dissemination, and public information functions that are required for the implementation of this title;

(4) assure that the Administration conduct and coordinate demonstration projects, evaluations, and service system assessments and other activities necessary to improve the availability and quality of treatment, prevention and related services;

(5) support activities that will improve the provision of treatment, prevention and related services, including the development of national mental health and substance abuse goals and model programs;

(6) in cooperation with the National Institutes of Health, the Centers for Disease Control and the Health Resources and

Services Administration develop educational materials and intervention strategies to reduce the risks of HIV or tuberculosis among substance abusers and individuals with mental illness and to develop appropriate mental health services for individuals with such illnesses;

(7) coordinate Federal policy with respect to the provision of treatment services for substance abuse utilizing anti-addiction medications, including methadone;

(8) conduct programs, and assure the coordination of such programs with activities of the National Institutes of Health and the Agency for Health Care Policy Research [5], as appropriate, to evaluate the process, outcomes and community impact of treatment and prevention services and systems of care in order to identify the manner in which such services can most effectively be provided;

(9) collaborate with the Director of the National Institutes of Health in the development of a system by which the relevant research findings of the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and, as appropriate, the Agency for Health Care Policy Research [6] are disseminated to service providers in a manner designed to improve the delivery and effectiveness of treatment and prevention services;

(10) encourage public and private entities that provide health insurance to provide benefits for substance abuse and mental health services;

(11) promote the integration of substance abuse and mental health services into the mainstream of the health care delivery system of the United States;

(12) monitor compliance by hospitals and other facilities with the requirements of sections 542 and 543;

(13) with respect to grant programs authorized under this title, assure that—

(A) all grants that are awarded for the provision of services are subject to performance and outcome evaluations; and

(B) all grants that are awarded to entities other than States are awarded only after the State in which the entity intends to provide services—

(i) is notified of the pendency of the grant application; and

(ii) is afforded an opportunity to comment on the merits of the application;

(14) assure that services provided with amounts appropriated under this title are provided bilingually, if appropriate;

(15) improve coordination among prevention programs, treatment facilities and nonhealth care systems such as employers, labor unions, and schools, and encourage the adoption of employee assistance programs and student assistance programs;

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[5] So in law. See section 101(a) of Public Law 102–321 (106 Stat. 324). Probably should have been "Agency for Health Care Policy and Research". The Agency, however, was redesignated as the Agency for Health Care Policy and Research by Public Law 106–129 (see 113 Stat. 1653).

[6] See footnote for paragraph (8).

(16) maintain a clearinghouse for substance abuse and mental health information to assure the widespread dissemination of such information to States, political subdivisions, educational agencies and institutions, treatment providers, and the general public;

(17) in collaboration with the National Institute on Aging, and in consultation with the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism and the National Institute of Mental Health, as appropriate, promote and evaluate substance abuse services for older Americans in need of such services, and mental health services for older Americans who are seriously mentally ill; and

(18) promote the coordination of service programs conducted by other departments, agencies, organizations and individuals that are or may be related to the problems of individuals suffering from mental illness or substance abuse, including liaisons with the Social Security Administration, Centers for Medicare & Medicaid Services, and other programs of the Department, as well as liaisons with the Department of Education, Department of Justice, and other Federal Departments and offices, as appropriate.

(e) ASSOCIATE ADMINISTRATOR FOR ALCOHOL PREVENTION AND TREATMENT POLICY.—

(1) IN GENERAL.—There may be in the Administration an Associate Administrator for Alcohol Prevention and Treatment Policy to whom the Administrator may delegate the functions of promoting, monitoring, and evaluating service programs for the prevention and treatment of alcoholism and alcohol abuse within the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment and the Center for Mental Health Services, and coordinating such programs among the Centers, and among the Centers and other public and private entities. The Associate Administrator also may ensure that alcohol prevention, education, and policy strategies are integrated into all programs of the Centers that address substance abuse prevention, education, and policy, and that the Center for Substance Abuse Prevention addresses the Healthy People 2010 goals and the National Dietary Guidelines of the Department of Health and Human Services and the Department of Agriculture related to alcohol consumption.

(2) PLAN.—

(A) The Administrator, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall develop, and periodically review and as appropriate revise, a plan for programs and policies to treat and prevent alcoholism and alcohol abuse. The plan shall be developed (and reviewed and revised) in collaboration with the Directors of the Centers of the Administration and in consultation with members of other Federal agencies and public and private entities.

(B) Not later than 1 year after the date of the enactment of the ADAMHA Reorganization Act, the Administrator shall submit to the Congress the first plan developed under subparagraph (A).

(3) REPORT.—

(A) Not less than once during each 2 years, the Administrator, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall prepare a report describing the alcoholism and alcohol abuse prevention and treatment programs undertaken by the Administration and its agencies, and the report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

(B) Each report under subparagraph (A) shall include a description of any revisions in the plan under paragraph (2) made during the preceding 2 years.

(C) Each report under subparagraph (A) shall be submitted to the Administrator for inclusion in the biennial report under subsection (k).

(f) ASSOCIATE ADMINISTRATOR FOR WOMEN'S SERVICES.—

(1) APPOINTMENT.—The Administrator, with the approval of the Secretary, shall appoint an Associate Administrator for Women's Services.

(2) DUTIES.—The Associate Administrator appointed under paragraph (1) shall—

(A) establish a committee to be known as the Coordinating Committee for Women's Services (hereafter in this subparagraph referred to as the ''Coordinating Committee''), which shall be composed of the Directors of the agencies of the Administration (or the designees of the Directors);

(B) acting through the Coordinating Committee, with respect to women's substance abuse and mental health services—

(i) identify the need for such services, and make an estimate each fiscal year of the funds needed to adequately support the services;

(ii) identify needs regarding the coordination of services;

(iii) encourage the agencies of the Administration to support such services; and

(iv) assure that the unique needs of minority women, including Native American, Hispanic, African-American and Asian women, are recognized and addressed within the activities of the Administration; and

(C) establish an advisory committee to be known as the Advisory Committee for Women's Services, which shall be composed of not more than 10 individuals, a majority of whom shall be women, who are not officers or employees of the Federal Government, to be appointed by the Administrator from among physicians, practitioners, treatment providers, and other health professionals, whose clinical practice, specialization, or professional expertise includes a significant focus on women's substance abuse and mental health conditions, that shall—

(i) advise the Associate Administrator on appropriate activities to be undertaken by the agencies of the Administration with respect to women's substance abuse and mental health services, including services which require a multidisciplinary approach;

(ii) collect and review data, including information provided by the Secretary (including the material referred to in paragraph (3)), and report biannually to the Administrator regarding the extent to which women are represented among senior personnel, and make recommendations regarding improvement in the participation of women in the workforce of the Administration; and

(iii) prepare, for inclusion in the biennial report required pursuant to subsection (k), a description of activities of the Committee, including findings made by the Committee regarding—

(I) the extent of expenditures made for women's substance abuse and mental health services by the agencies of the Administration; and

(II) the estimated level of funding needed for substance abuse and mental health services to meet the needs of women;

(D) improve the collection of data on women's health by—

(i) reviewing the current data at the Administration to determine its uniformity and applicability;

(ii) developing standards for all programs funded by the Administration so that data are, to the extent practicable, collected and reported using common reporting formats, linkages and definitions; and

(iii) reporting to the Administrator a plan for incorporating the standards developed under clause (ii) in all Administration programs and a plan to assure that the data so collected are accessible to health professionals, providers, researchers, and members of the public; and

(E) shall establish, maintain, and operate a program to provide information on women's substance abuse and mental health services.

(3) STUDY.—

(A) The Secretary, acting through the Assistant Secretary for Personnel, shall conduct a study to evaluate the extent to which women are represented among senior personnel at the Administration.

(B) Not later than 90 days after the date of the enactment of the ADAMHA Reorganization Act, the Assistant Secretary for Personnel shall provide the Advisory Committee for Women's Services with a study plan, including the methodology of the study and any sampling frames. Not later than 180 days after such date of enactment, the Assistant Secretary shall prepare and submit directly to the Advisory Committee a report concerning the results of the study conducted under subparagraph (A).

(C) The Secretary shall prepare and provide to the Advisory Committee for Women's Services any additional data as requested.

(4) DEFINITION.—For purposes of this subsection, the term ''women's substance abuse and mental health conditions'', with respect to women of all age, ethnic, and racial groups, means all aspects of substance abuse and mental illness—

(A) unique to or more prevalent among women; or

(B) with respect to which there have been insufficient services involving women or insufficient data.

(g) SERVICES OF EXPERTS.—

(1) IN GENERAL.—The Administrator may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of service) the services of not more than 20 experts or consultants who have professional qualifications. Such experts and consultants shall be obtained for the Administration and for each of its agencies.

(2) COMPENSATION AND EXPENSES.—

(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(c) of title 5, United States Code.

(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1), unless and until the expert or consultant agrees in writing to complete the entire period of assignment or one year, whichever is shorter, unless separated or reassigned for reasons beyond the control of the expert or consultant that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(h) PEER REVIEW GROUPS.—The Administrator shall, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates, establish such peer review groups and program advisory committees as are needed to carry out the requirements of this title and appoint and pay members of such groups, except that officers and employees of the United States shall not receive additional compensation for services as members of such groups. The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under this subsection.

(i) VOLUNTARY SERVICES.—The Administrator may accept voluntary and uncompensated services.

(j) ADMINISTRATION.—The Administrator shall ensure that programs and activities assigned under this title to the Administration

are fully administered by the respective Centers to which such programs and activities are assigned.

(k) REPORT CONCERNING ACTIVITIES AND PROGRESS.—Not later than February 10, 1994, and once every 2 years thereafter, the Administrator shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, the report containing—

(1) a description of the activities carried out by the Administration;

(2) a description of any measurable progress made in improving the availability and quality of substance abuse and mental health services;

(3) a description of the mechanisms by which relevant research findings of the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute of Mental Health have been disseminated to service providers or otherwise utilized by the Administration to further the purposes of this title; and

(4) any report required in this title to be submitted to the Adminstrator[7] for inclusion in the report under this subsection.

(l) APPLICATIONS FOR GRANTS AND CONTRACTS.—With respect to awards of grants, cooperative agreements, and contracts under this title, the Administrator, or the Director of the Center involved, as the case may be, may not make such an award unless—

(1) an application for the award is submitted to the official involved;

(2) with respect to carrying out the purpose for which the award is to be provided, the application provides assurances of compliance satisfactory to such official; and

(3) the application is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the official determines to be necessary to carry out the purpose for which the award is to be provided.

(m) EMERGENCY RESPONSE.—

(1) IN GENERAL.—Notwithstanding section 504 and except as provided in paragraph (2), the Secretary may use not to exceed 2.5 percent of all amounts appropriated under this title for a fiscal year to make noncompetitive grants, contracts or cooperative agreements to public entities to enable such entities to address emergency substance abuse or mental health needs in local communities.

(2) EXCEPTIONS.—Amounts appropriated under part C shall not be subject to paragraph (1).

(3) EMERGENCIES.—The Secretary shall establish criteria for determining that a substance abuse or mental health emergency exists and publish such criteria in the Federal Register prior to providing funds under this subsection.

(n) LIMITATION ON THE USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or

[7] So in law. See section 101(a) of Public Law 102–321 (106 Stat. 324). Probably should be "Administrator".

described in it is identifiable, obtained in the course of activities undertaken or supported under section 505 may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(o) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing grants, cooperative agreements, and contracts under this section, there are authorized to be appropriated $25,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

ADVISORY COUNCILS

SEC. 502. [42 U.S.C. 290aa–1] (a) APPOINTMENT.—

(1) IN GENERAL.—The Secretary shall appoint an advisory council for—

(A) the Substance Abuse and Mental Health Services Administration;

(B) the Center for Substance Abuse Treatment;

(C) the Center for Substance Abuse Prevention; and

(D) the Center for Mental Health Services.

Each such advisory council shall advise, consult with, and make recommendations to the Secretary and the Administrator or Director of the Administration or Center for which the advisory council is established concerning matters relating to the activities carried out by and through the Administration or Center and the policies respecting such activities.

(2) FUNCTION AND ACTIVITIES.—An advisory council—

(A)(i) may on the basis of the materials provided by the organization respecting activities conducted at the organization, make recommendations to the Administrator or Director of the Administration or Center for which it was established respecting such activities;

(ii) shall review applications submitted for grants and cooperative agreements for activities for which advisory council approval is required under section 504(d)(2) and recommend for approval applications for projects that show promise of making valuable contributions to the Administration's mission; and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the organization;

(B) may collect, by correspondence or by personal investigation, information as to studies and services that are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the organization was established and with the approval of the Administrator or Director, whichever is appropriate, make such information available through appropriate publications for the benefit

of public and private health entities and health professions personnel and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b) MEMBERSHIP.—

(1) IN GENERAL.—Each advisory council shall consist of nonvoting ex officio members and not more than 12 members to be appointed by the Secretary under paragraph (3).

(2) EX OFFICIO MEMBERS.—The ex officio members of an advisory council shall consist of—

(A) the Secretary;

(B) the Administrator;

(C) the Director of the Center for which the council is established;

(D) the Under Secretary for Health of the Department of Veterans Affairs;

(E) the Assistant Secretary for Defense for Health Affairs (or the designates of such officers); and

(F) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) APPOINTED MEMBERS.—Individuals shall be appointed to an advisory council under paragraph (1) as follows:

(A) Nine of the members shall be appointed by the Secretary from among the leading representatives of the health disciplines (including public health and behavioral and social sciences) relevant to the activities of the Administration or Center for which the advisory council is established.

(B) Three of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, public relations, law, health policy economics, or management.

(4) COMPENSATION.—Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The remaining members of an advisory council shall receive, for each day (including travel time) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent to the annual rate in effect for grade GS–18 of the General Schedule.

(c) TERMS OF OFFICE.—

(1) IN GENERAL.—The term of office of a member of an advisory council appointed under subsection (b) shall be 4 years, except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. The Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members not all expire in the same year. A member of an advisory council may serve after the expiration of such member's term until a successor has been appointed and taken office.

(2) REAPPOINTMENTS.—A member who has been appointed to an advisory council for a term of 4 years may not be reappointed to an advisory council during the 2-year period beginning on the date on which such 4-year term expired.

(3) TIME FOR APPOINTMENT.—If a vacancy occurs in an advisory council among the members under subsection (b), the Secretary shall make an appointment to fill such vacancy within 90 days from the date the vacancy occurs.

(d) CHAIR.—The Secretary shall select a member of an advisory council to serve as the chair of the council. The Secretary may so select an individual from among the appointed members, or may select the Administrator or the Director of the Center involved. The term of office of the chair shall be 2 years.

(e) MEETINGS.—An advisory council shall meet at the call of the chairperson or upon the request of the Administrator or Director of the Administration or Center for which the advisory council is established, but in no event less than 2 times during each fiscal year. The location of the meetings of each advisory council shall be subject to the approval of the Administrator or Director of Administration or Center for which the council was established.

(f) EXECUTIVE SECRETARY AND STAFF.—The Administrator or Director of the Administration or Center for which the advisory council is established shall designate a member of the staff of the Administration or Center for which the advisory council is established to serve as the Executive Secretary of the advisory council. The Administrator or Director shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Administrator or Director shall provide orientation and training for new members of the advisory council to provide for their effective participation in the functions of the advisory council.

REPORTS ON ALCOHOLISM, ALCOHOL ABUSE, AND DRUG ABUSE

SEC. 503. [42 U.S.C. 290aa–2] (a) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) containing current information on the health consequences of using alcoholic beverages,

(2) containing a description of current research findings made with respect to alcohol abuse and alcoholism, and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

(b) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) describing the health consequences and extent of drug abuse in the United States;

(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

SEC. 503A. [42 U.S.C. 290aa–2a] REPORT ON INDIVIDUALS WITH CO-OCCURRING MENTAL ILLNESS AND SUBSTANCE ABUSE DISORDERS.

(a) IN GENERAL.—Not later than 2 years after the date of the enactment of this section, the Secretary shall, after consultation with organizations representing States, mental health and substance abuse treatment providers, prevention specialists, individuals receiving treatment services, and family members of such individuals, prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce of the House of Representatives, a report on prevention and treatment services for individuals who have co-occurring mental illness and substance abuse disorders.

(b) REPORT CONTENT.—The report under subsection (a) shall be based on data collected from existing Federal and State surveys regarding the treatment of co-occurring mental illness and substance abuse disorders and shall include—

(1) a summary of the manner in which individuals with co-occurring disorders are receiving treatment, including the most up-to-date information available regarding the number of children and adults with co-occurring mental illness and substance abuse disorders and the manner in which funds provided under sections 1911 and 1921 are being utilized, including the number of such children and adults served with such funds;

(2) a summary of improvements necessary to ensure that individuals with co-occurring mental illness and substance abuse disorders receive the services they need;

(3) a summary of practices for preventing substance abuse among individuals who have a mental illness and are at risk of having or acquiring a substance abuse disorder; and

(4) a summary of evidenced-based practices for treating individuals with co-occurring mental illness and substance abuse disorders and recommendations for implementing such practices.

(c) FUNDS FOR REPORT.—The Secretary may obligate funds to carry out this section with such appropriations as are available.

SEC. 504.[8] [42 U.S.C. 290aa–3] PEER REVIEW.

(a) IN GENERAL.—The Secretary, after consultation with the Administrator, shall require appropriate peer review of grants, cooperative agreements, and contracts to be administered through the agency which exceed the simple acquisition threshold as defined in section 4(11) of the Office of Federal Procurement Policy Act.

(b) MEMBERS.—The members of any peer review group established under subsection (a) shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group. Not more than one-fourth of the members of any such peer review group shall be officers or employees of the United States.

(c) ADVISORY COUNCIL REVIEW.—If the direct cost of a grant or cooperative agreement (described in subsection (a)) exceeds the

[8] Section 504 appears according to the probable intent of the Congress. Section 3401(b) of Public Law 106–310 (114 Stat. 1218) provides that the section "is amended as follows:". No amendatory instructions were then given, but a substitute text was provided. The amendment probably should have instructed that section 504 "is amended to read as follows:".

simple acquisition threshold as defined by section 4(11) of the Office of Federal Procurement Policy Act, the Secretary may make such a grant or cooperative agreement only if such grant or cooperative agreement is recommended—

(1) after peer review required under subsection (a); and

(2) by the appropriate advisory council.

(d) CONDITIONS.—The Secretary may establish limited exceptions to the limitations contained in this section regarding participation of Federal employees and advisory council approval. The circumstances under which the Secretary may make such an exception shall be made public.

DATA COLLECTION [9]

SEC. 505. [42 U.S.C. 290aa–4] (a) The Secretary, acting through the Administrator, shall collect data each year on—

(1) the national incidence and prevalence of the various forms of mental illness and substance abuse; and

(2) the incidence and prevalence of such various forms in major metropolitan areas selected by the Administrator.

(b) With respect to the activities of the Administrator under subsection (a) relating to mental health, the Administrator shall ensure that such activities include, at a minimum, the collection of data on—

(1) the number and variety of public and nonprofit private treatment programs;

(2) the number and demographic characteristics of individuals receiving treatment through such programs;

(3) the type of care received by such individuals; and

(4) such other data as may be appropriate.

(c)(1) With respect to the activities of the Administrator under subsection (a) relating to substance abuse, the Administrator shall ensure that such activities include, at a minimum, the collection of data on—

(A) the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs;

(B) the number of deaths occurring as a result of substance abuse, as indicated in reports by coroners;

(C) the number and variety of public and private nonprofit treatment programs, including the number and type of patient slots available;

(D) the number of individuals seeking treatment through such programs, the number and demographic characteristics of individuals receiving such treatment, the percentage of individuals who complete such programs, and, with respect to individuals receiving such treatment, the length of time between an individual's request for treatment and the commencement of treatment;

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[9] Section 502 of Public Law 104–237 (110 Stat. 3112) provides as follows:

"The Secretary of Health and Human Services shall develop a public health monitoring program to monitor methamphetamine abuse in the United States. The program shall include the collection and dissemination of data related to methamphetamine abuse which can be used by public health officials in policy development.".

(E) the number of such individuals who return for treatment after the completion of a prior treatment in such programs and the method of treatment utilized during the prior treatment;

(F) the number of individuals receiving public assistance for such treatment programs;

(G) the costs of the different types of treatment modalities for drug and alcohol abuse and the aggregate relative costs of each such treatment modality provided within a State in each fiscal year;

(H) to the extent of available information, the number of individuals receiving treatment for alcohol or drug abuse who have private insurance coverage for the costs of such treatment;

(I) the extent of alcohol and drug abuse among high school students and among the general population; and

(J) the number of alcohol and drug abuse counselors and other substance abuse treatment personnel employed in public and private treatment facilities.

(2) Annual surveys shall be carried out in the collection of data under this subsection. Summaries and analyses of the data collected shall be made available to the public.

(d) After consultation with the States and with appropriate national organizations, the Administrator shall develop uniform criteria for the collection of data, using the best available technology, pursuant to this section.

SEC. 506. [42 U.S.C. 290aa–5] GRANTS FOR THE BENEFIT OF HOMELESS INDIVIDUALS.

(a) IN GENERAL.—The Secretary shall award grants, contracts and cooperative agreements to community-based public and private nonprofit entities for the purposes of providing mental health and substance abuse services for homeless individuals. In carrying out this section, the Secretary shall consult with the Interagency Council on the Homeless, established under section 201 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11311).

(b) PREFERENCES.—In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall give a preference to—

(1) entities that provide integrated primary health, substance abuse, and mental health services to homeless individuals;

(2) entities that demonstrate effectiveness in serving runaway, homeless, and street youth;

(3) entities that have experience in providing substance abuse and mental health services to homeless individuals;

(4) entities that demonstrate experience in providing housing for individuals in treatment for or in recovery from mental illness or substance abuse; and

(5) entities that demonstrate effectiveness in serving homeless veterans.

(c) SERVICES FOR CERTAIN INDIVIDUALS.—In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall not—

(1) prohibit the provision of services under such subsection to homeless individuals who are suffering from a substance

abuse disorder and are not suffering from a mental health disorder; and

(2) make payments under subsection (a) to any entity that has a policy of—

(A) excluding individuals from mental health services due to the existence or suspicion of substance abuse; or

(B) has a policy of excluding individuals from substance abuse services due to the existence or suspicion of mental illness.

(d) TERM OF THE AWARDS.—No entity may receive a grant, contract, or cooperative agreement under subsection (a) for more than 5 years.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

SEC. 506A. [42 U.S.C. 290aa–5a] ALCOHOL AND DRUG PREVENTION OR TREATMENT SERVICES FOR INDIANS AND NATIVE ALASKANS.[10]

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Native Alaskan entities and Indian tribes and tribal organizations, for the purpose of providing alcohol and drug prevention or treatment services for Indians and Native Alaskans.

(b) PRIORITY.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants that—

(1) propose to provide alcohol and drug prevention or treatment services on reservations;

(2) propose to employ culturally-appropriate approaches, as determined by the Secretary, in providing such services; and

(3) have provided prevention or treatment services to Native Alaskan entities and Indian tribes and tribal organizations for at least 1 year prior to applying for a grant under this section.

(c) DURATION.—The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for a period not to exceed 5 years.

(d) APPLICATION.—An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(e) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate. The final evaluation submitted by such entity shall include a recommendation as to whether such project shall continue.

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[10] Section 3307 of Public Law 106–310 (114 Stat. 1216) establishes a Commission on Indian and Native Alaskan Health Care and provides that the Commission "shall examine the health concerns of Indians and Native Alaskans who reside on reservations and tribal lands".

(f) REPORT.—Not later than 3 years after the date of the enactment of this section and annually thereafter, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the services provided pursuant to this section.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $15,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.

SEC. 506B. [42 U.S.C. 290aa–5b] GRANTS FOR ECSTASY AND OTHER CLUB DRUGS ABUSE PREVENTION.

(a) AUTHORITY.—The Administrator may make grants to, and enter into contracts and cooperative agreements with, public and nonprofit private entities to enable such entities—

(1) to carry out school-based programs concerning the dangers of the abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other drugs commonly referred to as "club drugs" using methods that are effective and science-based, including initiatives that give students the responsibility to create their own anti-drug abuse education programs for their schools; and

(2) to carry out community-based abuse and addiction prevention programs relating to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs that are effective and science-based.

(b) USE OF FUNDS.—Amounts made available under a grant, contract or cooperative agreement under subsection (a) shall be used for planning, establishing, or administering prevention programs relating to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs.

(c) USE OF FUNDS.—

(1) DISCRETIONARY FUNCTIONS.—Amounts provided to an entity under this section may be used—

(A) to carry out school-based programs that are focused on those districts with high or increasing rates of abuse and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs and targeted at populations that are most at risk to start abusing these drugs;

(B) to carry out community-based prevention programs that are focused on those populations within the community that are most at-risk for abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs;

(C) to assist local government entities to conduct appropriate prevention activities relating to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs;

(D) to train and educate State and local law enforcement officials, prevention and education officials, health professionals, members of community anti-drug coalitions and parents on the signs of abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs and the options for treatment and prevention;

(E) for planning, administration, and educational activities related to the prevention of abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs;

(F) for the monitoring and evaluation of prevention activities relating to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs and reporting and disseminating resulting information to the public; and

(G) for targeted pilot programs with evaluation components to encourage innovation and experimentation with new methodologies.

(2) PRIORITY.—The Administrator shall give priority in awarding grants under this section to rural and urban areas that are experiencing a high rate or rapid increases in abuse and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs.

(d) ALLOCATION AND REPORT.—

(1) PREVENTION PROGRAM ALLOCATION.—Not less than $500,000 of the amount appropriated in each fiscal year to carry out this section shall be made available to the Administrator, acting in consultation with other Federal agencies, to support and conduct periodic analyses and evaluations of effective prevention programs for abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs and the development of appropriate strategies for disseminating information about and implementing such programs.

(2) REPORT.—The Administrator shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions, the Committee on the Judiciary, and the Committee on Appropriations of the Senate, and the Committee on Commerce, the Committee on the Judiciary, and the Committee on Appropriations of the House of Representatives, a report containing the results of the analyses and evaluations conducted under paragraph (1).

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

(1) $10,000,000 for fiscal year 2001; and

(2) such sums as may be necessary for each succeeding fiscal year.

PART B—CENTERS AND PROGRAMS

Subpart 1—Center for Substance Abuse Treatment

CENTER FOR SUBSTANCE ABUSE TREATMENT

SEC. 507. [42 U.S.C. 290bb] (a) ESTABLISHMENT.—There is established in the Administration a Center for Substance Abuse Treatment (hereafter in this section referred to as the "Center"). The Center shall be headed by a Director (hereafter in this section referred to as the "Director") appointed by the Secretary from among individuals with extensive experience or academic qualifications in the treatment of substance abuse or in the evaluation of substance abuse treatment systems.

(b) DUTIES.—The Director of the Center shall—

(1) administer the substance abuse treatment block grant program authorized in section 1921;

(2) ensure that emphasis is placed on children and adolescents in the development of treatment programs;

(3) collaborate with the Attorney General to develop programs to provide substance abuse treatment services to individuals who have had contact with the Justice system, especially adolescents;

(4) collaborate with the Director of the Center for Substance Abuse Prevention in order to provide outreach services to identify individuals in need of treatment services, with emphasis on the provision of such services to pregnant and postpartum women and their infants and to individuals who abuse drugs intravenously;

(5) collaborate with the Director of the National Institute on Drug Abuse, with the Director of the National Institute on Alcohol Abuse and Alcoholism, and with the States to promote the study, dissemination, and implementation of research findings that will improve the delivery and effectiveness of treatment services;

(6) collaborate with the Administrator of the Health Resources and Services Administration and the Administrator of the Centers for Medicare & Medicaid Services to promote the increased integration into the mainstream of the health care system of the United States of programs for providing treatment services;

(7) evaluate plans submitted by the States pursuant to section 1932(a)(6) in order to determine whether the plans adequately provide for the availability, allocation, and effectiveness of treatment services;

(8) sponsor regional workshops on improving the quality and availability of treatment services;

(9) provide technical assistance to public and nonprofit private entities that provide treatment services, including technical assistance with respect to the process of submitting to the Director applications for any program of grants or contracts carried out by the Director;

(10) encourage the States to expand the availability (relative to fiscal year 1992) of programs providing treatment services through self-run, self-supported recovery based on the programs of housing operated pursuant to section 1925;

(11) carry out activities to educate individuals on the need for establishing treatment facilities within their communities;

(12) encourage public and private entities that provide health insurance to provide benefits for outpatient treatment services and other nonhospital-based treatment services;

(13) evaluate treatment programs to determine the quality and appropriateness of various forms of treatment, which shall be carried out through grants, contracts, or cooperative agreements provided to public or nonprofit private entities; and

(14) in carrying out paragraph (13), assess the quality, appropriateness, and costs of various treatment forms for specific patient groups.

(c) GRANTS AND CONTRACTS.—In carrying out the duties established in subsection (b), the Director may make grants to and enter into contracts and cooperative agreements with public and nonprofit private entities.

RESIDENTIAL TREATMENT PROGRAMS FOR PREGNANT AND POSTPARTUM WOMEN

SEC. 508. [42 U.S.C. 290bb–1] (a) IN GENERAL.—The Director of the Center for Substance Abuse Treatment shall provide awards of grants, cooperative agreement, or contracts to public and nonprofit private entities for the purpose of providing to pregnant and postpartum women treatment for substance abuse through programs in which, during the course of receiving treatment—

(1) the women reside in facilities provided by the programs;

(2) the minor children of the women reside with the women in such facilities, if the women so request; and

(3) the services described in subsection (d) are available to or on behalf of the women.

(b) AVAILABILITY OF SERVICES FOR EACH PARTICIPANT.—A funding agreement for an award under subsection (a) for an applicant is that, in the program operated pursuant to such subsection—

(1) treatment services and each supplemental service will be available through the applicant, either directly or through agreements with other public or nonprofit private entities; and

(2) the services will be made available to each woman admitted to the program.

(c) INDIVIDUALIZED PLAN OF SERVICES.—A funding agreement for an award under subsection (a) for an applicant is that—

(1) in providing authorized services for an eligible woman pursuant to such subsection, the applicant will, in consultation with the women, prepare an individualized plan for the provision to the woman of the services; and

(2) treatment services under the plan will include—

(A) individual, group, and family counseling, as appropriate, regarding substance abuse; and

(B) follow-up services to assist the woman in preventing a relapse into such abuse.

(d) REQUIRED SUPPLEMENTAL SERVICES.—In the case of an eligible woman, the services referred to in subsection (a)(3) are as follows:

(1) Prenatal and postpartum health care.

(2) Referrals for necessary hospital services.

(3) For the infants and children of the woman—

(A) pediatric health care, including treatment for any perinatal effects of maternal substance abuse and including screenings regarding the physical and mental development of the infants and children;

(B) counseling and other mental health services, in the case of children; and

(C) comprehensive social services.

(4) Providing supervision of children during periods in which the woman is engaged in therapy or in other necessary health or rehabilitative activities.

(5) Training in parenting.

(6) Counseling on the human immunodeficiency virus and on acquired immune deficiency syndrome.

(7) Counseling on domestic violence and sexual abuse.

(8) Counseling on obtaining employment, including the importance of graduating from a secondary school.

(9) Reasonable efforts to preserve and support the family units of the women, including promoting the appropriate involvement of parents and others, and counseling the children of the women.

(10) Planning for and counseling to assist reentry into society, both before and after discharge, including referrals to any public or nonprofit private entities in the community involved that provide services appropriate for the women and the children of the women.

(11) Case management services, including—

(A) assessing the extent to which authorized services are appropriate for the women and their children;

(B) in the case of the services that are appropriate, ensuring that the services are provided in a coordinated manner; and

(C) assistance in establishing eligibility for assistance under Federal, State, and local programs providing health services, mental health services, housing services, employment services, educational services, or social services.

(e) MINIMUM QUALIFICATIONS FOR RECEIPT OF AWARD.—

(1) CERTIFICATION BY RELEVANT STATE AGENCY.—With respect to the principal agency of the State involved that administers programs relating to substance abuse, the Director may make an award under subsection (a) to an applicant only if the agency has certified to the Director that—

(A) the applicant has the capacity to carry out a program described in subsection (a);

(B) the plans of the applicant for such a program are consistent with the policies of such agency regarding the treatment of substance abuse; and

(C) the applicant, or any entity through which the applicant will provide authorized services, meets all applicable State licensure or certification requirements regarding the provision of the services involved.

(2) STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraphs (B) and (C), the Director may make an award under subsection (a) only if, in the case of any authorized service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the applicant for the award will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the applicant will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement plan and is qualified to receive such payments.

(B)(i) In the case of an entity making an agreement pursuant to subparagraph (A)(ii) regarding the provision of services, the requirement established in such subparagraph regarding a participation agreement shall be waived by the Director if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits plan.

(ii) A determination by the Director of whether an entity referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

(C) With respect to any authorized service that is available pursuant to the State plan described in subparagraph (A), the requirements established in such subparagraph shall not apply to the provision of any such service by an institution for mental diseases to an individual who has attained 21 years of age and who has not attained 65 years of age. For purposes of the preceding sentence, the term ''institution for mental diseases'' has the meaning given such term in section 1905(i) of the Social Security Act.

(f) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—With respect to the costs of the program to be carried out by an applicant pursuant to subsection (a), a funding agreement for an award under such subsection is that the applicant will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that—

(A) for the first fiscal year for which the applicant receives payments under an award under such subsection, is not less than $1 for each $9 of Federal funds provided in the award;

(B) for any second such fiscal year, is not less than $1 for each $9 of Federal funds provided in the award; and

(C) for any subsequent such fiscal year, is not less than $1 for each $3 of Federal funds provided in the award.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(g) OUTREACH.—A funding agreement for an award under subsection (a) for an applicant is that the applicant will provide outreach services in the community involved to identify women who are engaging in substance abuse and to encourage the women to undergo treatment for such abuse.

(h) ACCESSIBILITY OF PROGRAM; CULTURAL CONTEXT OF SERVICES.—A funding agreement for an award under subsection (a) for an applicant is that—

(1) the program operated pursuant to such subsection will be operated at a location that is accessible to low-income pregnant and postpartum women; and

(2) authorized services will be provided in the language and the cultural context that is most appropriate.

(i) CONTINUING EDUCATION.—A funding agreement for an award under subsection (a) is that the applicant involved will provide for continuing education in treatment services for the individuals who will provide treatment in the program to be operated by the applicant pursuant to such subsection.

(j) IMPOSITION OF CHARGES.—A funding agreement for an award under subsection (a) for an applicant is that, if a charge is imposed for the provision of authorized services to on [11] behalf of an eligible woman, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any such woman with an income of less than 185 percent of the official poverty line, as established by the Director of the Office for Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(k) REPORTS TO DIRECTOR.—A funding agreement for an award under subsection (a) is that the applicant involved will submit to the Director a report—

(1) describing the utilization and costs of services provided under the award;

(2) specifying the number of women served, the number of infants served, and the type and costs of services provided; and

(3) providing such other information as the Director determines to be appropriate.

(l) REQUIREMENT OF APPLICATION.—The Director may make an award under subsection (a) only if an application for the award is submitted to the Director containing such agreements, and the application is in such form, is made in such manner, and contains such other agreements and such assurances and information as the Director determines to be necessary to carry out this section.

(m) EQUITABLE ALLOCATION OF AWARDS.—In making awards under subsection (a), the Director shall ensure that the awards are equitably allocated among the principal geographic regions of the United States, subject to the availability of qualified applicants for the awards.

(n) DURATION OF AWARD.—The period during which payments are made to an entity from an award under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Director of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This subsection may not be construed to establish a limitation on the number of awards under such subsection that may be made to an entity.

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[11] So in law. See section 108(a) of Public Law 102–321 (106 Stat. 336). Probably should be "to or on".

(o) EVALUATIONS; DISSEMINATION OF FINDINGS.—The Director shall, directly or through contract, provide for the conduct of evaluations of programs carried out pursuant to subsection (a). The Director shall disseminate to the States the findings made as a result of the evaluations.

(p) REPORTS TO CONGRESS.—Not later than October 1, 1994, the Director shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing programs carried out pursuant to this section. Every 2 years thereafter, the Director shall prepare a report describing such programs carried out during the preceding 2 years, and shall submit the report to the Administrator for inclusion in the biennial report under section 501(k). Each report under this subsection shall include a summary of any evaluations conducted under subsection (m) during the period with respect to which the report is prepared.

(q) DEFINITIONS.—For purposes of this section:

(1) The term ''authorized services'' means treatment services and supplemental services.

(2) The term ''eligible woman'' means a woman who has been admitted to a program operated pursuant to subsection (a).

(3) The term ''funding agreement under subsection (a)'', with respect to an award under subsection (a), means that the Director may make the award only if the applicant makes the agreement involved.

(4) The term ''treatment services'' means treatment for substance abuse, including the counseling and services described in subsection (c)(2).

(5) The term ''supplemental services'' means the services described in subsection (d).

(r) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary to[12] fiscal years 2001 through 2003.

SEC. 509. [42 U.S.C. 290bb–2] PRIORITY SUBSTANCE ABUSE TREATMENT NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority substance abuse treatment needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for treatment and rehabilitation and the conduct or support of evaluations of such projects;

(2) training and technical assistance; and

(3) targeted capacity response programs.

The Secretary may carry out the activities described in this section directly or through grants or cooperative agreements with States, political subdivisions of States, Indian tribes and tribal organizations, other public or nonprofit private entities.

(b) PRIORITY SUBSTANCE ABUSE TREATMENT NEEDS.—

[12] So in law. Probably should be ''for''. See section 3301(a) of Public Law 106–310 (114 Stat. 1207).

(1) IN GENERAL.—Priority substance abuse treatment needs of regional and national significance shall be determined by the Secretary after consultation with States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities under paragraph (1), the Secretary shall give special consideration to promoting the integration of substance abuse treatment services into primary health care systems.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, or cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under that project provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract, or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—The Secretary shall establish comprehensive information and education programs to disseminate and apply the findings of the knowledge development and application, training and technical assistance programs, and targeted capacity response programs under this section to the general public, to health professionals and other interested groups. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out substance abuse prevention and treatment programs.

(f) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated to carry out this section, $300,000,000 for fiscal

year 2001 and such sums as may be necessary for each of the fiscal years 2002 and 2003.

ACTION BY NATIONAL INSTITUTE ON DRUG ABUSE AND STATES CONCERNING MILITARY FACILITIES

SEC. 513.[13] [42 U.S.C. 290bb–6] (a) CENTER FOR SUBSTANCE ABUSE TREATMENT.—The Director of the Center for Substance Abuse Treatment shall—

(1) coordinate with the agencies represented on the Commission on Alternative Utilization of Military Facilities the utilization of military facilities or parts thereof, as identified by such Commission, established under the National Defense Authorization Act of 1989, that could be utilized or renovated to house nonviolent persons for drug treatment purposes;

(2) notify State agencies responsible for the oversight of drug abuse treatment entities and programs of the availability of space at the installations identified in paragraph (1); and

(3) assist State agencies responsible for the oversight of drug abuse treatment entities and programs in developing methods for adapting the installations described in paragraph (1) into residential treatment centers.

(b) STATES.—With regard to military facilities or parts thereof, as identified by the Commission on Alternative Utilization of Military Facilities established under section 3042 of the Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988, that could be utilized or renovated to house nonviolent persons for drug treatment purposes, State agencies responsible for the oversight of drug abuse treatment entities and programs shall—

(1) establish eligibility criteria for the treatment of individuals at such facilities;

(2) select treatment providers to provide drug abuse treatment at such facilities;

(3) provide assistance to treatment providers selected under paragraph (2) to assist such providers in securing financing to fund the cost of the programs at such facilities; and

(4) establish, regulate, and coordinate with the military official in charge of the facility, work programs for individuals receiving treatment at such facilities.

(c) RESERVATION OF SPACE.—Prior to notifying States of the availability of space at military facilities under subsection (a)(2), the Director may reserve space at such facilities to conduct research or demonstration projects.

SEC. 514. [42 U.S.C. 290bb–7] SUBSTANCE ABUSE TREATMENT SERVICES FOR CHILDREN AND ADOLESCENTS.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Native Alaskan entities and Indian tribes and tribal organizations, for the purpose of providing substance abuse treatment services for children and adolescents.

[13] Sections 510 through 512 were repealed by section 3301(c) of Public Law 106–310 (114 Stat. 1209).

(b) PRIORITY.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants who propose to—

(1) apply evidenced-based and cost effective methods for the treatment of substance abuse among children and adolescents;

(2) coordinate the provision of treatment services with other social service agencies in the community, including educational, juvenile justice, child welfare, and mental health agencies;

(3) provide a continuum of integrated treatment services, including case management, for children and adolescents with substance abuse disorders and their families;

(4) provide treatment that is gender-specific and culturally appropriate;

(5) involve and work with families of children and adolescents receiving treatment;

(6) provide aftercare services for children and adolescents and their families after completion of substance abuse treatment; and

(7) address the relationship between substance abuse and violence.

(c) DURATION OF GRANTS.—The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for periods not to exceed 5 fiscal years.

(d) APPLICATION.—An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(e) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or cooperative agreement, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $40,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.

SEC. 514A. [42 U.S.C. 290bb–8] EARLY INTERVENTION SERVICES FOR CHILDREN AND ADOLESCENTS.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including local educational agencies (as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801)), for the purpose of providing early intervention substance abuse services for children and adolescents.

(b) PRIORITY.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants who demonstrate an ability to—

(1) screen for and assess substance use and abuse by children and adolescents;

(2) make appropriate referrals for children and adolescents who are in need of treatment for substance abuse;

(3) provide early intervention services, including counseling and ancillary services, that are designed to meet the developmental needs of children and adolescents who are at risk for substance abuse; and

(4) develop networks with the educational, juvenile justice, social services, and other agencies and organizations in the State or local community involved that will work to identify children and adolescents who are in need of substance abuse treatment services.

(c) CONDITION.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall ensure that such grants, contracts, or cooperative agreements are allocated, subject to the availability of qualified applicants, among the principal geographic regions of the United States, to Indian tribes and tribal organizations, and to urban and rural areas.

(d) DURATION OF GRANTS.—The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for periods not to exceed 5 fiscal years.

(e) APPLICATION.—An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(f) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or cooperative agreement, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.

METHAMPHETAMINE AND AMPHETAMINE TREATMENT INITIATIVE

SEC. 514.[14] [42 U.S.C. 290bb–9] (a) GRANTS.—

(1) AUTHORITY TO MAKE GRANTS.—The Director of the Center for Substance Abuse Treatment may make grants to States and Indian tribes recognized by the United States that have a high rate, or have had a rapid increase, in methamphetamine or amphetamine abuse or addiction in order to permit such States and Indian tribes to expand activities in connection with the treatment of methamphetamine or amphetamine abuser or addiction in the specific geographical areas of such States or Indian tribes, as the case may be, where there is such a rate or has been such an increase.

[14] So in law. There are two sections 514. The first was added at the end of this subpart (subpart 1 of part B) by section 3104(a) of Public Law 106–310 (114 Stat. 1171). That section also added section 514A. Section 3632 of such Public Law (114 Stat. 1236) then added at the end of this subpart section 514 above.

(2) RECIPIENTS.—Any grants under paragraph (1) shall be directed to the substance abuse directors of the States, and of the appropriate tribal government authorities of the Indian tribes, selected by the Director to receive such grants.

(3) NATURE OF ACTIVITIES.—Any activities under a grant under paragraph (1) shall be based on reliable scientific evidence of their efficacy in the treatment of methamphetamine or amphetamine abuse or addiction.

(b) GEOGRAPHIC DISTRIBUTION.—The Director shall ensure that grants under subsection (a) are distributed equitably among the various regions of the country and among rural, urban, and suburban areas that are affected by methamphetamine or amphetamine abuse or addiction.

(c) ADDITIONAL ACTIVITIES.—The Director shall—

(1) evaluate the activities supported by grants under subsection (a);

(2) disseminate widely such significant information derived from the evaluation as the Director considers appropriate to assist States, Indian tribes, and private providers of treatment services for methamphetamine or amphetamine abuser or addiction in the treatment of methamphetamine or amphetamine abuse or addiction; and

(3) provide States, Indian tribes, and such providers with technical assistance in connection with the provision of such treatment.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section $10,000,000 for fiscal year 2000 and such sums as may be necessary for each of fiscal years 2001 and 2002.

(2) USE OF CERTAIN FUNDS.—Of the funds appropriated to carry out this section in any fiscal year, the lesser of 5 percent of such funds or $1,000,000 shall be available to the Director for purposes of carrying out subsection (c).

Subpart 2—Center for Substance Abuse Prevention

OFFICE FOR SUBSTANCE ABUSE PREVENTION

SEC. 515. [42 U.S.C. 290bb–21] (a) There is established in the Administration an Office for Substance Abuse Prevention (hereafter referred to in this part as the ''Prevention Center''). The Office[15] shall be headed by a Director appointed by the Secretary from individuals with extensive experience or academic qualifications in the prevention of drug or alcohol abuse.

(b) The Director of the Prevention Center shall—

(1) sponsor regional workshops on the prevention of drug and alcohol abuse;

(2) coordinate the findings of research sponsored by agencies of the Service on the prevention of drug and alcohol abuse;

[15] So in law. See subsections (a), (d), and (e) of section 113 of Public Law 102–321 (106 Stat. 345). Probably should be ''Prevention Center''.

(3) develop effective drug and alcohol abuse prevention literature (including literature on the adverse effects of cocaine free base (known as crack));

(4) in cooperation with the Secretary of Education, assure the widespread dissemination of prevention materials among States, political subdivisions, and school systems;

(5) support clinical training programs for substance abuse counselors and other health professionals involved in drug abuse education, prevention,;[16]

(6) in cooperation with the Director of the Centers for Disease Control[17], develop educational materials to reduce the risks of acquired immune deficiency syndrome among intravenous drug abusers;

(7) conduct training, technical assistance, data collection, and evaluation activities of programs supported under the Drug Free Schools and Communities Act of 1986;

(8) support the development of model, innovative, community-based programs to discourage alcohol and drug abuse among young people;

(9) collaborate with the Attorney General of the Department of Justice to develop programs to prevent drug abuse among high risk youth;

(10) prepare for distribution documentary films and public service announcements for television and radio to educate the public, especially adolescent audiences, concerning the dangers to health resulting from the consumption of alcohol and drugs and, to the extent feasible, use appropriate private organizations and business concerns in the preparation of such announcements; and

(11) develop and support innovative demonstration programs designed to identify and deter the improper use or abuse of anabolic steroids by students, especially students in secondary schools.

(c) The Director may make grants and enter into contracts and cooperative agreements in carrying out subsection (b).

(d) The Director of the Prevention Center shall establish a national data base providing information on programs for the prevention of substance abuse. The data base shall contain information appropriate for use by public entities and information appropriate for use by nonprofit private entities.

SEC. 516. [42 U.S.C. 290bb–22] PRIORITY SUBSTANCE ABUSE PREVENTION NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority substance abuse prevention needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

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[16] So in law. See section 113(c)(1) of Public Law 102–321 (106 Stat. 345).

[17] So in law. See section 113(b) of Public Law 102–321 (106 Stat. 345). Probably should be "Centers for Disease Control and Prevention". Section 515 formerly was section 508, and after such redesignation, section 312(d)(10) of Public Law 102–531 (106 Stat. 3505) attempted to amend "section 508(b)(6)" with respect to adding "and Prevention".

(1) knowledge development and application projects for prevention and the conduct or support of evaluations of such projects;

(2) training and technical assistance; and

(3) targeted capacity response programs.

The Secretary may carry out the activities described in this section directly or through grants or cooperative agreements with States, political subdivisions of States, Indian tribes and tribal organizations, or other public or nonprofit private entities.

(b) PRIORITY SUBSTANCE ABUSE PREVENTION NEEDS.—

(1) IN GENERAL.—Priority substance abuse prevention needs of regional and national significance shall be determined by the Secretary in consultation with the States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities under paragraph (1), the Secretary shall give special consideration to—

(A) applying the most promising strategies and research-based primary prevention approaches; and

(B) promoting the integration of substance abuse prevention information and activities into primary health care systems.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, and cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under that project provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract, or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings

with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—The Secretary shall establish comprehensive information and education programs to disseminate the findings of the knowledge development and application, training and technical assistance programs, and targeted capacity response programs under this section to the general public and to health professionals. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out substance abuse prevention and treatment programs.

(f) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated to carry out this section, $300,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

PREVENTION, TREATMENT, AND REHABILITATION MODEL PROJECTS FOR HIGH RISK YOUTH

SEC. 517. [42 U.S.C. 290bb–23] (a) The Secretary, through the Director of the Prevention Center, shall make grants to public and nonprofit private entities for projects to demonstrate effective models for the prevention, treatment, and rehabilitation of drug abuse and alcohol abuse among high risk youth.

(b)(1) In making grants for drug abuse and alcohol abuse prevention projects under this section, the Secretary shall give priority to applications for projects directed at children of substance abusers, latchkey children, children at risk of abuse or neglect, preschool children eligible for services under the Head Start Act, children at risk of dropping out of school, children at risk of becoming adolescent parents, and children who do not attend school and who are at risk of being unemployed.

(2) In making grants for drug abuse and alcohol abuse treatment and rehabilitation projects under this section, the Secretary shall give priority to projects which address the relationship between drug abuse or alcohol abuse and physical child abuse, sexual child abuse, emotional child abuse, dropping out of school, unemployment, delinquency, pregnancy, violence, suicide, or mental health problems.

(3) In making grants under this section, the Secretary shall give priority to applications from community based organizations for projects to develop innovative models with multiple, coordinated services for the prevention or for the treatment and rehabilitation of drug abuse or alcohol abuse by high risk youth.

(4) In making grants under this section, the Secretary shall give priority to applications for projects to demonstrate effective models with multiple, coordinated services which may be replicated and which are for the prevention or for the treatment and rehabilitation of drug abuse or alcohol abuse by high risk youth.

(5) In making grants under this section, the Secretary shall give priority to applications that employ research designs adequate for evaluating the effectiveness of the program.

(c) The Secretary shall ensure that projects under subsection (a) include strategies for reducing the use of alcoholic beverages and

tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(d) To the extent feasible, the Secretary shall make grants under this section in all regions of the United States, and shall ensure the distribution of grants under this section among urban and rural areas.

(e) In order to receive a grant for a project under this section for a fiscal year, a public or nonprofit private entity shall submit an application to the Secretary, acting through the Office. The Secretary may provide to the Governor of the State the opportunity to review and comment on such application. Such application shall be in such form, shall contain such information, and shall be submitted at such time as the Secretary may by regulation prescribe.

(f) The Director [18] of the Office shall evaluate projects conducted with grants under this section.

(g) For purposes of this section, the term "high risk youth" means an individual who has not attained the age of 21 years, who is at high risk of becoming, or who has become, a drug abuser or an alcohol abuser, and who—

(1) is identified as a child of a substance abuser;
(2) is a victim of physical, sexual, or psychological abuse;
(3) has dropped out of school;
(4) has become pregnant;
(5) is economically disadvantaged;
(6) has committed a violent or delinquent act;
(7) has experienced mental health problems;
(8) has attempted suicide;
(9) has experienced long-term physical pain due to injury; or
(10) has experienced chronic failure in school.

(h) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.

SEC. 519.[19] [42 U.S.C. 290bb–25] GRANTS FOR SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall make grants to public and nonprofit private entities for the purpose of carrying out programs—

(A) to provide the services described in subsection (b) to children of substance abusers;

(B) to provide the applicable services described in subsection (c) to families in which a member is a substance abuser;

(C) to identify such children and such families through youth service agencies, family social services, child care providers, Head Start, schools and after-school programs, early childhood development programs, community-based family resource and support centers, the criminal justice

[18] So in law. See section 114, and subsections (a), (d), and (e) of section 113, of Public Law 102–321 (106 Stat. 346, 345). Probably should be "Prevention Center".

[19] Section 518 was repealed by section 3202(b) of Public Law 106–310 (114 Stat. 1210).

system, health, substance abuse and mental health providers through screenings conducted during regular childhood examinations and other examinations, self and family member referrals, substance abuse treatment services, and other providers of services to children and families; and

(D) to provide education and training to health, substance abuse and mental health professionals, and other providers of services to children and families through youth service agencies, family social services, child care, Head Start, schools and after-school programs, early childhood development programs, community-based family resource and support centers, the criminal justice system, and other providers of services to children and families.

(2) ADMINISTRATIVE CONSULTATIONS.—The Administrator of the Administration for Children, Youth, and Families and the Administrator of the Health Resources and Services Administration shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i)(I) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(II) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments; and

(ii) the entity will identify children who may be eligible for medical assistance under a State program under title XIX or XXI of the Social Security Act.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees to make available (directly or through agreements

with other entities) to children of substance abusers each of the following services:

(1) Periodic evaluation of children for developmental, psychological, alcohol and drug, and medical problems.

(2) Primary pediatric care.

(3) Other necessary health and mental health services.

(4) Therapeutic intervention services for children, including provision of therapeutic child care.

(5) Developmentally and age-appropriate drug and alcohol early intervention, treatment and prevention services.

(6) Counseling related to the witnessing of chronic violence.

(7) Referrals for, and assistance in establishing eligibility for, services provided under—

(A) education and special education programs;

(B) Head Start programs established under the Head Start Act;

(C) other early childhood programs;

(D) employment and training programs;

(E) public assistance programs provided by Federal, State, or local governments; and

(F) programs offered by vocational rehabilitation agencies, recreation departments, and housing agencies.

(8) Additional developmental services that are consistent with the provision of early intervention services, as such term is defined in part C of the Individuals with Disabilities Education Act.

Services shall be provided under paragraphs (2) through (8) by a public health nurse, social worker, or similar professional, or by a trained worker from the community who is supervised by a professional, or by an entity, where the professional or entity provides assurances that the professional or entity is licensed or certified by the State if required and is complying with applicable licensure or certification requirements.

(c) SERVICES FOR AFFECTED FAMILIES.—The Secretary may make a grant under subsection (a) only if, in the case of families in which a member is a substance abuser, the applicant involved agrees to make available (directly or through agreements with other entities) each of the following services, as applicable to the family member involved:

(1) Services as follows, to be provided by a public health nurse, social worker, or similar professional, or by a trained worker from the community who is supervised by a professional, or by an entity, where the professional or entity provides assurances that the professional or entity is licensed or certified by the State if required and is complying with applicable licensure or certification requirements:

(A) Counseling to substance abusers on the benefits and availability of substance abuse treatment services and services for children of substance abusers.

(B) Assistance to substance abusers in obtaining and using substance abuse treatment services and in obtaining the services described in subsection (b) for their children.

(C) Visiting and providing support to substance abusers, especially pregnant women, who are receiving substance

abuse treatment services or whose children are receiving services under subsection (b).

(D) Aggressive outreach to family members with substance abuse problems.

(E) Inclusion of consumer in the development, implementation, and monitoring of Family Services Plan.

(2) In the case of substance abusers:

(A) Alcohol and drug treatment services, including screening and assessment, diagnosis, detoxification, individual, group and family counseling, relapse prevention, pharmacotherapy treatment, after-care services, and case management.

(B) Primary health care and mental health services, including prenatal and post partum care for pregnant women.

(C) Consultation and referral regarding subsequent pregnancies and life options and counseling on the human immunodeficiency virus and acquired immune deficiency syndrome.

(D) Where appropriate, counseling regarding family violence.

(E) Career planning and education services.

(F) Referrals for, and assistance in establishing eligibility for, services described in subsection (b)(7).

(3) In the case of substance abusers, spouses of substance abusers, extended family members of substance abusers, caretakers of children of substance abusers, and other people significantly involved in the lives of substance abusers or the children of substance abusers:

(A) An assessment of the strengths and service needs of the family and the assignment of a case manager who will coordinate services for the family.

(B) Therapeutic intervention services, such as parental counseling, joint counseling sessions for families and children, and family therapy.

(C) Child care or other care for the child to enable the parent to attend treatment or other activities and respite care services.

(D) Parenting education services and parent support groups which include child abuse and neglect prevention techniques.

(E) Support services, including, where appropriate, transportation services.

(F) Where appropriate, referral of other family members to related services such as job training.

(G) Aftercare services, including continued support through parent groups and home visits.

(d) TRAINING FOR PROVIDERS OF SERVICES TO CHILDREN AND FAMILIES.—The Secretary may make a grant under subsection (a) for the training of health, substance abuse and mental health professionals and other providers of services to children and families through youth service agencies, family social services, child care providers, Head Start, schools and after-school programs, early childhood development programs, community-based family resource

centers, the criminal justice system, and other providers of services to children and families. Such training shall be to assist professionals in recognizing the drug and alcohol problems of their clients and to enhance their skills in identifying and understanding the nature of substance abuse, and obtaining substance abuse early intervention, prevention and treatment resources.

(e) ELIGIBLE ENTITIES.—The Secretary shall distribute the grants through the following types of entities:

(1) Alcohol and drug early intervention, prevention or treatment programs, especially those providing treatment to pregnant women and mothers and their children.

(2) Public or nonprofit private entities that provide health or social services to disadvantaged populations, and that have—

(A) expertise in applying the services to the particular problems of substance abusers and the children of substance abusers; or

(B) an affiliation or contractual relationship with one or more substance abuse treatment programs or pediatric health or mental health providers and family mental health providers.

(3) Consortia of public or nonprofit private entities that include at least one substance abuse treatment program.

(4) Indian tribes.

(f) FEDERAL SHARE.—The Federal share of a program carried out under subsection (a) shall be 90 percent. The Secretary shall accept the value of in-kind contributions, including facilities and personnel, made by the grant recipient as a part or all of the non-Federal share of grants.

(g) RESTRICTIONS ON USE OF GRANT.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(h) SUBMISSION TO SECRETARY OF CERTAIN INFORMATION.—The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary—

(1) a description of the population that is to receive services under this section and a description of such services that are to be provided and measurable goals and objectives;

(2) a description of the mechanism that will be used to involve the local public agencies responsible for health, including

maternal and child health[20] mental health, child welfare, education, juvenile justice, developmental disabilities, and substance abuse in planning and providing services under this section, as well as evidence that the proposal has been coordinated with the State agencies responsible for administering those programs, the State agency responsible for administering alcohol and drug programs, the State lead agency, and the State Interagency Coordinating Council under part H of the Individuals with Disabilities Education Act; and;[21]

(3) such other information as the Secretary determines to be appropriate.

(i) REPORTS TO SECRETARY.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that for each fiscal year for which the applicant receives such a grant the applicant, in accordance with uniform standards developed by the Secretary, will submit to the Secretary a report containing—

(1) a description of specific services and activities provided under the grant;

(2) information regarding progress toward meeting the program's stated goals and objectives;

(3) information concerning the extent of use of services provided under the grant, including the number of referrals to related services and information on other programs or services accessed by children, parents, and other caretakers;

(4) information concerning the extent to which parents were able to access and receive treatment for alcohol and drug abuse and sustain participation in treatment over time until the provider and the individual receiving treatment agree to end such treatment, and the extent to which parents re-enter treatment after the successful or unsuccessful termination of treatment;

(5) information concerning the costs of the services provided and the source of financing for health care services;

(6) information concerning—

(A) the number and characteristics of families, parents, and children served, including a description of the type and severity of childhood disabilities, and an analysis of the number of children served by age;

(B) the number of children served who remained with their parents during the period in which entities provided services under this section; and

(C) the number of case workers or other professionals trained to identify and address substance abuse issues.

(7) information on hospitalization or emergency room use by the family members participating in the program; and

(8) such other information as the Secretary determines to be appropriate.

(j) REQUIREMENT OF APPLICATION.—The Secretary may make any grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

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[20] The lack of a comma would be so in law. See section 3106(e)(1)(A) of Public Law 106–310 (114 Stat. 1177).

[21] The superfluous semicolon would be so in law. See section 3106(e)(1)(C) of Public Law 106–310 (114 Stat. 1177).

(2) the application contains the agreements required in this section and the information required in subsection (h); and

(3) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(k) EVALUATIONS.—The Secretary shall periodically conduct evaluations to determine the effectiveness of programs supported under subsection (a)—

(1) in reducing the incidence of alcohol and drug abuse among substance abusers participating in the programs;

(2) in preventing adverse health conditions in children of substance abusers;

(3) in promoting better utilization of health and developmental services and improving the health, developmental, and psychological status of children receiving services under the program; and

(4) in improving parental and family functioning, including increased participation in work or employment-related activities and decreased participation in welfare programs.

(l) REPORT TO CONGRESS.—Not later than 2 years after the date on which amounts are first appropriated under subjection (o), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report that contains a description of programs carried out under this section. At a minimum, the report shall contain—

(1) information concerning the number and type of programs receiving grants;

(2) information concerning the type and use of services offered; and

(3) information concerning—

(A) the number and characteristics of families, parents, and children served; and

(B) the number of children served who remained with their parents during or after the period in which entities provided services under this section.[22]

analyzed by the type of entity described in subsection (d)[23] that provided services;[22]

(m) DATA COLLECTION.—The Secretary shall periodically collect and report on information concerning the numbers of children in substance abusing families, including information on the age, gender and ethnicity of the children, the composition and income of the family, and the source of health care finances. The periodic report shall include a quantitative estimate of the prevalence of alcohol and drug problems in families involved in the child welfare system,

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[22] The period at the end of subparagraph (B), and the semicolon at the end of paragraph (3), would be so in law. See section 3106(h) of Public Law 106–310 (114 Stat. 1178). The period probably should be a semicolon, and the semicolon probably should be a period.

[23] The reference to subsection (d) probably should be a reference to subsection (e). Section 3106(l) of Public Law 106–310 (114 Stat. 1178) would redesignate subsection (d) as subsection (e) and make conforming changes in cross-references. One of the conforming changes would be to subsection (m), and would strike "(d)" and insert "(e)". The reference to subsection (d) appears in subsection (l), however, not subsection (m).

the barriers to treatment and prevention services facing these families, and policy recommendations for removing the identified barriers, including training for child welfare workers.

(n) DEFINITIONS.—For purposes of this section:

(1) The term "caretaker", with respect to a child of a substance abuser, means any individual acting in a parental role regarding the child (including any birth parent, foster parent, adoptive parent, relative of such a child, or other individual acting in such a role).

(2) The term "children of substance abusers" means—

(A) children who have lived or are living in a household with a substance abuser who is acting in a parental role regarding the children; and

(B) children who have been prenatally exposed to alcohol or other drugs.

(3) The term "Indian tribe" means any tribe, band, nation, or other organized group or community of Indians, including any Alaska Native village (as defined in, or established pursuant to, the Alaska Native Claims Settlement Act), that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(4) The term "public or nonprofit private entities that provide health or social services to disadvantaged populations" includes community-based organizations, local public health departments, community action agencies, hospitals, community health centers, child welfare agencies, developmental disabilities service providers, and family resource and support programs.

(5) The term "substance abuse" means the abuse of alcohol or other drugs.

(o) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

SEC. 519A. [42 U.S.C. 290bb–25a] GRANTS FOR STRENGTHENING FAMILIES.

(a) PROGRAM AUTHORIZED.—The Secretary, acting through the Director of the Prevention Center, may make grants to public and nonprofit private entities to develop and implement model substance abuse prevention programs to provide early intervention and substance abuse prevention services for individuals of high-risk families and the communities in which such individuals reside.

(b) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applicants that—

(1) have proven experience in preventing substance abuse by individuals of high-risk families and reducing substance abuse in communities of such individuals;

(2) have demonstrated the capacity to implement community-based partnership initiatives that are sensitive to the diverse backgrounds of individuals of high-risk families and the communities of such individuals;

(3) have experience in providing technical assistance to support substance abuse prevention programs that are community-based;

(4) have demonstrated the capacity to implement research-based substance abuse prevention strategies; and

(5) have implemented programs that involve families, residents, community agencies, and institutions in the implementation and design of such programs.

(c) DURATION OF GRANTS.—The Secretary shall award grants under subsection (a) for a period not to exceed 5 years.

(d) USE OF FUNDS.—An applicant that is awarded a grant under subsection (a) shall—

(1) in the first fiscal year that such funds are received under the grant, use such funds to develop a model substance abuse prevention program; and

(2) in the fiscal year following the first fiscal year that such funds are received, use such funds to implement the program developed under paragraph (1) to provide early intervention and substance abuse prevention services to—

(A) strengthen the environment of children of high risk families by targeting interventions at the families of such children and the communities in which such children reside;

(B) strengthen protective factors, such as—

(i) positive adult role models;

(ii) messages that oppose substance abuse;

(iii) community actions designed to reduce accessibility to and use of illegal substances; and

(iv) willingness of individuals of families in which substance abuse occurs to seek treatment for substance abuse;

(C) reduce family and community risks, such as family violence, alcohol or drug abuse, crime, and other behaviors that may effect healthy child development and increase the likelihood of substance abuse; and

(D) build collaborative and formal partnerships between community agencies, institutions, and businesses to ensure that comprehensive high quality services are provided, such as early childhood education, health care, family support programs, parent education programs, and home visits for infants.

(e) APPLICATION.—To be eligible to receive a grant under subsection (a), an applicant shall prepare and submit to the Secretary an application that—

(1) describes a model substance abuse prevention program that such applicant will establish;

(2) describes the manner in which the services described in subsection (d)(2) will be provided; and

(3) describe in as much detail as possible the results that the entity expects to achieve in implementing such a program.

(f) MATCHING FUNDING.—The Secretary may not make a grant to a entity under subsection (a) unless that entity agrees that, with respect to the costs to be incurred by the entity in carrying out the program for which the grant was awarded, the entity will make

available non-Federal contributions in an amount that is not less than 40 percent of the amount provided under the grant.

(g) REPORT TO SECRETARY.—An applicant that is awarded a grant under subsection (a) shall prepare and submit to the Secretary a report in such form and containing such information as the Secretary may require, including an assessment of the efficacy of the model substance abuse prevention program implemented by the applicant and the short, intermediate, and long term results of such program.

(h) EVALUATIONS.—The Secretary shall conduct evaluations, based in part on the reports submitted under subsection (g), to determine the effectiveness of the programs funded under subsection (a) in reducing substance use in high-risk families and in making communities in which such families reside in stronger. The Secretary shall submit such evaluations to the appropriate committees of Congress.

(i) HIGH-RISK FAMILIES.—In this section, the term "high-risk family" means a family in which the individuals of such family are at a significant risk of using or abusing alcohol or any illegal substance.

(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $3,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

SEC. 519B. [42 U.S.C. 290bb–25b] PROGRAMS TO REDUCE UNDERAGE DRINKING.

(a) IN GENERAL.—The Secretary shall make awards of grants, cooperative agreements, or contracts to public and nonprofit private entities, including Indian tribes and tribal organizations, to enable such entities to develop plans for and to carry out school-based (including institutions of higher education) and community-based programs for the prevention of alcoholic-beverage consumption by individuals who have not attained the legal drinking age.

(b) ELIGIBILITY REQUIREMENTS.—To be eligible to receive an award under subsection (a), an entity shall provide any assurances to the Secretary which the Secretary may require, including that the entity will—

(1) annually report to the Secretary on the effectiveness of the prevention approaches implemented by the entity;

(2) use science based and age appropriate approaches; and

(3) involve local public health officials and community prevention program staff in the planning and implementation of the program.

(c) EVALUATION.—The Secretary shall evaluate each project under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(d) GEOGRAPHICAL DISTRIBUTION.—The Secretary shall ensure that awards will be distributed equitably among the regions of the country and among urban and rural areas.

(e) DURATION OF AWARD.—With respect to an award under subsection (a), the period during which payments under such award are made to the recipient may not exceed 5 years. The preceding sentence may not be construed as establishing a limitation on the

number of awards under such subsection that may be made to the recipient.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

SEC. 519C. [42 U.S.C. 290bb–25c] SERVICES FOR INDIVIDUALS WITH FETAL ALCOHOL SYNDROME.

(a) IN GENERAL.—The Secretary shall make awards of grants, cooperative agreements, or contracts to public and nonprofit private entities, including Indian tribes and tribal organizations, to provide services to individuals diagnosed with fetal alcohol syndrome or alcohol-related birth defects.

(b) USE OF FUNDS.—An award under subsection (a) may, subject to subsection (d), be used to—

(1) screen and test individuals to determine the type and level of services needed;

(2) develop a comprehensive plan for providing services to the individual;

(3) provide mental health counseling;

(4) provide substance abuse prevention services and treatment, if needed;

(5) coordinate services with other social programs including social services, justice system, educational services, health services, mental health and substance abuse services, financial assistance programs, vocational services and housing assistance programs;

(6) provide vocational services;

(7) provide health counseling;

(8) provide housing assistance;

(9) parenting skills training;

(10) overall case management;

(11) supportive services for families of individuals with Fetal Alcohol Syndrome; and

(12) provide other services and programs, to the extent authorized by the Secretary after consideration of recommendations made by the National Task Force on Fetal Alcohol Syndrome.

(c) REQUIREMENTS.—To be eligible to receive an award under subsection (a), an applicant shall—

(1) demonstrate that the program will be part of a coordinated, comprehensive system of care for such individuals;

(2) demonstrate an established communication with other social programs in the community including social services, justice system, financial assistance programs, health services, educational services, mental health and substance abuse services, vocational services and housing assistance services;

(3) show a history of working with individuals with fetal alcohol syndrome or alcohol-related birth defects;

(4) provide assurance that the services will be provided in a culturally and linguistically appropriate manner; and

(5) provide assurance that at the end of the 5-year award period, other mechanisms will be identified to meet the needs of the individuals and families served under such award.

(d) RELATIONSHIP TO PAYMENTS UNDER OTHER PROGRAMS.—An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the expenses of providing any service under this section to an individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) DURATION OF AWARDS.—With respect to an award under subsection (a), the period during which payments under such award are made to the recipient may not exceed 5 years.

(f) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(g) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2) ALLOCATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, not less than $300,000 shall, for purposes relating to fetal alcohol syndrome and alcohol-related birth defects, be made available for collaborative, coordinated interagency efforts with the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Child Health and Human Development, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Department of Education, and the Department of Justice.

SEC. 519D. [42 U.S.C. 290bb–25d] CENTERS OF EXCELLENCE ON SERVICES FOR INDIVIDUALS WITH FETAL ALCOHOL SYNDROME AND ALCOHOL-RELATED BIRTH DEFECTS AND TREATMENT FOR INDIVIDUALS WITH SUCH CONDITIONS AND THEIR FAMILIES.

(a) IN GENERAL.—The Secretary shall make awards of grants, cooperative agreements, or contracts to public or nonprofit private entities for the purposes of establishing not more than four centers of excellence to study techniques for the prevention of fetal alcohol syndrome and alcohol-related birth defects and adaptations of innovative clinical interventions and service delivery improvements for the provision of comprehensive services to individuals with fetal alcohol syndrome or alcohol-related birth defects and their families and for providing training on such conditions.

(b) USE OF FUNDS.—An award under subsection (a) may be used to—

(1) study adaptations of innovative clinical interventions and service delivery improvements strategies for children and adults with fetal alcohol syndrome or alcohol-related birth defects and their families;

(2) identify communities which have an exemplary comprehensive system of care for such individuals so that they can provide technical assistance to other communities attempting to set up such a system of care;

(3) provide technical assistance to communities who do not have a comprehensive system of care for such individuals and their families;

(4) train community leaders, mental health and substance abuse professionals, families, law enforcement personnel, judges, health professionals, persons working in financial assistance programs, social service personnel, child welfare professionals, and other service providers on the implications of fetal alcohol syndrome and alcohol-related birth defects, the early identification of and referral for such conditions;

(5) develop innovative techniques for preventing alcohol use by women in child bearing years; [24]

(6) perform other functions, to the extent authorized by the Secretary after consideration of recommendations made by the National Task Force on Fetal Alcohol Syndrome.

(c) REPORT.—

(1) IN GENERAL.—A recipient of an award under subsection (a) shall at the end of the period of funding report to the Secretary on any innovative techniques that have been discovered for preventing alcohol use among women of child bearing years.

(2) DISSEMINATION OF FINDINGS.—The Secretary shall upon receiving a report under paragraph (1) disseminate the findings to appropriate public and private entities.

(d) DURATION OF AWARDS.—With respect to an award under subsection (a), the period during which payments under such award are made to the recipient may not exceed 5 years.

(e) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

SEC. 519E.[25] [42 U.S.C. 290bb–25e] PREVENTION OF METHAMPHETAMINE AND INHALANT ABUSE AND ADDICTION.

(a) GRANTS.—The Director of the Center for Substance Abuse Prevention (referred to in this section as the ''Director'') may make grants to and enter into contracts and cooperative agreements with public and nonprofit private entities to enable such entities—

(1) to carry out school-based programs concerning the dangers of methamphetamine or inhalant abuse and addiction, using methods that are effective and evidence-based, including

[24] So in law. Probably should read ''; and''. See section 3110 of Public Law 106–310 (114 Stat. 1185).

[25] The placement of section 519E is according to the probable intent of the Congress. Section 3104(c) of Public Law 106–310 (114 Stat. 1173) added the section to this subpart, but did not specify the specific placement of the section.

initiatives that give students the responsibility to create their own anti-drug abuse education programs for their schools; and

(2) to carry out community-based methamphetamine or inhalant abuse and addiction prevention programs that are effective and evidence-based.

(b) USE OF FUNDS.—Amounts made available under a grant, contract or cooperative agreement under subsection (a) shall be used for planning, establishing, or administering methamphetamine or inhalant prevention programs in accordance with subsection (c).

(c) PREVENTION PROGRAMS AND ACTIVITIES.—

(1) IN GENERAL.—Amounts provided under this section may be used—

(A) to carry out school-based programs that are focused on those districts with high or increasing rates of methamphetamine or inhalant abuse and addiction and targeted at populations which are most at risk to start methamphetamine or inhalant abuse;

(B) to carry out community-based prevention programs that are focused on those populations within the community that are most at-risk for methamphetamine or inhalant abuse and addiction;

(C) to assist local government entities to conduct appropriate methamphetamine or inhalant prevention activities;

(D) to train and educate State and local law enforcement officials, prevention and education officials, members of community anti-drug coalitions and parents on the signs of methamphetamine or inhalant abuse and addiction and the options for treatment and prevention;

(E) for planning, administration, and educational activities related to the prevention of methamphetamine or inhalant abuse and addiction;

(F) for the monitoring and evaluation of methamphetamine or inhalant prevention activities, and reporting and disseminating resulting information to the public; and

(G) for targeted pilot programs with evaluation components to encourage innovation and experimentation with new methodologies.

(2) PRIORITY.—The Director shall give priority in making grants under this section to rural and urban areas that are experiencing a high rate or rapid increases in methamphetamine or inhalant abuse and addiction.

(d) ANALYSES AND EVALUATION.—

(1) IN GENERAL.—Up to $500,000 of the amount available in each fiscal year to carry out this section shall be made available to the Director, acting in consultation with other Federal agencies, to support and conduct periodic analyses and evaluations of effective prevention programs for methamphetamine or inhalant abuse and addiction and the development of appropriate strategies for disseminating information about and implementing these programs.

(2) ANNUAL REPORTS.—The Director shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and Committee on Appropriations of the House

of Representatives, an annual report with the results of the analyses and evaluation under paragraph (1).

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out subsection (a), $10,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

Subpart 3—Center for Mental Health Services

CENTER FOR MENTAL HEALTH SERVICES

SEC. 520. [42 U.S.C. 290bb–31] (a) ESTABLISHMENT.—There is established in the Administration a Center for Mental Health Services (hereafter in this section referred to as the "Center"). The Center shall be headed by a Director (hereafter in this section referred to as the "Director") appointed by the Secretary from among individuals with extensive experience or academic qualifications in the provision of mental health services or in the evaluation of mental health service systems.

(b) DUTIES.—The Director of the Center shall—

(1) design national goals and establish national priorities for—

(A) the prevention of mental illness; and

(B) the promotion of mental health;

(2) encourage and assist local entities and State agencies to achieve the goals and priorities described in paragraph (1);

(3) collaborate with the Department of Education and the Department of Justice to develop programs to assist local communities in addressing violence among children and adolescents;

(4) develop and coordinate Federal prevention policies and programs and to assure increased focus on the prevention of mental illness and the promotion of mental health;

(5) develop improved methods of treating individuals with mental health problems and improved methods of assisting the families of such individuals;

(6) administer the mental health services block grant program authorized in section 1911;

(7) promote policies and programs at Federal, State, and local levels and in the private sector that foster independence and protect the legal rights of persons with mental illness, including carrying out the provisions of the Protection and Advocacy of Mentally Ill Individuals Act;

(8) carry out the programs under part C;

(9) carry out responsibilities for the Human Resource Development program, and programs of clinical training for professional and paraprofessional personnel pursuant to section 303[26];

[26] The probable intent of the Congress is that the paragraph read "(9) carry out responsibilities for the Human Resource Development Program;". See section 3112(c)(4) of Public Law 106–310 (114 Stat. 1188), which provides that paragraph (9) is amended "by striking 'program and programs' and all that follows through '303' and inserting 'programs'". The amendment cannot be executed because the term to be struck does not appear in paragraph (9). (Compare "program and programs" and "program, and programs".)

(10) conduct services-related assessments, including evaluations of the organization and financing of care, self-help and consumer-run programs, mental health economics, mental health service systems, rural mental health, and improve the capacity of State to conduct evaluations of publicly funded mental health programs;

(11) establish a clearinghouse for mental health information to assure the widespread dissemination of such information to States, political subdivisions, educational agencies and institutions, treatment and prevention service providers, and the general public, including information concerning the practical application of research supported by the National Institute of Mental Health that is applicable to improving the delivery of services;

(12) provide technical assistance to public and private entities that are providers of mental health services;

(13) monitor and enforce obligations incurred by community mental health centers pursuant to the Community Mental Health Centers Act (as in effect prior to the repeal of such Act on August 13, 1981, by section 902(e)(2)(B) of Public Law 97–35 (95 Stat. 560));

(14) conduct surveys with respect to mental health, such as the National Reporting Program; and

(15) assist States in improving their mental health data collection.

(c) GRANTS AND CONTRACTS.—In carrying out the duties established in subsection (b), the Director may make grants to and enter into contracts and cooperative agreements with public and nonprofit private entities.

SEC. 520A. [42 U.S.C. 290bb–32] PRIORITY MENTAL HEALTH NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority mental health needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for prevention, treatment, and rehabilitation, and the conduct or support of evaluations of such projects;

(2) training and technical assistance programs;

(3) targeted capacity response programs; and

(4) systems change grants including statewide family network grants and client-oriented and consumer run self-help activities.

The Secretary may carry out the activities described in this subsection directly or through grants or cooperative agreements with States, political subdivisions of States, Indian tribes and tribal organizations, other public or private nonprofit entities.

(b) PRIORITY MENTAL HEALTH NEEDS.—

(1) DETERMINATION OF NEEDS.—Priority mental health needs of regional and national significance shall be determined by the Secretary in consultation with States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities described in paragraph (1), the Secretary shall give special consideration to promoting the integration of mental health services into primary health care systems.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, and cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under this section provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—

(1) IN GENERAL.—The Secretary shall establish information and education programs to disseminate and apply the findings of the knowledge development and application, training, and technical assistance programs, and targeted capacity response programs, under this section to the general public, to health care professionals, and to interested groups. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out mental health services.

(2) RURAL AND UNDERSERVED AREAS.—In disseminating information on evidence-based practices in the provision of children's mental health services under this subsection, the Secretary shall ensure that such information is distributed to rural and medically underserved areas.

(f) AUTHORIZATION OF APPROPRIATION.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, $300,000,000 for fiscal year 2001, and

such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2) DATA INFRASTRUCTURE.—If amounts are not appropriated for a fiscal year to carry out section 1971 with respect to mental health, then the Secretary shall make available, from the amounts appropriated for such fiscal year under paragraph (1), an amount equal to the sum of $6,000,000 and 10 percent of all amounts appropriated for such fiscal year under such paragraph in excess of $100,000,000, to carry out such section 1971.

SEC. 520C.[27] [42 U.S.C. 290bb–34] YOUTH INTERAGENCY RESEARCH, TRAINING, AND TECHNICAL ASSISTANCE CENTERS.

(a) PROGRAM AUTHORIZED.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, and in consultation with the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Director of the Bureau of Justice Assistance and the Director of the National Institutes of Health—

(1) shall award grants or contracts to public or nonprofit private entities to establish not more than four research, training, and technical assistance centers to carry out the activities described in subsection (c); and

(2) shall award a competitive grant to 1 additional research, training, and technical assistance center to carry out the activities described in subsection (d).

(b) APPLICATION.—A public or private nonprofit entity desiring a grant or contract under subsection (a) shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(c) AUTHORIZED ACTIVITIES.—A center established under a grant or contract under subsection (a)(1) shall—

(1) provide training with respect to state-of-the-art mental health and justice-related services and successful mental health and substance abuse-justice collaborations that focus on children and adolescents, to public policymakers, law enforcement administrators, public defenders, police, probation officers, judges, parole officials, jail administrators and mental health and substance abuse providers and administrators;

(2) engage in research and evaluations concerning State and local justice and mental health systems, including system redesign initiatives, and disseminate information concerning the results of such evaluations;

(3) provide direct technical assistance, including assistance provided through toll-free telephone numbers, concerning issues such as how to accommodate individuals who are being processed through the courts under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), what types of mental health or substance abuse service approaches are effective within the judicial system, and how community-based mental health or substance abuse services can be more effective, including relevant regional, ethnic, and gender-related considerations; and

[27]Section 520B was repealed by section 3201(b)(2) of Public Law 106–310 (114 Stat. 1190).

(4) provide information, training, and technical assistance to State and local governmental officials to enhance the capacity of such officials to provide appropriate services relating to mental health or substance abuse.

(d) ADDITIONAL CENTER.—The additional research, training, and technical assistance center established under subsection (a)(2) shall provide appropriate information, training, and technical assistance to States, political subdivisions of a State, Federally recognized Indian tribes, tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations for—

(1) the development or continuation of statewide or tribal youth suicide early intervention and prevention strategies;

(2) ensuring the surveillance of youth suicide early intervention and prevention strategies;

(3) studying the costs and effectiveness of statewide youth suicide early intervention and prevention strategies in order to provide information concerning relevant issues of importance to State, tribal, and national policymakers;

(4) further identifying and understanding causes and associated risk factors for youth suicide;

(5) analyzing the efficacy of new and existing youth suicide early intervention techniques and technology;

(6) ensuring the surveillance of suicidal behaviors and nonfatal suicidal attempts;

(7) studying the effectiveness of State-sponsored statewide and tribal youth suicide early intervention and prevention strategies on the overall wellness and health promotion strategies related to suicide attempts;

(8) promoting the sharing of data regarding youth suicide with Federal agencies involved with youth suicide early intervention and prevention, and State-sponsored statewide or tribal youth suicide early intervention and prevention strategies for the purpose of identifying previously unknown mental health causes and associated risk factors for suicide in youth;

(9) evaluating and disseminating outcomes and best practices of mental and behavioral health services at institutions of higher education; and

(10) other activities determined appropriate by the Secretary.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) For the purpose of awarding grants or contracts under subsection (a)(1), there is authorized to be appropriated $4,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.

(2) For the purpose of awarding a grant under subsection (a)(2), there are authorized to be appropriated $3,000,000 for fiscal year 2005, $4,000,000 for fiscal year 2006, and $5,000,000 for fiscal year 2007.

SEC. 520D. [42 U.S.C. 290bb–35] SERVICES FOR YOUTH OFFENDERS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services, and in consultation with the Director of the Center for Substance Abuse Treatment, the Administrator of the Office of Juvenile Justice and Delinquency Prevention, and the Director of the Special Education Programs, shall

award grants on a competitive basis to State or local juvenile justice agencies to enable such agencies to provide aftercare services for youth offenders who have been discharged from facilities in the juvenile or criminal justice system and have serious emotional disturbances or are at risk of developing such disturbances.

(b) USE OF FUNDS.—A State or local juvenile justice agency receiving a grant under subsection (a) shall use the amounts provided under the grant—

(1) to develop a plan describing the manner in which the agency will provide services for each youth offender who has a serious emotional disturbance and has been detained or incarcerated in facilities within the juvenile or criminal justice system;

(2) to provide a network of core or aftercare services or access to such services for each youth offender, including diagnostic and evaluation services, substance abuse treatment services, outpatient mental health care services, medication management services, intensive home-based therapy, intensive day treatment services, respite care, and therapeutic foster care;

(3) to establish a program that coordinates with other State and local agencies providing recreational, social, educational, vocational, or operational services for youth, to enable the agency receiving a grant under this section to provide community-based system of care services for each youth offender that addresses the special needs of the youth and helps the youth access all of the aforementioned services; and

(4) using not more than 20 percent of funds received, to provide planning and transition services as described in paragraph (3) for youth offenders while such youth are incarcerated or detained.

(c) APPLICATION.—A State or local juvenile justice agency that desires a grant under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(d) REPORT.—Not later than 3 years after the date of the enactment of this section and annually thereafter, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce of the House of Representatives, a report that describes the services provided pursuant to this section.

(e) DEFINITIONS.—In this section:

(1) SERIOUS EMOTIONAL DISTURBANCE.—The term ''serious emotional disturbance'' with respect to a youth offender means an offender who currently, or at any time within the 1-year period ending on the day on which services are sought under this section, has a diagnosable mental, behavioral, or emotional disorder that functionally impairs the offender's life by substantially limiting the offender's role in family, school, or community activities, and interfering with the offender's ability to achieve or maintain one or more developmentally-appropriate social, behavior, cognitive, communicative, or adaptive skills.

(2) COMMUNITY-BASED SYSTEM OF CARE.—The term ''community-based system of care'' means the provision of services for

the youth offender by various State or local agencies that in an interagency fashion or operating as a network addresses the recreational, social, educational, vocational, mental health, substance abuse, and operational needs of the youth offender.

(3) YOUTH OFFENDER.—The term "youth offender" means an individual who is 21 years of age or younger who has been discharged from a State or local juvenile or criminal justice system, except that if the individual is between the ages of 18 and 21 years, such individual has had contact with the State or local juvenile or criminal justice system prior to attaining 18 years of age and is under the jurisdiction of such a system at the time services are sought.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $40,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

SEC. 520E. [42 U.S.C. 290bb–36] YOUTH SUICIDE EARLY INTERVENTION AND PREVENTION STRATEGIES.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall award grants or cooperative agreements to eligible entities to—

(1) develop and implement State-sponsored statewide or tribal youth suicide early intervention and prevention strategies in schools, educational institutions, juvenile justice systems, substance abuse programs, mental health programs, foster care systems, and other child and youth support organizations;

(2) support public organizations and private nonprofit organizations actively involved in State-sponsored statewide or tribal youth suicide early intervention and prevention strategies and in the development and continuation of State-sponsored statewide youth suicide early intervention and prevention strategies;

(3) provide grants to institutions of higher education to coordinate the implementation of State-sponsored statewide or tribal youth suicide early intervention and prevention strategies;

(4) collect and analyze data on State-sponsored statewide or tribal youth suicide early intervention and prevention services that can be used to monitor the effectiveness of such services and for research, technical assistance, and policy development; and

(5) assist eligible entities, through State-sponsored statewide or tribal youth suicide early intervention and prevention strategies, in achieving targets for youth suicide reductions under title V of the Social Security Act.

(b) ELIGIBLE ENTITY.—

(1) DEFINITION.—In this section, the term "eligible entity" means—

(A) a State;

(B) a public organization or private nonprofit organization designated by a State to develop or direct the State-sponsored statewide youth suicide early intervention and prevention strategy; or

(C) a Federally recognized Indian tribe or tribal organization (as defined in the Indian Self-Determination and Education Assistance Act) or an urban Indian organization (as defined in the Indian Health Care Improvement Act) that is actively involved in the development and continuation of a tribal youth suicide early intervention and prevention strategy.

(2) LIMITATION.—In carrying out this section, the Secretary shall ensure that each State is awarded only 1 grant or cooperative agreement under this section. For purposes of the preceding sentence, a State shall be considered to have been awarded a grant or cooperative agreement if the eligible entity involved is the State or an entity designated by the State under paragraph (1)(B). Nothing in this paragraph shall be construed to apply to entities described in paragraph (1)(C).

(c) PREFERENCE.—In providing assistance under a grant or cooperative agreement under this section, an eligible entity shall give preference to public organizations, private nonprofit organizations, political subdivisions, institutions of higher education, and tribal organizations actively involved with the State-sponsored statewide or tribal youth suicide early intervention and prevention strategy that—

(1) provide early intervention and assessment services, including screening programs, to youth who are at risk for mental or emotional disorders that may lead to a suicide attempt, and that are integrated with school systems, educational institutions, juvenile justice systems, substance abuse programs, mental health programs, foster care systems, and other child and youth support organizations;

(2) demonstrate collaboration among early intervention and prevention services or certify that entities will engage in future collaboration;

(3) employ or include in their applications a commitment to evaluate youth suicide early intervention and prevention practices and strategies adapted to the local community;

(4) provide timely referrals for appropriate community-based mental health care and treatment of youth who are at risk for suicide in child-serving settings and agencies;

(5) provide immediate support and information resources to families of youth who are at risk for suicide;

(6) offer access to services and care to youth with diverse linguistic and cultural backgrounds;

(7) offer appropriate postsuicide intervention services, care, and information to families, friends, schools, educational institutions, juvenile justice systems, substance abuse programs, mental health programs, foster care systems, and other child and youth support organizations of youth who recently completed suicide;

(8) offer continuous and up-to-date information and awareness campaigns that target parents, family members, child care professionals, community care providers, and the general public and highlight the risk factors associated with youth suicide and the life-saving help and care available from early intervention and prevention services;

(9) ensure that information and awareness campaigns on youth suicide risk factors, and early intervention and prevention services, use effective communication mechanisms that are targeted to and reach youth, families, schools, educational institutions, and youth organizations;

(10) provide a timely response system to ensure that child-serving professionals and providers are properly trained in youth suicide early intervention and prevention strategies and that child-serving professionals and providers involved in early intervention and prevention services are properly trained in effectively identifying youth who are at risk for suicide;

(11) provide continuous training activities for child care professionals and community care providers on the latest youth suicide early intervention and prevention services practices and strategies;

(12) conduct annual self-evaluations of outcomes and activities, including consulting with interested families and advocacy organizations;

(13) provide services in areas or regions with rates of youth suicide that exceed the national average as determined by the Centers for Disease Control and Prevention; and

(14) obtain informed written consent from a parent or legal guardian of an at-risk child before involving the child in a youth suicide early intervention and prevention program.

(d) REQUIREMENT FOR DIRECT SERVICES.—Not less than 85 percent of grant funds received under this section shall be used to provide direct services, of which not less than 5 percent shall be used for activities authorized under subsection (a)(3).

(e) COORDINATION AND COLLABORATION.—

(1) IN GENERAL.—In carrying out this section, the Secretary shall collaborate with relevant Federal agencies and suicide working groups responsible for early intervention and prevention services relating to youth suicide.

(2) CONSULTATION.—In carrying out this section, the Secretary shall consult with—

(A) State and local agencies, including agencies responsible for early intervention and prevention services under title XIX of the Social Security Act, the State Children's Health Insurance Program under title XXI of the Social Security Act, and programs funded by grants under title V of the Social Security Act;

(B) local and national organizations that serve youth at risk for suicide and their families;

(C) relevant national medical and other health and education specialty organizations;

(D) youth who are at risk for suicide, who have survived suicide attempts, or who are currently receiving care from early intervention services;

(E) families and friends of youth who are at risk for suicide, who have survived suicide attempts, who are currently receiving care from early intervention and prevention services, or who have completed suicide;

(F) qualified professionals who possess the specialized knowledge, skills, experience, and relevant attributes

needed to serve youth at risk for suicide and their families; and

(G) third-party payers, managed care organizations, and related commercial industries.

(3) POLICY DEVELOPMENT.—In carrying out this section, the Secretary shall—

(A) coordinate and collaborate on policy development at the Federal level with the relevant Department of Health and Human Services agencies and suicide working groups; and

(B) consult on policy development at the Federal level with the private sector, including consumer, medical, suicide prevention advocacy groups, and other health and education professional-based organizations, with respect to State-sponsored statewide or tribal youth suicide early intervention and prevention strategies.

(f) RULE OF CONSTRUCTION; RELIGIOUS AND MORAL ACCOMMODATION.—Nothing in this section shall be construed to require suicide assessment, early intervention, or treatment services for youth whose parents or legal guardians object based on the parents' or legal guardians' religious beliefs or moral objections.

(g) EVALUATIONS AND REPORT.—

(1) EVALUATIONS BY ELIGIBLE ENTITIES.—Not later than 18 months after receiving a grant or cooperative agreement under this section, an eligible entity shall submit to the Secretary the results of an evaluation to be conducted by the entity concerning the effectiveness of the activities carried out under the grant or agreement.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to the appropriate committees of Congress a report concerning the results of—

(A) the evaluations conducted under paragraph (1); and

(B) an evaluation conducted by the Secretary to analyze the effectiveness and efficacy of the activities conducted with grants, collaborations, and consultations under this section.

(h) RULE OF CONSTRUCTION; STUDENT MEDICATION.—Nothing in this section or section 520E–1 shall be construed to allow school personnel to require that a student obtain any medication as a condition of attending school or receiving services.

(i) PROHIBITION.—Funds appropriated to carry out this section, section 520C, section 520E–1, or section 520E–2 shall not be used to pay for or refer for abortion.

(j) PARENTAL CONSENT.—States and entities receiving funding under this section and section 520E–1 shall obtain prior written, informed consent from the child's parent or legal guardian for assessment services, school-sponsored programs, and treatment involving medication related to youth suicide conducted in elementary and secondary schools. The requirement of the preceding sentence does not apply in the following cases:

(1) In an emergency, where it is necessary to protect the immediate health and safety of the student or other students.

(2) Other instances, as defined by the State, where parental consent cannot reasonably be obtained.

(k) RELATION TO EDUCATION PROVISIONS.—Nothing in this section or section 520E–1 shall be construed to supersede section 444 of the General Education Provisions Act, including the requirement of prior parental consent for the disclosure of any education records. Nothing in this section or section 520E–1 shall be construed to modify or affect parental notification requirements for programs authorized under the Elementary and Secondary Education Act of 1965 (as amended by the No Child Left Behind Act of 2001; Public Law 107–110).

(l) DEFINITIONS.—In this section:

(1) EARLY INTERVENTION.—The term ''early intervention'' means a strategy or approach that is intended to prevent an outcome or to alter the course of an existing condition.

(2) EDUCATIONAL INSTITUTION; INSTITUTION OF HIGHER EDUCATION; SCHOOL.—The term—

(A) ''educational institution'' means a school or institution of higher education;

(B) ''institution of higher education'' has the meaning given such term in section 101 of the Higher Education Act of 1965; and

(C) ''school'' means an elementary or secondary school (as such terms are defined in section 9101 of the Elementary and Secondary Education Act of 1965).

(3) PREVENTION.—The term ''prevention'' means a strategy or approach that reduces the likelihood or risk of onset, or delays the onset, of adverse health problems that have been known to lead to suicide.

(4) YOUTH.—The term ''youth'' means individuals who are between 10 and 24 years of age.

(m) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $7,000,000 for fiscal year 2005, $18,000,000 for fiscal year 2006, and $30,000,000 for fiscal year 2007.

(2) PREFERENCE.—If less than $3,500,000 is appropriated for any fiscal year to carry out this section, in awarding grants and cooperative agreements under this section during the fiscal year, the Secretary shall give preference to States that have rates of suicide that significantly exceed the national average as determined by the Centers for Disease Control and Prevention.

SEC. 520E–1. [42 U.S.C. 290bb–36a] SUICIDE PREVENTION FOR CHILDREN AND ADOLESCENTS[28].

(a) IN GENERAL.—The Secretary shall award grants or cooperative agreements to public organizations, private nonprofit organizations, political subdivisions, consortia of political subdivisions, consortia of States, or Federally recognized Indian tribes or tribal organizations to design early intervention and prevention

[28] Section 3(b)(1) of Public Law 108–355 (118 Stat. 1407) provides for an amendment to section 520E (prior to its redesignation as section 520E–1) to strike ''CHILDREN AND ADOLESCENTS'' and insert ''YOUTH''. The amendment was not executed because it probably should have been made to strike ''**CHILDREN AND ADOLESCENTS**'' and insert ''**YOUTH**''.

strategies that will complement the State-sponsored statewide or tribal youth suicide early intervention and prevention strategies developed pursuant to section 520E.

(b) COLLABORATION.—In carrying out subsection (a), the Secretary shall ensure that activities under this section are coordinated with the relevant Department of Health and Human Services agencies and suicide working groups.

(c) REQUIREMENTS.—A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or federally recognized Indian tribe or tribal organization desiring a grant, contract, or cooperative agreement under this section shall demonstrate that the suicide prevention program such entity proposes will—

(1)(A) comply with the State-sponsored statewide early intervention and prevention strategy as developed under section 520E; and

(B) in the case of a consortium of States, receive the support of all States involved;

(2) provide for the timely assessment, treatment, or referral for mental health or substance abuse services of youth at risk for suicide;

(3) be based on suicide prevention practices and strategies that are adapted to the local community;

(4) integrate its suicide prevention program into the existing health care system in the community including general, mental, and behavioral health services, and substance abuse services;

(5) be integrated into other systems in the community that address the needs of youth including the school systems, educational institutions, juvenile justice system, substance abuse programs, mental health programs, foster care systems, and community child and youth support organizations;

(6) use primary prevention methods to educate and raise awareness in the local community by disseminating evidence-based information about suicide prevention;

(7) include suicide prevention, mental health, and related information and services for the families and friends of those who completed suicide, as needed;

(8) offer access to services and care to youth with diverse linguistic and cultural backgrounds;

(9) conduct annual self-evaluations of outcomes and activities, including consulting with interested families and advocacy organizations;[29]

(10) ensure that staff used in the program are trained in suicide prevention and that professionals involved in the system of care have received training in identifying persons at risk of suicide.

(d) USE OF FUNDS.—Amounts provided under a grant or cooperative agreement under this section shall be used to supplement, and not supplant, Federal and non-Federal funds available for carrying out the activities described in this section. Applicants shall provide financial information to demonstrate compliance with this section.

[29] So in law. Probably should include "and" after the semicolon at the end of paragraph (9).

(e) CONDITION.—An applicant for a grant or cooperative agreement under subsection (a) shall demonstrate to the Secretary that the application complies with the State-sponsored statewide early intervention and prevention strategy as developed under section 520E and the applicant has the support of the local community and relevant public health officials.

(f) SPECIAL POPULATIONS.—In awarding grants and cooperative agreements under subsection (a), the Secretary shall ensure that such awards are made in a manner that will focus on the needs of communities or groups that experience high or rapidly rising rates of suicide.

(g) APPLICATION.—A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or Federally recognized Indian tribe or tribal organization receiving a grant or cooperative agreement under subsection (a) shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require. Such application shall include a plan for the rigorous evaluation of activities funded under the grant or cooperative agreement, including a process and outcome evaluation.

(h) DISTRIBUTION OF AWARDS.—In awarding grants and cooperative agreements under subsection (a), the Secretary shall ensure that such awards are distributed among the geographical regions of the United States and between urban and rural settings.

(i) EVALUATION.—A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or Federally recognized Indian tribe or tribal organization receiving a grant or cooperative agreement under subsection (a) shall prepare and submit to the Secretary at the end of the program period, an evaluation of all activities funded under this section.

(j) DISSEMINATION AND EDUCATION.—The Secretary shall ensure that findings derived from activities carried out under this section are disseminated to State, county and local governmental agencies and public and private nonprofit organizations active in promoting suicide prevention and family support activities.

(k) DURATION OF PROJECTS.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award may be made to the recipient may not exceed 3 years.

(l) STUDY.—Within 1 year after the date of the enactment of this section, the Secretary shall, directly or by grant or contract, initiate a study to assemble and analyze data to identify—

(1) unique profiles of children under 13 who attempt or complete suicide;

(2) unique profiles of youths between ages 13 and 24 who attempt or complete suicide; and

(3) a profile of services available to these groups and the use of these services by children and youths from paragraphs (1) and (2).

(m) DEFINITIONS.—In this section, the terms "early intervention", "educational institution", "institution of higher education", "prevention", "school", and "youth" have the meanings given to those terms in section 520E.

(n) AUTHORIZATION OF APPROPRIATION.—For purposes of carrying out this section, there is authorized to be appropriated $75,000,000 for fiscal year 2001 and such sums as may be necessary for each of the fiscal years 2002 through 2003.

SEC. 520E–2. [42 U.S.C. 290bb–36b] MENTAL AND BEHAVIORAL HEALTH SERVICES ON CAMPUS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services, in consultation with the Secretary of Education, may award grants on a competitive basis to institutions of higher education to enhance services for students with mental and behavioral health problems that can lead to school failure, such as depression, substance abuse, and suicide attempts, so that students will successfully complete their studies.

(b) USE OF FUNDS.—The Secretary may not make a grant to an institution of higher education under this section unless the institution agrees to use the grant only for—

(1) educational seminars;

(2) the operation of hot lines;

(3) preparation of informational material;

(4) preparation of educational materials for families of students to increase awareness of potential mental and behavioral health issues of students enrolled at the institution of higher education;

(5) training programs for students and campus personnel to respond effectively to students with mental and behavioral health problems that can lead to school failure, such as depression, substance abuse, and suicide attempts; or

(6) the creation of a networking infrastructure to link colleges and universities that do not have mental health services with health care providers who can treat mental and behavioral health problems.

(c) ELIGIBLE GRANT RECIPIENTS.—Any institution of higher education receiving a grant under this section may carry out activities under the grant through—

(1) college counseling centers;

(2) college and university psychological service centers;

(3) mental health centers;

(4) psychology training clinics; or

(5) institution of higher education supported, evidence-based, mental health and substance abuse programs.

(d) APPLICATION.—An institution of higher education desiring a grant under this section shall prepare and submit an application to the Secretary at such time and in such manner as the Secretary may require. At a minimum, the application shall include the following:

(1) A description of identified mental and behavioral health needs of students at the institution of higher education.

(2) A description of Federal, State, local, private, and institutional resources currently available to address the needs described in paragraph (1) at the institution of higher education.

(3) A description of the outreach strategies of the institution of higher education for promoting access to services, including a proposed plan for reaching those students most in need of mental health services.

(4) A plan to evaluate program outcomes, including a description of the proposed use of funds, the program objectives, and how the objectives will be met.

(5) An assurance that the institution will submit a report to the Secretary each fiscal year on the activities carried out with the grant and the results achieved through those activities.

(e) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may make a grant under this section to an institution of higher education only if the institution agrees to make available (directly or through donations from public or private entities) non-Federal contributions in an amount that is not less than $1 for each $1 of Federal funds provided in the grant, toward the costs of activities carried out with the grant (as described in subsection (b)) and other activities by the institution to reduce student mental and behavioral health problems.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required under paragraph (1) may be in cash or in kind. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(3) WAIVER.—The Secretary may waive the requirement established in paragraph (1) with respect to an institution of higher education if the Secretary determines that extraordinary need at the institution justifies the waiver.

(f) REPORTS.—For each fiscal year that grants are awarded under this section, the Secretary shall conduct a study on the results of the grants and submit to the Congress a report on such results that includes the following:

(1) An evaluation of the grant program outcomes, including a summary of activities carried out with the grant and the results achieved through those activities.

(2) Recommendations on how to improve access to mental and behavioral health services at institutions of higher education, including efforts to reduce the incidence of suicide and substance abuse.

(g) DEFINITION.—In this section, the term ''institution of higher education'' has the meaning given such term in section 101 of the Higher Education Act of 1965.

(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2005, $5,000,000 for fiscal year 2006, and $5,000,000 for fiscal year 2007.

SEC. 520F. [42 U.S.C. 290bb–37] GRANTS FOR EMERGENCY MENTAL HEALTH CENTERS.

(a) PROGRAM AUTHORIZED.—The Secretary shall award grants to States, political subdivisions of States, Indian tribes, and tribal organizations to support the designation of hospitals and health centers as Emergency Mental Health Centers.

(b) HEALTH CENTER.—In this section, the term "health center" has the meaning given such term in section 330, and includes community health centers and community mental health centers.

(c) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that such grants awarded under subsection (a) are equitably distributed among the geographical regions of the United States, between urban and rural populations, and between different settings of care including health centers, mental health centers, hospitals, and other psychiatric units or facilities.

(d) APPLICATION.—A State, political subdivision of a State, Indian tribe, or tribal organization that desires a grant under subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the rigorous evaluation of activities carried out with funds received under this section.

(e) USE OF FUNDS.—

(1) IN GENERAL.—A State, political subdivision of a State, Indian tribe, or tribal organization receiving a grant under subsection (a) shall use funds from such grant to establish or designate hospitals and health centers as Emergency Mental Health Centers.

(2) EMERGENCY MENTAL HEALTH CENTERS.—Such Emergency Mental Health Centers described in paragraph (1)—

(A) shall—

(i) serve as a central receiving point in the community for individuals who may be in need of emergency mental health services;

(ii) purchase, if needed, any equipment necessary to evaluate, diagnose and stabilize an individual with a mental illness;

(iii) provide training, if needed, to the medical personnel staffing the Emergency Mental Health Center to evaluate, diagnose, stabilize, and treat an individual with a mental illness; and

(iv) provide any treatment that is necessary for an individual with a mental illness or a referral for such individual to another facility where such treatment may be received; and

(B) may establish and train a mobile crisis intervention team to respond to mental health emergencies within the community.

(f) EVALUATION.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) shall prepare and submit an evaluation to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including an evaluation of activities carried out with funds received under this section and a process and outcomes evaluation.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $25,000,000 for fiscal year 2001 and such sums as may be necessary for each of the fiscal years 2002 through 2003.

SEC. 520G. [42 U.S.C. 290bb–38] GRANTS FOR JAIL DIVERSION PROGRAMS.

(a) PROGRAM AUTHORIZED.—The Secretary shall make up to 125 grants to States, political subdivisions of States, Indian tribes, and tribal organizations, acting directly or through agreements with other public or nonprofit entities, to develop and implement programs to divert individuals with a mental illness from the criminal justice system to community-based services.

(b) ADMINISTRATION.—

(1) CONSULTATION.—The Secretary shall consult with the Attorney General and any other appropriate officials in carrying out this section.

(2) REGULATORY AUTHORITY.—The Secretary shall issue regulations and guidelines necessary to carry out this section, including methodologies and outcome measures for evaluating programs carried out by States, political subdivisions of States, Indian tribes, and tribal organizations receiving grants under subsection (a).

(c) APPLICATIONS.—

(1) IN GENERAL.—To receive a grant under subsection (a), the chief executive of a State, chief executive of a subdivision of a State, Indian tribe or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary shall reasonably require.

(2) CONTENT.—Such application shall—

(A) contain an assurance that—

(i) community-based mental health services will be available for the individuals who are diverted from the criminal justice system, and that such services are based on the best known practices, reflect current research findings, include case management, assertive community treatment, medication management and access, integrated mental health and co-occurring substance abuse treatment, and psychiatric rehabilitation, and will be coordinated with social services, including life skills training, housing placement, vocational training, education job placement, and health care;

(ii) there has been relevant interagency collaboration between the appropriate criminal justice, mental health, and substance abuse systems; and

(iii) the Federal support provided will be used to supplement, and not supplant, State, local, Indian tribe, or tribal organization sources of funding that would otherwise be available;

(B) demonstrate that the diversion program will be integrated with an existing system of care for those with mental illness;

(C) explain the applicant's inability to fund the program adequately without Federal assistance;

(D) specify plans for obtaining necessary support and continuing the proposed program following the conclusion of Federal support; and

(E) describe methodology and outcome measures that will be used in evaluating the program.

(d) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) may use funds received under such grant to—

(1) integrate the diversion program into the existing system of care;

(2) create or expand community-based mental health and co-occurring mental illness and substance abuse services to accommodate the diversion program;

(3) train professionals involved in the system of care, and law enforcement officers, attorneys, and judges; and

(4) provide community outreach and crisis intervention.

(e) FEDERAL SHARE.—

(1) IN GENERAL.—The Secretary shall pay to a State, political subdivision of a State, Indian tribe, or tribal organization receiving a grant under subsection (a) the Federal share of the cost of activities described in the application.

(2) FEDERAL SHARE.—The Federal share of a grant made under this section shall not exceed 75 percent of the total cost of the program carried out by the State, political subdivision of a State, Indian tribe, or tribal organization. Such share shall be used for new expenses of the program carried out by such State, political subdivision of a State, Indian tribe, or tribal organization.

(3) NON-FEDERAL SHARE.—The non-Federal share of payments made under this section may be made in cash or in kind fairly evaluated, including planned equipment or services. The Secretary may waive the requirement of matching contributions.

(f) GEOGRAPHIC DISTRIBUTION.—The Secretary shall ensure that such grants awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(g) TRAINING AND TECHNICAL ASSISTANCE.—Training and technical assistance may be provided by the Secretary to assist a State, political subdivision of a State, Indian tribe, or tribal organization receiving a grant under subsection (a) in establishing and operating a diversion program.

(h) EVALUATIONS.—The programs described in subsection (a) shall be evaluated not less than one time in every 12-month period using the methodology and outcome measures identified in the grant application.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003.

SEC. 520H. [42 U.S.C. 290bb–39] IMPROVING OUTCOMES FOR CHILDREN AND ADOLESCENTS THROUGH SERVICES INTEGRATION BETWEEN CHILD WELFARE AND MENTAL HEALTH SERVICES.

(a) IN GENERAL.—The Secretary shall award grants, contracts or cooperative agreements to States, political subdivisions of States, Indian tribes, and tribal organizations to provide integrated child

welfare and mental health services for children and adolescents under 19 years of age in the child welfare system or at risk for becoming part of the system, and parents or caregivers with a mental illness or a mental illness and a co-occurring substance abuse disorder.

(b) DURATION.—With respect to a grant, contract or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(c) APPLICATION.—

(1) IN GENERAL.—To be eligible to receive an award under subsection (a), a State, political subdivision of a State, Indian tribe, or tribal organization shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(2) CONTENT.—An application submitted under paragraph (1) shall—

(A) describe the program to be funded under the grant, contract or cooperative agreement;

(B) explain how such program reflects best practices in the provision of child welfare and mental health services; and

(C) provide assurances that—

(i) persons providing services under the grant, contract or cooperative agreement are adequately trained to provide such services; and

(ii) the services will be provided in accordance with subsection (d).

(d) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant, contract, or cooperative agreement under subsection (a) shall use amounts made available through such grant, contract or cooperative agreement to—

(1) provide family-centered, comprehensive, and coordinated child welfare and mental health services, including prevention, early intervention and treatment services for children and adolescents, and for their parents or caregivers;

(2) ensure a single point of access for such coordinated services;

(3) provide integrated mental health and substance abuse treatment for children, adolescents, and parents or caregivers with a mental illness and a co-occurring substance abuse disorder;

(4) provide training for the child welfare, mental health and substance abuse professionals who will participate in the program carried out under this section;

(5) provide technical assistance to child welfare and mental health agencies;

(6) develop cooperative efforts with other service entities in the community, including education, social services, juvenile justice, and primary health care agencies;

(7) coordinate services with services provided under the Medicaid program and the State Children's Health Insurance Program under titles XIX and XXI of the Social Security Act;

(8) provide linguistically appropriate and culturally competent services; and

(9) evaluate the effectiveness and cost-efficiency of the integrated services that measure the level of coordination, outcome measures for parents or caregivers with a mental illness or a mental illness and a co-occurring substance abuse disorder, and outcome measures for children.

(e) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that grants, contracts, and cooperative agreements awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(f) EVALUATION.—The Secretary shall evaluate each program carried out by a State, political subdivision of a State, Indian tribe, or tribal organization under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $10,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

SEC. 520I. [42 U.S.C. 290bb–40] GRANTS FOR THE INTEGRATED TREATMENT OF SERIOUS MENTAL ILLNESS AND CO-OCCURRING SUBSTANCE ABUSE.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to States, political subdivisions of States, Indian tribes, tribal organizations, and private nonprofit organizations for the development or expansion of programs to provide integrated treatment services for individuals with a serious mental illness and a co-occurring substance abuse disorder.

(b) PRIORITY.—In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall give priority to applicants that emphasize the provision of services for individuals with a serious mental illness and a co-occurring substance abuse disorder who—

(1) have a history of interactions with law enforcement or the criminal justice system;

(2) have recently been released from incarceration;

(3) have a history of unsuccessful treatment in either an inpatient or outpatient setting;

(4) have never followed through with outpatient services despite repeated referrals; or

(5) are homeless.

(c) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under subsection (a) shall use funds received under such grant—

(1) to provide fully integrated services rather than serial or parallel services;

(2) to employ staff that are cross-trained in the diagnosis and treatment of both serious mental illness and substance abuse;

(3) to provide integrated mental health and substance abuse services at the same location;

(4) to provide services that are linguistically appropriate and culturally competent;

(5) to provide at least 10 programs for integrated treatment of both mental illness and substance abuse at sites that previously provided only mental health services or only substance abuse services; and

(6) to provide services in coordination with other existing public and private community programs.

(d) CONDITION.—The Secretary shall ensure that a State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under subsection (a) maintains the level of effort necessary to sustain existing mental health and substance abuse programs for other populations served by mental health systems in the community.

(e) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that grants, contracts, or cooperative agreements awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(f) DURATION.—The Secretary shall award grants, contract, or cooperative agreements under this subsection for a period of not more than 5 years.

(g) APPLICATION.—A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that desires a grant, contract, or cooperative agreement under this subsection shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require. Such application shall include a plan for the rigorous evaluation of activities funded with an award under such subsection, including a process and outcomes evaluation.

(h) EVALUATION.—A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under this subsection shall prepare and submit a plan for the rigorous evaluation of the program funded under such grant, contract, or agreement, including both process and outcomes evaluation, and the submission of an evaluation at the end of the project period.

(i) AUTHORIZATION OF APPROPRIATION.—There is authorized to be appropriated to carry out this subsection $40,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003.

SEC. 520J. [42 U.S.C. 290bb–41] TRAINING GRANTS.

(a) IN GENERAL.—The Secretary shall award grants in accordance with the provisions of this section.

(b) MENTAL ILLNESS AWARENESS TRAINING GRANTS.—

(1) IN GENERAL.—The Secretary shall award grants to States, political subdivisions of States, Indian tribes, tribal organizations, and nonprofit private entities to train teachers and other relevant school personnel to recognize symptoms of childhood and adolescent mental disorders, to refer family members to the appropriate mental health services if necessary, to train

emergency services personnel to identify and appropriately respond to persons with a mental illness, and to provide education to such teachers and personnel regarding resources that are available in the community for individuals with a mental illness.

(2) EMERGENCY SERVICES PERSONNEL[30].—In this subsection, the term "emergency services personnel" includes paramedics, firefighters, and emergency medical technicians.

(3) DISTRIBUTION OF AWARDS[31].—The Secretary shall ensure that such grants awarded under this subsection are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(4) APPLICATION.—A State, political subdivision of a State, Indian tribe, tribal organization, or nonprofit private entity that desires a grant under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the rigorous evaluation of activities that are carried out with funds received under a grant under this subsection.

(5) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, tribal organization, or nonprofit private entity receiving a grant under this subsection shall use funds from such grant to—

(A) train teachers and other relevant school personnel to recognize symptoms of childhood and adolescent mental disorders and appropriately respond;

(B) train emergency services personnel to identify and appropriately respond to persons with a mental illness; and

(C) provide education to such teachers and personnel regarding resources that are available in the community for individuals with a mental illness.

(6) EVALUATION.—A State, political subdivision of a State, Indian tribe, tribal organization, or nonprofit private entity that receives a grant under this subsection shall prepare and submit an evaluation to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including an evaluation of activities carried out with funds received under the grant under this subsection and a process and outcome evaluation.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $25,000,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 through 2003.

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[30] So in law. Words in the heading (except the first) probably should be all small caps. See section 3213 of Public Law 106–310 (114 Stat. 1206).

[31] See footnote for paragraph (2).

PART C—PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS

SEC. 521. [42 U.S.C. 290cc–21] FORMULA GRANTS TO STATES.

For the purpose of carrying out section 522, the Secretary, acting through the Director of the Center for Mental Health Services, shall for each of the fiscal years 1991 through 1994[32] make an allotment for each State in an amount determined in accordance with section 524. The Secretary shall make payments, as grants, each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 529.

SEC. 522. [42 U.S.C. 290cc–22] PURPOSE OF GRANTS.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless the State involved agrees that the payments will be expended solely for making grants to political subdivisions of the State, and to nonprofit private entities (including community-based veterans organizations and other community organizations), for the purpose of providing the services specified in subsection (b) to individuals who—

(1)(A) are suffering from serious mental illness; or

(B) are suffering from serious mental illness and from substance abuse; and

(2) are homeless or at imminent risk of becoming homeless.

(b) SPECIFICATION OF SERVICES.—The services referred to in subsection (a) are—

(1) outreach services;

(2) screening and diagnostic treatment services;

(3) habilitation and rehabilitation services;

(4) community mental health services;

(5) alcohol or drug treatment services;

(6) staff training, including the training of individuals who work in shelters, mental health clinics, substance abuse programs, and other sites where homeless individuals require services;

(7) case management services, including—

(A) preparing a plan for the provision of community mental health services to the eligible homeless individual involved, and reviewing such plan not less than once every 3 months;

(B) providing assistance in obtaining and coordinating social and maintenance services for the eligible homeless individuals, including services relating to daily living activities, personal financial planning, transportation services, and habilitation and rehabilitation services, prevocational and vocational services, and housing services;

(C) providing assistance to the eligible homeless individual in obtaining income support services, including

[32] Probably should be "2001 through 2003". Section 3203(b) of Public Law 106–310 (114 Stat. 1191) amended section 535(a) of this act, which provides the authorization of appropriations for this part, by striking "1991 through 1994" and inserting "2001 through 2003". Such Public Law did not conform the reference in section 521 above.

housing assistance, food stamps, and supplemental security income benefits;

(D) referring the eligible homeless individual for such other services as may be appropriate; and

(E) providing representative payee services in accordance with section 1631(a)(2) of the Social Security Act if the eligible homeless individual is receiving aid under title XVI of such act and if the applicant is designated by the Secretary to provide such services;

(8) supportive and supervisory services in residential settings;

(9) referrals for primary health services, job training, educational services, and relevant housing services;

(10) subject to subsection (h)(1)—

(A) minor renovation, expansion, and repair of housing;

(B) planning of housing;

(C) technical assistance in applying for housing assistance;

(D) improving the coordination of housing services;

(E) security deposits;

(F) the costs associated with matching eligible homeless individuals with appropriate housing situations; and

(G) 1-time rental payments to prevent eviction; and

(11) other appropriate services, as determined by the Secretary.

(c) COORDINATION.—The Secretary may not make payments under section 521 unless the State involved agrees to make grants pursuant to subsection (a) only to entities that have the capacity to provide, directly or through arrangements, the services specified in section 522(b), including coordinating the provision of services in order to meet the needs of eligible homeless individuals who are both mentally ill and suffering from substance abuse.

(d) SPECIAL CONSIDERATION REGARDING VETERANS.—The Secretary may not make payments under section 521 unless the State involved agrees that, in making grants to entities pursuant to subsection (a), the State will give special consideration to entities with a demonstrated effectiveness in serving homeless veterans.

(e) SPECIAL RULES.—The Secretary may not make payments under section 521 unless the State involved agrees that grants pursuant to subsection (a) will not be made to any entity that—

(1) has a policy of excluding individuals from mental health services due to the existence or suspicion of substance abuse; or

(2) has a policy of excluding individuals from substance abuse services due to the existence or suspicion of mental illness.

(f) ADMINISTRATIVE EXPENSES.—The Secretary may not make payments under section 521 unless the State involved agrees that not more than 4 percent of the payments will be expended for administrative expenses regarding the payments.

(g) MAINTENANCE OF EFFORT.—The Secretary may not make payments under section 521 unless the State involved agrees that the State will maintain State expenditures for services specified in subsection (b) at a level that is not less than the average level of such

expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive such payments.

(h) RESTRICTIONS ON USE OF FUNDS.—The Secretary may not make payments under section 521 unless the State involved agrees that—

(1) not more than 20 percent of the payments will be expended for housing services under subsection (b)(10); and

(2) the payments will not be expended—

(A) to support emergency shelters or construction of housing facilities;

(B) for inpatient psychiatric treatment costs or inpatient substance abuse treatment costs; or

(C) to make cash payments to intended recipients of mental health or substance abuse services.

(i) WAIVER FOR TERRITORIES.—With respect to the United States Virgin Islands, Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, the Secretary may waive the provisions of this part that the Secretary determines to be appropriate.

SEC. 523. [42 U.S.C. 290cc–23] REQUIREMENT OF MATCHING FUNDS.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless, with respect to the costs of providing services pursuant to section 522, the State involved agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward such costs in an amount that is not less than $1 for each $3 of Federal funds provided in such payments.

(b) DETERMINATION OF AMOUNT.—Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, shall not be included in determining the amount of such non-Federal contributions.

(c) LIMITATION REGARDING GRANTS BY STATES.—The Secretary may not make payments under section 521 unless the State involved agrees that the State will not require the entities to which grants are provided pursuant to section 522(a) to provide non-Federal contributions in excess of the non-Federal contributions described in subsection (a).

SEC. 524. [42 U.S.C. 290cc–24] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) MINIMUM ALLOTMENT.—The allotment for a State under section 521 for a fiscal year shall be the greater of—

(1) $300,000 for each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, and $50,000 for each of Guam, the Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands; and

(2) an amount determined in accordance with subsection (b).

(b) DETERMINATION UNDER FORMULA.—The amount referred to in subsection (a)(2) is the product of—

(1) an amount equal to the amount appropriated under section 535(a) for the fiscal year; and

(2) a percentage equal to the quotient of—

(A) an amount equal to the population living in urbanized areas of the State involved, as indicated by the most recent data collected by the Bureau of the Census; and

(B) an amount equal to the population living in urbanized areas of the United States, as indicated by the sum of the respective amounts determined for the States under subparagraph (A).

SEC. 525. [42 U.S.C. 290cc–25] CONVERSION TO CATEGORICAL PROGRAM IN EVENT OF FAILURE OF STATE REGARDING EXPENDITURE OF GRANTS.

(a) IN GENERAL.—Subject to subsection (c), the Secretary shall, from the amounts specified in subsection (b), make grants to public and nonprofit private entities for the purpose of providing to eligible homeless individuals the services specified in section 522(b).

(b)[33] SPECIFICATION OF FUNDS.—The amounts referred to in subsection (a) are any amounts made available in appropriations Acts for allotments under section 521 that are not paid to a State as a result of—

(A) the failure of the State to submit an application under section 529;

(B) the failure of the State, in the determination of the Secretary, to prepare the application in accordance with such section or to submit the application within a reasonable period of time; or

(C) the State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State.

(c) REQUIREMENT OF PROVISION OF SERVICES IN STATE INVOLVED.—With respect to grants under subsection (a), amounts made available under subsection (b) as a result of the State involved shall be available only for grants to provide services in such State.

SEC. 526. [42 U.S.C. 290cc–26] PROVISION OF CERTAIN INFORMATION FROM STATE.

The Secretary may not make payments under section 521 to a State unless, as part of the application required in section 529, the State submits to the Secretary a statement—

(1) identifying existing programs providing services and housing to eligible homeless individuals and identify gaps in the delivery systems of such programs;

(2) containing a plan for providing services and housing to eligible homeless individuals, which plan—

(A) describes the coordinated and comprehensive means of providing services and housing to homeless individuals; and

(B) includes documentation that suitable housing for eligible homeless individuals will accompany the provision of services to such individuals;

(3) describes the source of the non-Federal contributions described in section 523;

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[33] So in law. Subparagraphs (A) through (C) probably should be redesignated as paragraphs (1) through (3), respectively. See section 511 of Public Law 104–645 (104 Stat. 4729).

(4) contains assurances that the non-Federal contributions described in section 523 will be available at the beginning of the grant period;

(5) describe any voucher system that may be used to carry out this part; and

(6) contain such other information or assurances as the Secretary may reasonably require.

SEC. 527. [42 U.S.C. 290cc–27] DESCRIPTION OF INTENDED EXPENDITURES OF GRANT.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless—

(1) as part of the application required in section 529, the State involved submits to the Secretary a description of the intended use for the fiscal year of the amounts for which the State is applying pursuant to such section;

(2) such description identifies the geographic areas within the State in which the greatest numbers of homeless individuals with a need for mental health, substance abuse, and housing services are located;

(3) such description provides information relating to the programs and activities to be supported and services to be provided, including information relating to coordinating such programs and activities with any similar programs and activities of public and private entities; and

(4) the State agrees that such description will be revised throughout the year as may be necessary to reflect substantial changes in the programs and activities assisted by the State pursuant to section 522.

(b) OPPORTUNITY FOR PUBLIC COMMENT.—The Secretary may not make payments under section 521 unless the State involved agrees that, in developing and carrying out the description required in subsection (a), the State will provide public notice with respect to the description (including any revisions) and such opportunities as may be necessary to provide interested persons, such as family members, consumers, and mental health, substance abuse, and housing agencies, an opportunity to present comments and recommendations with respect to the description.

(c) RELATIONSHIP TO STATE COMPREHENSIVE MENTAL HEALTH SERVICES PLAN.—

(1) IN GENERAL.—The Secretary may not make payments under section 521 unless the services to be provided pursuant to the description required in subsection (a) are consistent with the State comprehensive mental health services plan required in subpart 2 of part B of title XIX.

(2) SPECIAL RULE.—The Secretary may not make payments under section 521 unless the services to be provided pursuant to the description required in subsection (a) have been considered in the preparation of, have been included in, and are consistent with, the State comprehensive mental health services plan referred to in paragraph (1).

SEC. 528. [42 U.S.C. 290cc–28] REQUIREMENT OF REPORTS BY STATES.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless the State involved agrees that, by not later than

January 31 of each fiscal year, the State will prepare and submit to the Secretary a report in such form and containing such information as the Secretary determines (after consultation with the Administrator of the Substance Abuse and Mental Health Services Administration) to be necessary for—

(1) securing a record and a description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts; and

(2) determining whether such amounts were expended in accordance with the provisions of this part.

(b) AVAILABILITY TO PUBLIC OF REPORTS.—The Secretary may not make payments under section 521 unless the State involved agrees to make copies of the reports described in subsection (a) available for public inspection.

(c) EVALUATIONS BY COMPTROLLER GENERAL.—The Administrator of the Substance Abuse and Mental Health Services Administration shall evaluate at least once every 3 years the expenditures of grants under this part by eligible entities in order to ensure that expenditures are consistent with the provisions of this part, and shall include in such evaluation recommendations regarding changes needed in program design or operations.

SEC. 529. [42 U.S.C. 290cc–29] REQUIREMENT OF APPLICATION.

The Secretary may not make payments under section 521 unless the State involved—

(1) submits to the Secretary an application for the payments containing agreements and information in accordance with this part;

(2) the agreements are made through certification from the chief executive officer of the State; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

SEC. 530. [42 U.S.C. 290cc–30] TECHNICAL ASSISTANCE.

The Secretary, through[34] the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse, shall provide technical assistance to eligible entities in developing planning and operating programs in accordance with the provisions of this part.

SEC. 531. [42 U.S.C. 290cc–31] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

[34] Section 162(2) of Public Law 102–321 (106 Stat. 375) provides that section 530 is amended by striking out "through the National" and all that follows through "Abuse" and inserting in lieu thereof "through the agencies of the Administration". The amendment cannot be executed because it does not specify to which instance of the term "Abuse" the amendment applies. Additionally, section 163(a)(3) of such law described an amendment that could not be executed, as the amendment included instructions to strike "on Alcohol Abuse" while "of Alcohol Abuse" is the term in section 530. This latter amendment attempted to insert "Administrator of the Substance Abuse and Mental Health Services Administration". Subsequently, such section 163(a)(3) was struck by section 2(b)(2) of Public Law 102–352 (106 Stat. 939).

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 521 that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 529.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 521.

(b) WITHHOLDING OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), withhold payments due under section 521 if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 529.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 521 in accordance with the agreements referred to in such paragraph.

(3) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the agreements referred to in such paragraph.

(c) OPPORTUNITY FOR HEARING.—Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing.

(d) RULE OF CONSTRUCTION.—Notwithstanding any other provision of this part, a State receiving payments under section 521 may not, with respect to any agreements required to be contained in the application submitted under section 529, be considered to be in violation of any such agreements by reason of the fact that the State, in the regular course of providing services under section 522(b) to eligible homeless individuals, incidentally provides services to homeless individuals who are not eligible homeless individuals.

SEC. 532. [42 U.S.C. 290cc–32] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—

(1) A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 521.

(2) A person with knowledge of the occurrence of any event affecting the right of the person to receive any amounts from payments made to the State under section 521 may not conceal or fail to disclose any such event with the intent of securing such an amount that the person is not authorized to receive or securing such an amount in an amount greater than the amount the person is authorized to receive.

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may

for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 533. [42 U.S.C. 290cc–33] NONDISCRIMINATION.

(a) IN GENERAL.—

(1) RULE OF CONSTRUCTION REGARDING CERTAIN CIVIL RIGHTS LAWS.—For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under section 521 shall be considered to be programs and activities receiving Federal financial assistance.

(2) PROHIBITION.—No person shall on the ground of sex or religion be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 521.

(b) ENFORCEMENT.—

(1) REFERRALS TO ATTORNEY GENERAL AFTER NOTICE.—Whenever the Secretary finds that a State, or an entity that has received a payment pursuant to section 521, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request the chief executive officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(A) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted;

(B) exercise the powers and functions provided by the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, title IX of the Education Amendments of 1972, or title VI of the Civil Rights Act of 1964, as may be applicable; or

(C) take such other actions as may be authorized by law.

(2) AUTHORITY OF ATTORNEY GENERAL.—When a matter is referred to the Attorney General pursuant to paragraph (1)(A), or whenever the Attorney General has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

SEC. 534. [42 U.S.C. 290cc–34] DEFINITIONS.

For purposes of this part:

(1) ELIGIBLE HOMELESS INDIVIDUAL.—The term ''eligible homeless individual'' means an individual described in section 522(a).

(2) HOMELESS INDIVIDUAL.—The term ''homeless individual'' has the meaning given such term in section 330(h)(5).

(3) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(4) SUBSTANCE ABUSE.—The term ''substance abuse'' means the abuse of alcohol or other drugs.

SEC. 535. [42 U.S.C. 290cc–35] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there is authorized to be appropriated $75,000,000 for each of the fiscal years 2001 through 2003.

(b) EFFECT OF INSUFFICIENT APPROPRIATIONS FOR MINIMUM ALLOTMENTS.—

(1) IN GENERAL.—If the amounts made available under subsection (a) for a fiscal year are insufficient for providing each State with an allotment under section 521 of not less than the applicable amount under section 524(a)(1), the Secretary shall, from such amounts as are made available under such subsection, make grants to the States for providing to eligible homeless individuals the services specified in section 522(b).

(2) RULE OF CONSTRUCTION.—Paragraph (1) may not be construed to require the Secretary to make a grant under such paragraph to each State.

PART D—MISCELLANEOUS PROVISIONS RELATING TO SUBSTANCE ABUSE AND MENTAL HEALTH

SEC. 541. [42 U.S.C. 290dd] SUBSTANCE ABUSE AMONG GOVERNMENT AND OTHER EMPLOYEES.

(a) PROGRAMS AND SERVICES.—

(1) DEVELOPMENT.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall be responsible for fostering substance abuse prevention and treatment programs and services in State and local governments and in private industry.

(2) MODEL PROGRAMS.—

(A) IN GENERAL.—Consistent with the responsibilities described in paragraph (1), the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall develop a variety of model programs suitable for replication on a cost-effective basis in different types of business concerns and State and local governmental entities.

(B) DISSEMINATION OF INFORMATION.—The Secretary, acting through the Administrator of the Substance Abuse

and Mental Health Services Administration, shall disseminate information and materials relative to such model programs to the State agencies responsible for the administration of substance abuse prevention, treatment, and rehabilitation activities and shall, to the extent feasible provide technical assistance to such agencies as requested.

(b) DEPRIVATION OF EMPLOYMENT.—

(1) PROHIBITION.—No person may be denied or deprived of Federal civilian employment or a Federal professional or other license or right solely on the grounds of prior substance abuse.

(2) APPLICATION.—This subsection shall not apply to employment in—

(A) the Central Intelligence Agency;

(B) the Federal Bureau of Investigation;

(C) the National Security Agency;

(D) any other department or agency of the Federal Government designated for purposes of national security by the President; or

(E) in any position in any department or agency of the Federal Government, not referred to in subparagraphs (A) through (D), which position is determined pursuant to regulations prescribed by the head of such agency or department to be a sensitive position.

(3) REHABILITATION ACT.—The inapplicability of the prohibition described in paragraph (1) to the employment described in paragraph (2) shall not be construed to reflect on the applicability of the Rehabilitation Act of 1973 or other anti-discrimination laws to such employment.

(c) CONSTRUCTION.—This section shall not be construed to prohibit the dismissal from employment of a Federal civilian employee who cannot properly function in his employment.

SEC. 542. [42 U.S.C. 290dd–1] ADMISSION OF SUBSTANCE ABUSERS TO PRIVATE AND PUBLIC HOSPITALS AND OUTPATIENT FACILITIES.

(a) NONDISCRIMINATION.—Substance abusers who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their substance abuse, by any private or public general hospital, or outpatient facility (as defined in section 1624(4)) which receives support in any form from any program supported in whole or in part by funds appropriated to any Federal department or agency.

(b) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall issue regulations for the enforcement of the policy of subsection (a) with respect to the admission and treatment of substance abusers in hospitals and outpatient facilities which receive support of any kind from any program administered by the Secretary. Such regulations shall include procedures for determining (after opportunity for a hearing if requested) if a violation of subsection (a) has occurred, notification of failure to comply with such subsection, and opportunity for a violator to comply with such subsection. If the Secretary determines that a hospital or outpatient facility subject to such regulations has violated subsection (a) and such violation continues after an opportunity

has been afforded for compliance, the Secretary may suspend or revoke, after opportunity for a hearing, all or part of any support of any kind received by such hospital from any program administered by the Secretary. The Secretary may consult with the officials responsible for the administration of any other Federal program from which such hospital or outpatient facility receives support of any kind, with respect to the suspension or revocation of such other Federal support for such hospital or outpatient facility.

(2) DEPARTMENT OF VETERANS AFFAIRS.—The Secretary of Veterans Affairs, acting through the Under Secretary for Health, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary under paragraph (1) to the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance abuse. In prescribing and implementing regulations pursuant to this paragraph, the Secretary shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

SEC. 543. [42 U.S.C. 290dd–2] CONFIDENTIALITY OF RECORDS.

(a) REQUIREMENT.—Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b).

(b) PERMITTED DISCLOSURE.—

(1) CONSENT.—The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) METHOD FOR DISCLOSURE.—Whether or not the patient, with respect to whom any given record referred to in subsection (a) is maintained, gives written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) USE OF RECORDS IN CRIMINAL PROCEEDINGS.—Except as authorized by a court order granted under subsection (b)(2)(C), no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) APPLICATION.—The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when such individual ceases to be a patient.

(e) NONAPPLICABILITY.—The prohibitions of this section do not apply to any interchange of records—

(1) within the Uniformed Services or within those components of the Department of Veterans Affairs furnishing health care to veterans; or

(2) between such components and the Uniformed Services.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) PENALTIES.—Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with title 18, United States Code.

(g) REGULATIONS.—Except as provided in subsection (h), the Secretary shall prescribe regulations to carry out the purposes of this section. Such regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) APPLICATION TO DEPARTMENT OF VETERANS AFFAIRS.—The Secretary of Veterans Affairs, acting through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary of Health and Human Services under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance abuse. In prescribing and implementing regulations pursuant to this subsection, the Secretary of Veterans Affairs shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

PART E—CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES

SEC. 561. [42 U.S.C. 290ff] COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES.

(a) GRANTS TO CERTAIN PUBLIC ENTITIES.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services, shall make grants to public entities for the purpose of providing comprehensive community mental health services to children with a serious emotional disturbance.

(2) DEFINITION OF PUBLIC ENTITY.—For purposes of this part, the term "public entity" means any State, any political subdivision of a State, and any Indian tribe or tribal organization (as defined in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act).

(b) CONSIDERATIONS IN MAKING GRANTS.—

(1) REQUIREMENT OF STATUS AS GRANTEE UNDER PART B OF TITLE XIX.—The Secretary may make a grant under subsection (a) to a public entity only if—

(A) in the case of a public entity that is a State, the State is such a grantee under section 1911;

(B) in the case of a public entity that is a political subdivision of a State, the State in which the political subdivision is located is such a grantee; and

(C) in the case of a public entity that is an Indian tribe or tribal organization, the State in which the tribe or tribal organization is located is such a grantee.

(2) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under subsection (a) only if, in the case of any service under such subsection that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the public entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the public entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under subsection (a), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a

waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(3) CERTAIN CONSIDERATIONS.—In making grants under subsection (a), the Secretary shall—

(A) equitably allocate such assistance among the principal geographic regions of the United States;

(B) consider the extent to which the public entity involved has a need for the grant; and

(C) in the case of any public entity that is a political subdivision of a State or that is an Indian tribe or tribal organization—

(i) shall consider any comments regarding the application of the entity for such a grant that are received by the Secretary from the State in which the entity is located; and

(ii) shall give special consideration to the entity if the State agrees to provide a portion of the non-Federal contributions required in subsection (c) regarding such a grant.

(c) MATCHING FUNDS.—

(1) IN GENERAL.—A funding agreement for a grant under subsection (a) is that the public entity involved will, with respect to the costs to be incurred by the entity in carrying out the purpose described in such subsection, make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that—

(A) for the first fiscal year for which the entity receives payments from a grant under such subsection, is not less than $1 for each $3 of Federal funds provided in the grant;

(B) for any second or third such fiscal year, is not less than $1 for each $3 of Federal funds provided in the grant;

(C) for any fourth such fiscal year, is not less than $1 for each $1 of Federal funds provided in the grant; and

(D) for any fifth and sixth such fiscal year, is not less than $2 for each $1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) In making a determination of the amount of non-Federal contributions for purposes of subparagraph (A), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the public entity involved toward the purpose described in subsection (a) for the 2-year period preceding the first fiscal year for which the entity receives a grant under such section.

SEC. 562. [42 U.S.C. 290ff–1] REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.

(a) SYSTEMS OF COMPREHENSIVE CARE.—

(1) IN GENERAL.—A funding agreement for a grant under section 561(a) is that, with respect to children with a serious emotional disturbance, the public entity involved will carry out the purpose described in such section only through establishing and operating 1 or more systems of care for making each of the mental health services specified in subsection (c) available to each child provided access to the system. In providing for such a system, the public entity may make grants to, and enter into contracts with, public and nonprofit private entities.

(2) STRUCTURE OF SYSTEM.—A funding agreement for a grant under section 561(a) is that a system of care under paragraph (1) will—

(A) be established in a community selected by the public entity involved;

(B) consist of such public agencies and nonprofit private entities in the community as are necessary to ensure that each of the services specified in subsection (c) is available to each child provided access to the system;

(C) be established pursuant to agreements that the public entity enters into with the agencies and entities described in subparagraph (B);

(D) coordinate the provision of the services of the system; and

(E) establish an office whose functions are to serve as the location through which children are provided access to the system, to coordinate the provision of services of the system, and to provide information to the public regarding the system.

(3) COLLABORATION OF LOCAL PUBLIC ENTITIES.—A funding agreement for a grant under section 561(a) is that, for purposes of the establishment and operation of a system of care under paragraph (1), the public entity involved will seek collaboration among all public agencies that provide human services in the community in which the system is established, including but not limited to those providing mental health services, educational services, child welfare services, or juvenile justice services.

(b) LIMITATION ON AGE OF CHILDREN PROVIDED ACCESS TO SYSTEM.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a) will not provide an individual with access to the system if the individual is more than 21 years of age.

(c) REQUIRED MENTAL HEALTH SERVICES OF SYSTEM.—A funding agreement for a grant under section 561(a) is that mental health services provided by a system of care under subsection (a) will include, with respect to a serious emotional disturbance in a child—

(1) diagnostic and evaluation services;

(2) outpatient services provided in a clinic, office, school or other appropriate location, including individual, group and family counseling services, professional consultation, and review and management of medications;

(3) emergency services, available 24-hours a day, 7 days a week;

(4) intensive home-based services for children and their families when the child is at imminent risk of out-of-home placement;

(5) intensive day-treatment services;

(6) respite care;

(7) therapeutic foster care services, and services in therapeutic foster family homes or individual therapeutic residential homes, and groups homes caring for not more than 10 children; and

(8) assisting the child in making the transition from the services received as a child to the services to be received as an adult.

(d) REQUIRED ARRANGEMENTS REGARDING OTHER APPROPRIATE SERVICES.—

(1) IN GENERAL.—A funding agreement for a grant under section 561(a) is that—

(A) a system of care under subsection (a) will enter into a memorandum of understanding with each of the providers specified in paragraph (2) in order to facilitate the availability of the services of the provider involved to each child provided access to the system; and

(B) the grant under such section 561(a), and the non-Federal contributions made with respect to the grant, will not be expended to pay the costs of providing such non-mental health services to any individual.

(2) SPECIFICATION OF NON-MENTAL HEALTH SERVICES.—The providers referred to in paragraph (1) are providers of medical services other than mental health services, providers of educational services, providers of vocational counseling and vocational rehabilitation services, and providers of protection and advocacy services with respect to mental health.

(3) FACILITATION OF SERVICES OF CERTAIN PROGRAMS.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a) will, for purposes of paragraph (1), enter into a memorandum of understanding regarding facilitation of—

(A) services available pursuant to title XIX of the Social Security Act, including services regarding early periodic screening, diagnosis, and treatment;

(B) services available under parts B and C of the Individuals with Disabilities Education Act; and

(C) services available under other appropriate programs, as identified by the Secretary.

(e) GENERAL PROVISIONS REGARDING SERVICES OF SYSTEM.—

(1) CASE MANAGEMENT SERVICES.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a) will provide for the case management of each child provided access to the system in order to ensure that—

(A) the services provided through the system to the child are coordinated and that the need of each such child for the services is periodically reassessed;

(B) information is provided to the family of the child on the extent of progress being made toward the objectives established for the child under the plan of services implemented for the child pursuant to section 563; and

(C) the system provides assistance with respect to—

(i) establishing the eligibility of the child, and the family of the child, for financial assistance and services under Federal, State, or local programs providing for health services, mental health services, educational services, social services, or other services; and

(ii) seeking to ensure that the child receives appropriate services available under such programs.

(2) OTHER PROVISIONS.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a), in providing the services of the system, will—

(A) provide the services of the system in the cultural context that is most appropriate for the child and family involved;

(B) ensure that individuals providing such services to the child can effectively communicate with the child and family in the most direct manner;

(C) provide the services without discriminating against the child or the family of the child on the basis of race, religion, national origin, sex, disability, or age;

(D) seek to ensure that each child provided access to the system of care remains in the least restrictive, most normative environment that is clinically appropriate; and

(E) provide outreach services to inform individuals, as appropriate, of the services available from the system, including identifying children with a serious emotional disturbance who are in the early stages of such disturbance.

(3) RULE OF CONSTRUCTION.—An agreement made under paragraph (2) may not be construed—

(A) with respect to subparagraph (C) of such paragraph—

(i) to prohibit a system of care under subsection (a) from requiring that, in housing provided by the grantee for purposes of residential treatment services authorized under subsection (c), males and females be segregated to the extent appropriate in the treatment of the children involved; or

(ii) to prohibit the system of care from complying with the agreement made under subsection (b); or

(B) with respect to subparagraph (D) of such paragraph, to authorize the system of care to expend the grant under section 561(a) (or the non-Federal contributions made with respect to the grant) to provide legal services or any service with respect to which expenditures regarding the grant are prohibited under subsection (d)(1)(B).

(f) RESTRICTIONS ON USE OF GRANT.—A funding agreement for a grant under section 561(a) is that the grant, and the non-Federal contributions made with respect to the grant, will not be expended—

(1) to purchase or improve real property (including the construction or renovation of facilities);

(2) to provide for room and board in residential programs serving 10 or fewer children;

(3) to provide for room and board or other services or expenditures associated with care of children in residential treatment centers serving more than 10 children or in inpatient hospital settings, except intensive home-based services and other services provided on an ambulatory or outpatient basis; or

(4) to provide for the training of any individual, except training authorized in section 564(a)(2) and training provided through any appropriate course in continuing education whose duration does not exceed 2 days.

(g) WAIVERS.—The Secretary may waive one or more of the requirements of subsection (c) for a public entity that is an Indian Tribe or tribal organization, or American Samoa, Guam, the Marshall Islands, the Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, or the United States Virgin Islands if the Secretary determines, after peer review, that the system of care is family-centered and uses the least restrictive environment that is clinically appropriate.

SEC. 563. [42 U.S.C. 290ff–2] INDIVIDUALIZED PLAN FOR SERVICES.

(a) IN GENERAL.—A funding agreement for a grant under section 561(a) is that a system of care under section 562(a) will develop and carry out an individualized plan of services for each child provided access to the system, and that the plan will be developed and carried out with the participation of the family of the child and, unless clinically inappropriate, with the participation of the child.

(b) MULTIDISCIPLINARY TEAM.—A funding agreement for a grant under section 561(a) is that the plan required in subsection (a) will be developed, and reviewed and as appropriate revised not less than once each year, by a multidisciplinary team of appropriately qualified individuals who provide services through the system, including as appropriate mental health services, other health services, educational services, social services, and vocational counseling and rehabilitation;[35]

(c) COORDINATION WITH SERVICES UNDER INDIVIDUALS WITH DISABILITIES EDUCATION ACT.—A funding agreement for a grant under section 561(a) is that, with respect to a plan under subsection (a) for a child, the multidisciplinary team required in subsection (b) will—

(1) in developing, carrying out, reviewing, and revising the plan consider any individualized education program in effect for the child pursuant to part B of the Individuals with Disabilities Education Act;

(2) ensure that the plan is consistent with such individualized education program and provides for coordinating services under the plan with services under such program; and

(3) ensure that the memorandum of understanding entered into under section 562(d)(3)(B) regarding such Act includes provisions regarding compliance with this subsection.

[35] So in law. See section 119 of Public Law 102–321 (106 Stat. 349). Probably should be a period.

(d) CONTENTS OF PLAN.—A funding agreement for a grant under section 561(a) is that the plan required in subsection (a) for a child will—

(1) identify and state the needs of the child for the services available pursuant to section 562 through the system;

(2) provide for each of such services that is appropriate to the circumstances of the child, including, except in the case of children who are less than 14 years of age, the provision of appropriate vocational counseling and rehabilitation, and transition services (as defined in section 602 of the Individuals with Disabilities Education Act);

(3) establish objectives to be achieved regarding the needs of the child and the methodology for achieving the objectives; and

(4) designate an individual to be responsible for providing the case management required in section 562(e)(1) or certify that case management services will be provided to the child as part of the individualized education program of the child under the Individuals with Disabilities Education Act.

SEC. 564. [42 U.S.C. 290ff–3] ADDITIONAL PROVISIONS.

(a) OPTIONAL SERVICES.—In addition to services described in subsection (c) of section 562, a system of care under subsection (a) of such section may, in expending a grant under section 561(a), provide for—

(1) preliminary assessments to determine whether a child should be provided access to the system;

(2) training in—

(A) the administration of the system;

(B) the provision of intensive home-based services under paragraph (4) of section 562(c), intensive day treatment under paragraph (5) of such section, and foster care or group homes under paragraph (7) of such section; and

(C) the development of individualized plans for purposes of section 563;

(3) recreational activities for children provided access to the system; and

(4) such other services as may be appropriate in providing for the comprehensive needs with respect to mental health of children with a serious emotional disturbance.

(b) COMPREHENSIVE PLAN.—The Secretary may make a grant under section 561(a) only if, with respect to the jurisdiction of the public entity involved, the entity has submitted to the Secretary, and has had approved by the Secretary, a plan for the development of a jurisdiction-wide system of care for community-based services for children with a serious emotional disturbance that specifies the progress the public entity has made in developing the jurisdiction-wide system, the extent of cooperation across agencies serving children in the establishment of the system, the Federal and non-Federal resources currently committed to the establishment of the system, and the current gaps in community services and the manner in which the grant under section 561(a) will be expended to address such gaps and establish local systems of care.

(c) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—A funding agreement for a grant under section 561(a) is that, if a charge is

imposed for the provision of services under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the family of the child involved; and

(3) will not be imposed on any child whose family has income and resources of equal to or less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(d) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—A funding agreement for a grant under section 561(a) is that the grant, and the non-Federal contributions made with respect to the grant, will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) LIMITATION ON ADMINISTRATIVE EXPENSES.—A funding agreement for a grant under section 561(a) is that not more than 2 percent of the grant will be expended for administrative expenses incurred with respect to the grant by the public entity involved.

(f) REPORTS TO SECRETARY.—A funding agreement for a grant under section 561(a) is that the public entity involved will annually submit to the Secretary a report on the activities of the entity under the grant that includes a description of the number of children provided access to systems of care operated pursuant to the grant, the demographic characteristics of the children, the types and costs of services provided pursuant to the grant, the availability and use of third-party reimbursements, estimates of the unmet need for such services in the jurisdiction of the entity, and the manner in which the grant has been expended toward the establishment of a jurisdiction-wide system of care for children with a serious emotional disturbance, and such other information as the Secretary may require with respect to the grant.

(g) DESCRIPTION OF INTENDED USES OF GRANT.—The Secretary may make a grant under section 561(a) only if—

(1) the public entity involved submits to the Secretary a description of the purposes for which the entity intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the jurisdiction of the entity with a need for services under this section; and

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprofit entities.

(h) REQUIREMENT OF APPLICATION.—The Secretary may make a grant under section 561(a) only if an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in subsection (g), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 565. [42 U.S.C. 290ff–4] GENERAL PROVISIONS.

(a) DURATION OF SUPPORT.—The period during which payments are made to a public entity from a grant under section 561(a) may not exceed 6 fiscal years.

(b) TECHNICAL ASSISTANCE.—

(1) IN GENERAL.—The Secretary shall, upon the request of a public entity receiving a grant under section 561(a)—

(A) provide technical assistance to the entity regarding the process of submitting to the Secretary applications for grants under section 561(a); and

(B) provide to the entity training and technical assistance with respect to the planning, development, and operation of systems of care pursuant to section 562.

(2) AUTHORITY FOR GRANTS AND CONTRACTS.—The Secretary may provide technical assistance under subsection (a) directly or through grants to, or contracts with, public and nonprofit private entities.

(c) EVALUATIONS AND REPORTS BY SECRETARY.—

(1) IN GENERAL.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 561(a). The evaluations shall assess the effectiveness of the systems of care operated pursuant to such section, including longitudinal studies of outcomes of services provided by such systems, other studies regarding such outcomes, the effect of activities under this part on the utilization of hospital and other institutional settings, the barriers to and achievements resulting from interagency collaboration in providing community-based services to children with a serious emotional disturbance, and assessments by parents of the effectiveness of the systems of care.

(2) REPORT TO CONGRESS.—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated under subsection (c), and annually thereafter, submit to the Congress a report summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this section as the Secretary determines to be appropriate.

(d) DEFINITIONS.—For purposes of this part:

(1) The term "child" means an individual not more than 21 years of age.

(2) The term "family", with respect to a child provided access to a system of care under section 562(a), means—

(A) the legal guardian of the child; and

(B) as appropriate regarding mental health services for the child, the parents of the child (biological or adoptive, as the case may be) and any foster parents of the child.

(3) The term "funding agreement", with respect to a grant under section 561(a) to a public entity, means that the Secretary may make such a grant only if the public entity makes the agreement involved.

(4) The term "serious emotional disturbance" includes, with respect to a child, any child who has a serious emotional disorder, a serious behavioral disorder, or a serious mental disorder.

(e) RULE OF CONSTRUCTION.—Nothing in this part shall be construed as limiting the rights of a child with a serious emotional disturbance under the Individuals with Disabilities Education Act.

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2)[36] LIMITATION REGARDING TECHNICAL ASSISTANCE.—Not more than 10 percent of the amounts appropriated under paragraph (1) for a fiscal year may be expended for carrying out subsection (b).

PART F—MODEL COMPREHENSIVE PROGRAM FOR TREATMENT OF SUBSTANCE ABUSE[37]

PART G—PROJECTS FOR CHILDREN AND VIOLENCE

SEC. 581. [42 U.S.C. 290hh] CHILDREN AND VIOLENCE.

(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Education and the Attorney General, shall carry out directly or through grants, contracts or cooperative agreements with public entities a program to assist local communities in developing ways to assist children in dealing with violence.

(b) ACTIVITIES.—Under the program under subsection (a), the Secretary may—

(1) provide financial support to enable local communities to implement programs to foster the health and development of children;

(2) provide technical assistance to local communities with respect to the development of programs described in paragraph (1);

(3) provide assistance to local communities in the development of policies to address violence when and if it occurs;

(4) assist in the creation of community partnerships among law enforcement, education systems and mental health and substance abuse service systems; and

(5) establish mechanisms for children and adolescents to report incidents of violence or plans by other children or adolescents to commit violence.

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[36] Indentation is so in law. See section 2017(2)(C)(ii) of Public Law 103–43 (107 Stat. 218).

[37] The part designation and heading for part F are so in law. Part F formerly consisted of section 571. That section was repealed by section 3301(c)(4) of Public Law 106–310 (114 Stat. 1209), but there was no conforming amendment to strike the designation and heading for part F.

(c) REQUIREMENTS.—An application for a grant, contract or cooperative agreement under subsection (a) shall demonstrate that—

(1) the applicant will use amounts received to create a partnership described in subsection (b)(4) to address issues of violence in schools;

(2) the activities carried out by the applicant will provide a comprehensive method for addressing violence, that will include—

(A) security;

(B) educational reform;

(C) the review and updating of school policies;

(D) alcohol and drug abuse prevention and early intervention services;

(E) mental health prevention and treatment services; and

(F) early childhood development and psychosocial services; and

(3) the applicant will use amounts received only for the services described in subparagraphs (D), (E), and (F) of paragraph (2).

(d) GEOGRAPHICAL DISTRIBUTION.—The Secretary shall ensure that grants, contracts or cooperative agreements under subsection (a) will be distributed equitably among the regions of the country and among urban and rural areas.

(e) DURATION OF AWARDS.—With respect to a grant, contract or cooperative agreement under subsection (a), the period during which payments under such an award will be made to the recipient may not exceed 5 years.

(f) EVALUATION.—The Secretary shall conduct an evaluation of each project carried out under this section and shall disseminate the results of such evaluations to appropriate public and private entities.

(g) INFORMATION AND EDUCATION.—The Secretary shall establish comprehensive information and education programs to disseminate the findings of the knowledge development and application under this section to the general public and to health care professionals.

(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $100,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

SEC. 582. [42 U.S.C. 290hh–1] GRANTS TO ADDRESS THE PROBLEMS OF PERSONS WHO EXPERIENCE VIOLENCE RELATED STRESS.

(a) IN GENERAL.—The Secretary shall award grants, contracts or cooperative agreements to public and nonprofit private entities, as well as to Indian tribes and tribal organizations, for the purpose of developing programs focusing on the behavioral and biological aspects of psychological trauma response and for developing knowledge with regard to evidence-based practices for treating psychiatric disorders of children and youth resulting from witnessing or experiencing a traumatic event.

(b) PRIORITIES.—In awarding grants, contracts or cooperative agreements under subsection (a) related to the development of knowledge on evidence-based practices for treating disorders associated with psychological trauma, the Secretary shall give priority to

mental health agencies and programs that have established clinical and basic research experience in the field of trauma-related mental disorders.

(c) GEOGRAPHICAL DISTRIBUTION.—The Secretary shall ensure that grants, contracts or cooperative agreements under subsection (a) with respect to centers of excellence are distributed equitably among the regions of the country and among urban and rural areas.

(d) EVALUATION.—The Secretary, as part of the application process, shall require that each applicant for a grant, contract or cooperative agreement under subsection (a) submit a plan for the rigorous evaluation of the activities funded under the grant, contract or agreement, including both process and outcomes evaluation, and the submission of an evaluation at the end of the project period.

(e) DURATION OF AWARDS.—With respect to a grant, contract or cooperative agreement under subsection (a), the period during which payments under such an award will be made to the recipient may not exceed 5 years. Such grants, contracts or agreements may be renewed.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(g) SHORT TITLE.—This section may be cited as the ''Donald J. Cohen National Child Traumatic Stress Initiative''.

PART H—REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN FACILITIES

SEC. 591. [290ii] REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN FACILITIES.

(a) IN GENERAL.—A public or private general hospital, nursing facility, intermediate care facility, or other health care facility, that receives support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency shall protect and promote the rights of each resident of the facility, including the right to be free from physical or mental abuse, corporal punishment, and any restraints or involuntary seclusions imposed for purposes of discipline or convenience.

(b) REQUIREMENTS.—Restraints and seclusion may only be imposed on a resident of a facility described in subsection (a) if—

(1) the restraints or seclusion are imposed to ensure the physical safety of the resident, a staff member, or others; and

(2) the restraints or seclusion are imposed only upon the written order of a physician, or other licensed practitioner permitted by the State and the facility to order such restraint or seclusion, that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained).

(c) CURRENT LAW.—This part shall not be construed to affect or impede any Federal or State law or regulations that provide greater protections than this part regarding seclusion and restraint.

(d) DEFINITIONS.—In this section:

(1) RESTRAINTS.—The term "restraints" means—

(A) any physical restraint that is a mechanical or personal restriction that immobilizes or reduces the ability of an individual to move his or her arms, legs, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or any other methods that involves the physical holding of a resident for the purpose of conducting routine physical examinations or tests or to protect the resident from falling out of bed or to permit the resident to participate in activities without the risk of physical harm to the resident (such term does not include a physical escort); and

(B) a drug or medication that is used as a restraint to control behavior or restrict the resident's freedom of movement that is not a standard treatment for the resident's medical or psychiatric condition.

(2) SECLUSION.—The term "seclusion" means a behavior control technique involving locked isolation. Such term does not include a time out.

(3) PHYSICAL ESCORT.—The term "physical escort" means the temporary touching or holding of the hand, wrist, arm, shoulder or back for the purpose of inducing a resident who is acting out to walk to a safe location.

(4) TIME OUT.—The term "time out" means a behavior management technique that is part of an approved treatment program and may involve the separation of the resident from the group, in a non-locked setting, for the purpose of calming. Time out is not seclusion.

SEC. 592. [290ii–1] REPORTING REQUIREMENT.

(a) IN GENERAL.—Each facility to which the Protection and Advocacy for Mentally Ill Individuals Act of 1986[38] applies shall notify the appropriate agency, as determined by the Secretary, of each death that occurs at each such facility while a patient is restrained or in seclusion, of each death occurring within 24 hours after the patient has been removed from restraints and seclusion, or where it is reasonable to assume that a patient's death is a result of such seclusion or restraint. A notification under this section shall include the name of the resident and shall be provided not later than 7 days after the date of the death of the individual involved.

(b) FACILITY.—In this section, the term "facility" has the meaning given the term "facilities" in section 102(3) of the Protection and Advocacy for Mentally Ill Individuals Act of 1986[39] (42 U.S.C. 10802(3)).

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[38] Probably should be Protection and Advocacy for Individuals with Mental Illness Act. See section 3206(a) of Public Law 106–310 (114 Stat. 1193).

[39] See footnote for subsection (a).

SEC. 593.[40] [290ii–3] REGULATIONS AND ENFORCEMENT.

(a) TRAINING.—Not later than 1 year after the date of the enactment of this part, the Secretary, after consultation with appropriate State and local protection and advocacy organizations, physicians, facilities, and other health care professionals and patients, shall promulgate regulations that require facilities to which the Protection and Advocacy for Mentally Ill Individuals Act of 1986[41] (42 U.S.C. 10801 et seq.) applies, to meet the requirements of subsection (b).

(b) REQUIREMENTS.—The regulations promulgated under subsection (a) shall require that—

(1) facilities described in subsection (a) ensure that there is an adequate number of qualified professional and supportive staff to evaluate patients, formulate written individualized, comprehensive treatment plans, and to provide active treatment measures;

(2) appropriate training be provided for the staff of such facilities in the use of restraints and any alternatives to the use of restraints; and

(3) such facilities provide complete and accurate notification of deaths, as required under section 592(a).

(c) ENFORCEMENT.—A facility to which this part applies that fails to comply with any requirement of this part, including a failure to provide appropriate training, shall not be eligible for participation in any program supported in whole or in part by funds appropriated to any Federal department or agency.

PART I—REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN NON-MEDICAL, COMMUNITY-BASED FACILITIES FOR CHILDREN AND YOUTH

SEC. 595. [290jj] REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN NON-MEDICAL, COMMUNITY-BASED FACILITIES FOR CHILDREN AND YOUTH.

(a) PROTECTION OF RIGHTS.—

(1) IN GENERAL.—A public or private non-medical, community-based facility for children and youth (as defined in regulations to be promulgated by the Secretary) that receives support in any form from any program supported in whole or in part with funds appropriated under this Act shall protect and promote the rights of each resident of the facility, including the right to be free from physical or mental abuse, corporal punishment, and any restraints or involuntary seclusions imposed for purposes of discipline or convenience.

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[40] Section 593 appears according to the probable intent of the Congress. Section 3207 of Public Law 106–310 (114 Stat. 1196) added sections 591 and 592, and closing quotations were provided at the end of section 592. Immediately following that section, however, section 593 appeared in quotations, and closing quotations were provided at the end of the section. The probable intent of the Congress is that closing quotations should not have been provided at the end of section 592.

[41] See footnote for subsection (a).

(2) NONAPPLICABILITY.—Notwithstanding this part, a facility that provides inpatient psychiatric treatment services for individuals under the age of 21, as authorized and defined in subsections (a)(16) and (h) of section 1905 of the Social Security Act, shall comply with the requirements of part H.

(3) APPLICABILITY OF MEDICAID PROVISIONS.—A non-medical, community-based facility for children and youth funded under the Medicaid program under title XIX of the Social Security Act shall continue to meet all existing requirements for participation in such program that are not affected by this part.

(b) REQUIREMENTS.—

(1) IN GENERAL.—Physical restraints and seclusion may only be imposed on a resident of a facility described in subsection (a) if—

(A) the restraints or seclusion are imposed only in emergency circumstances and only to ensure the immediate physical safety of the resident, a staff member, or others and less restrictive interventions have been determined to be ineffective; and

(B) the restraints or seclusion are imposed only by an individual trained and certified, by a State-recognized body (as defined in regulation promulgated by the Secretary) and pursuant to a process determined appropriate by the State and approved by the Secretary, in the prevention and use of physical restraint and seclusion, including the needs and behaviors of the population served, relationship building, alternatives to restraint and seclusion, de-escalation methods, avoiding power struggles, thresholds for restraints and seclusion, the physiological and psychological impact of restraint and seclusion, monitoring physical signs of distress and obtaining medical assistance, legal issues, position asphyxia, escape and evasion techniques, time limits, the process for obtaining approval for continued restraints, procedures to address problematic restraints, documentation, processing with children, and follow-up with staff, and investigation of injuries and complaints.

(2) INTERIM PROCEDURES RELATING TO TRAINING AND CERTIFICATION.—

(A) IN GENERAL.—Until such time as the State develops a process to assure the proper training and certification of facility personnel in the skills and competencies referred in paragraph (1)(B), the facility involved shall develop and implement an interim procedure that meets the requirements of subparagraph (B).

(B) REQUIREMENTS.—A procedure developed under subparagraph (A) shall—

(i) ensure that a supervisory or senior staff person with training in restraint and seclusion who is competent to conduct a face-to-face assessment (as defined in regulations promulgated by the Secretary), will assess the mental and physical well-being of the child or youth being restrained or secluded and assure that the restraint or seclusion is being done in a safe manner;

(ii) ensure that the assessment required under clause (i) take place as soon as practicable, but in no case later than 1 hour after the initiation of the restraint or seclusion; and

(iii) ensure that the supervisory or senior staff person continues to monitor the situation for the duration of the restraint and seclusion.

(3) LIMITATIONS.—

(A) IN GENERAL.—The use of a drug or medication that is used as a restraint to control behavior or restrict the resident's freedom of movement that is not a standard treatment for the resident's medical or psychiatric condition in nonmedical community-based facilities for children and youth described in subsection (a)(1) is prohibited.

(B) PROHIBITION.—The use of mechanical restraints in non-medical, community-based facilities for children and youth described in subsection (a)(1) is prohibited.

(C) LIMITATION.—A non-medical, community-based facility for children and youth described in subsection (a)(1) may only use seclusion when a staff member is continuously face-to-face monitoring the resident and when strong licensing or accreditation and internal controls are in place.

(c) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—Nothing in this section shall be construed as prohibiting the use of restraints for medical immobilization, adaptive support, or medical protection.

(2) CURRENT LAW.—This part shall not be construed to affect or impede any Federal or State law or regulations that provide greater protections than this part regarding seclusion and restraint.

(d) DEFINITIONS.—In this section:

(1) MECHANICAL RESTRAINT.—The term "mechanical restraint" means the use of devices as a means of restricting a resident's freedom of movement.

(2) PHYSICAL ESCORT.—The term "physical escort" means the temporary touching or holding of the hand, wrist, arm, shoulder or back for the purpose of inducing a resident who is acting out to walk to a safe location.

(3) PHYSICAL RESTRAINT.—The term "physical restraint" means a personal restriction that immobilizes or reduces the ability of an individual to move his or her arms, legs, or head freely. Such term does not include a physical escort.

(4) SECLUSION.—The term "seclusion" means a behavior control technique involving locked isolation. Such term does not include a time out.

(5) TIME OUT.—The term "time out" means a behavior management technique that is part of an approved treatment program and may involve the separation of the resident from the group, in a non-locked setting, for the purpose of calming. Time out is not seclusion.

SEC. 595A. [290jj–1] REPORTING REQUIREMENT.

Each facility to which this part applies shall notify the appropriate State licensing or regulatory agency, as determined by the Secretary—

(1) of each death that occurs at each such facility. A notification under this section shall include the name of the resident and shall be provided not later than 24 hours after the time of the individuals death; and

(2) of the use of seclusion or restraints in accordance with regulations promulgated by the Secretary, in consultation with the States.

SEC. 595B. [290jj–2] REGULATIONS AND ENFORCEMENT.

(a) TRAINING.—Not later than 6 months after the date of the enactment of this part, the Secretary, after consultation with appropriate State, local, public and private protection and advocacy organizations, health care professionals, social workers, facilities, and patients, shall promulgate regulations that—

(1) require States that license non-medical, community-based residential facilities for children and youth to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance with Federal regulations and to meet the requirements of subsection (b);

(2) require States to develop and implement such licensing rules and monitoring requirements within 1 year after the promulgation of the regulations referred to in the matter preceding paragraph (1); and

(3) support the development of national guidelines and standards on the quality, quantity, orientation and training, required under this part, as well as the certification or licensure of those staff responsible for the implementation of behavioral intervention concepts and techniques.

(b) REQUIREMENTS.—The regulations promulgated under subsection (a) shall require—

(1) that facilities described in subsection (a) ensure that there is an adequate number of qualified professional and supportive staff to evaluate residents, formulate written individualized, comprehensive treatment plans, and to provide active treatment measures;

(2) the provision of appropriate training and certification of the staff of such facilities in the prevention and use of physical restraint and seclusion, including the needs and behaviors of the population served, relationship building, alternatives to restraint, de-escalation methods, avoiding power struggles, thresholds for restraints, the physiological impact of restraint and seclusion, monitoring physical signs of distress and obtaining medical assistance, legal issues, position asphyxia, escape and evasion techniques, time limits for the use of restraint and seclusion, the process for obtaining approval for continued restraints and seclusion, procedures to address problematic restraints, documentation, processing with children, and follow-up with staff, and investigation of injuries and complaints; and

(3) that such facilities provide complete and accurate notification of deaths, as required under section 595A(1).

(c) ENFORCEMENT.—A State to which this part applies that fails to comply with any requirement of this part, including a failure to provide appropriate training and certification, shall not be eligible for participation in any program supported in whole or in part by funds appropriated under this Act.

PART G [42]—SERVICES PROVIDED THROUGH RELIGIOUS ORGANIZATIONS [43]

SEC. 581. [42] [290kk] APPLICABILITY TO DESIGNATED PROGRAMS.

(a) DESIGNATED PROGRAMS.—Subject to subsection (b), this part applies to discretionary and formula grant programs administered by the Substance Abuse and Mental Health Services Administration that make awards of financial assistance to public or private entities for the purpose of carrying out activities to prevent or treat substance abuse (in this part referred to as a "designated program"). Designated programs include the program under subpart II of part B of title XIX (relating to formula grants to the States).

(b) LIMITATION.—This part does not apply to any award of financial assistance under a designated program for a purpose other than the purpose specified in subsection (a).

(c) DEFINITIONS.—For purposes of this part (and subject to subsection (b)):

(1) The term "designated program" has the meaning given such term in subsection (a).

(2) The term "financial assistance" means a grant, cooperative agreement, or contract.

(3) The term "program beneficiary" means an individual who receives program services.

(4) The term "program participant" means a public or private entity that has received financial assistance under a designated program.

(5) The term "program services" means treatment for substance abuse, or preventive services regarding such abuse, provided pursuant to an award of financial assistance under a designated program.

(6) The term "religious organization" means a nonprofit religious organization.

SEC. 582. [290kk–1] RELIGIOUS ORGANIZATIONS AS PROGRAM PARTICIPANTS.

(a) IN GENERAL.—Notwithstanding any other provision of law, a religious organization, on the same basis as any other nonprofit private provider—

(1) may receive financial assistance under a designated program; and

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[42] There are two parts G in this title. The first was added by section 3101 of Public Law 106–310 (114 Stat. 1168) and relates to projects for children and violence; that part also begins with section 581. Sections 3207 and 3208 of such Public Law (114 Stat. 1195, 1197) added parts H and I, respectively.

Subsequently, part G above was added by section 144 of the Community Renewal Tax Relief Act of 2000 (as enacted into law by section 1(a)(7) of Public Law 106–554; 114 Stat. 2763A–619), which provides that title V of this act "is amended by adding at the end the following part:", thereby placing that part G after the part I added by Public Law 106–310.

[43] Section 1955 of this act also relates to religious organizations as providers of substance abuse services. That section was added by section 3305 of Public Law 106–310 (114 Stat. 1212).

(2) may be a provider of services under a designated program.

(b) RELIGIOUS ORGANIZATIONS.—The purpose of this section is to allow religious organizations to be program participants on the same basis as any other nonprofit private provider without impairing the religious character of such organizations, and without diminishing the religious freedom of program beneficiaries.

(c) NONDISCRIMINATION AGAINST RELIGIOUS ORGANIZATIONS.—

(1) ELIGIBILITY AS PROGRAM PARTICIPANTS.—Religious organizations are eligible to be program participants on the same basis as any other nonprofit private organization as long as the programs are implemented consistent with the Establishment Clause and Free Exercise Clause of the First Amendment to the United States Constitution. Nothing in this Act shall be construed to restrict the ability of the Federal Government, or a State or local government receiving funds under such programs, to apply to religious organizations the same eligibility conditions in designated programs as are applied to any other nonprofit private organization.

(2) NONDISCRIMINATION.—Neither the Federal Government nor a State or local government receiving funds under designated programs shall discriminate against an organization that is or applies to be a program participant on the basis that the organization has a religious character.

(d) RELIGIOUS CHARACTER AND FREEDOM.—

(1) RELIGIOUS ORGANIZATIONS.—Except as provided in this section, any religious organization that is a program participant shall retain its independence from Federal, State, and local government, including such organization's control over the definition, development, practice, and expression of its religious beliefs.

(2) ADDITIONAL SAFEGUARDS.—Neither the Federal Government nor a State shall require a religious organization to—

(A) alter its form of internal governance; or

(B) remove religious art, icons, scripture, or other symbols,

in order to be a program participant.

(e) EMPLOYMENT PRACTICES.—Nothing in this section shall be construed to modify or affect the provisions of any other Federal or State law or regulation that relates to discrimination in employment. A religious organization's exemption provided under section 702 of the Civil Rights Act of 1964 regarding employment practices shall not be affected by its participation in, or receipt of funds from, a designated program.

(f) RIGHTS OF PROGRAM BENEFICIARIES.—

(1) IN GENERAL.—If an individual who is a program beneficiary or a prospective program beneficiary objects to the religious character of a program participant, within a reasonable period of time after the date of such objection such program participant shall refer such individual to, and the appropriate Federal, State, or local government that administers a designated program or is a program participant shall provide to such individual (if otherwise eligible for such services), program services that—

(A) are from an alternative provider that is accessible to, and has the capacity to provide such services to, such individual; and

(B) have a value that is not less than the value of the services that the individual would have received from the program participant to which the individual had such objection.

Upon referring a program beneficiary to an alternative provider, the program participant shall notify the appropriate Federal, State, or local government agency that administers the program of such referral.

(2) NOTICES.—Program participants, public agencies that refer individuals to designated programs, and the appropriate Federal, State, or local governments that administer designated programs or are program participants shall ensure that notice is provided to program beneficiaries or prospective program beneficiaries of their rights under this section.

(3) ADDITIONAL REQUIREMENTS.—A program participant making a referral pursuant to paragraph (1) shall—

(A) prior to making such referral, consider any list that the State or local government makes available of entities in the geographic area that provide program services; and

(B) ensure that the individual makes contact with the alternative provider to which the individual is referred.

(4) NONDISCRIMINATION.—A religious organization that is a program participant shall not in providing program services or engaging in outreach activities under designated programs discriminate against a program beneficiary or prospective program beneficiary on the basis of religion or religious belief.

(g) FISCAL ACCOUNTABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), any religious organization that is a program participant shall be subject to the same regulations as other recipients of awards of Federal financial assistance to account, in accordance with generally accepted auditing principles, for the use of the funds provided under such awards.

(2) LIMITED AUDIT.—With respect to the award involved, a religious organization that is a program participant shall segregate Federal amounts provided under award into a separate account from non-Federal funds. Only the award funds shall be subject to audit by the government.

(h) COMPLIANCE.—With respect to compliance with this section by an agency, a religious organization may obtain judicial review of agency action in accordance with chapter 7 of title 5, United States Code.

SEC. 583. [290kk–2] LIMITATIONS ON USE OF FUNDS FOR CERTAIN PURPOSES.

No funds provided under a designated program shall be expended for sectarian worship, instruction, or proselytization.

SEC. 584. [290kk–3] EDUCATIONAL REQUIREMENTS FOR PERSONNEL IN DRUG TREATMENT PROGRAMS.

(a) FINDINGS.—The Congress finds that—

(1) establishing unduly rigid or uniform educational qualification for counselors and other personnel in drug treatment programs may undermine the effectiveness of such programs; and

(2) such educational requirements for counselors and other personnel may hinder or prevent the provision of needed drug treatment services.

(b) NONDISCRIMINATION.—In determining whether personnel of a program participant that has a record of successful drug treatment for the preceding three years have satisfied State or local requirements for education and training, a State or local government shall not discriminate against education and training provided to such personnel by a religious organization, so long as such education and training includes basic content substantially equivalent to the content provided by nonreligious organizations that the State or local government would credit for purposes of determining whether the relevant requirements have been satisfied.

FEDERAL FOOD, DRUG, AND COSMETIC ACT[1], as amended

CHAPTER I—SHORT TITLE

SECTION 1. [21 U.S.C. 301] This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. [21 U.S.C. 321] For the purposes of this Act—[2]

(a)(1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f)[3] The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended

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[1] Public Law 75–717, June 25, 1938, 52 Stat. 1040, 21 U.S.C. 301 et seq.

[2] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

[3] The following additional definitions applicable to this act are provided for in other acts:

Butter. The act of March 4, 1923 (21 U.S.C. 321a), defines butter as "the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for."

Package. The act of July 24, 1919 (21 U.S.C. 321b), states "The word 'package' shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale."

Nonfat Dry Milk, Milk. The act of July 2, 1956 (21 U.S.C. 321c), defines nonfat dry milk as "the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.", and defines milk to mean sweet milk of cows.

to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p)[4] The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

[4] The amendments made to this act by the Drug Amendments of 1962 included amendments establishing the requirement that new drugs be effective. Section 107(c) of such Public Law concerned the applicability of the amendments.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 409(h)(6), and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of—

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if—

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph[5] pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following);

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of

[5] Paragraph (s) was added by Public Law 85–929, which was enacted Sept. 6, 1958.

identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe," as used in paragraph (s) of this section and in sections 409, 512, 571, and 721, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term "animal feed", as used in paragraph (w)[6] of this section, in section 512, and in provisions of this Act referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal,

[6] So in law. Probably should be paragraph "(v)".

and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 505(j) for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 306, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 307 and 308, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 306, the term "high managerial agent"—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 306 and 307, the term "drug product" means a drug subject to regulation under section 505, 512, or 802 of this Act or under section 351 of the Public Health Service Act.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

(ii) complies with section 411(c)(1)(B)(ii);

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth

in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include—

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507[7], or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

(ii) The term "compounded positron emission tomography drug"—

(1) means a drug that—

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) PRIORITY SUPPLEMENT.—The term "priority supplement" means a drug application referred to in section 101(4) of the

[7] So in law. Section 507 was repealed by section 125(b)(1) of Public Law 105–115 (111 Stat. 2325).

Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(ll)(1) The term ''single-use device'' means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term ''reprocessed'', with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term ''recycled'' rather than the term ''reprocessed''.

(3) The term ''original device'' means a new, unused single-use device.

(mm)(1) The term ''critical reprocessed single-use device'' means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term ''semi-critical reprocessed single-use device'' means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term ''major species'' means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

(oo) The term ''minor species'' means animals other than humans that are not major species.

(pp) The term ''minor use'' means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq)[8] The term ''major food allergen'' means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).

[8] Section 203(d) of Public Law 108–282 provides that this definition shall become effective on Jan. 1, 2006.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. [21 U.S.C. 331] The following acts and the causing thereof are hereby prohibited: [9]

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 505, or 564.

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 504, 564, 703, or 704(a); or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i).,[10] 515(f), 519, or 564 or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drugs a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section

[9] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

[10] So in law.

404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573.,[11] 704, 708, or 721 concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section..[12] This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(m)[13] The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register in accordance with section 510, the failure to provide any information required by section 510(j) or 510(k); or the failure to provide a notice required by section 510(j)(2).

(q)(1) The failure or refusal to (A) comply with any requirement prescribed under section 518 or 520(g), (B) furnish any notification or other material or information required by or under section 519 or 520(g), or (C) comply with a requirement under section 522.

(2) With respect to any device, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

(r) The movement of a device in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device as detained.

(s) The failure to provide the notice required by section 412(c) or 412(e), the failure to make the reports required by section 412(f)(1)(B), the failure to retain the records required by section

[11] So in law.
[12] So in law. See the amendment made by section 403 of Public Law 104–170 (110 Stat. 1514).
[13] Paragraph (l) was struck by section 421 of Public Law 105–115 (111 Stat. 2380).

412(b)(4), or the failure to meet the requirements prescribed under section 412(f)(3).

(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), or the distribution of drugs in violation of section 503(e) or the failure to otherwise comply with the requirements of section 503(e).

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.

(z)[14] The dissemination of information in violation of section 551.

(aa) The importation of a prescription drug in violation of section 804, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

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[14] Paragraph (z) was added by subsection (b) of section 401(b) of Public Law 105–115 (111 Stat. 2364). Subsection (e) of such section provides as follows:

"(e) SUNSET.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.".

(bb) The transfer of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 306(b)(3).

(dd) The failure to register in accordance with section 415.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m).

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

INJUNCTION PROCEEDINGS

SEC. 302. [21 U.S.C. 332] (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown [15] to restrain violations of section 301, except paragraphs (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury.

PENALTIES

SEC. 303. [21 U.S.C. 333] (a)(1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both.

(b)(1) Notwithstanding subsection (a), any person who violates section 301(t) by—

(A) knowingly importing a drug in violation of section 801(d)(1),

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 503(c)(1),

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 503(c)(2), or

[15] So in law. Probably should be followed by a comma.

(D) knowingly distributing drugs in violation of section 503(e)(2)(A),

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 301(t) because of a violation of section 503(c)(1) or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 503(b) or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than $100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 301(t) because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 503(c)(1) or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 301(t) because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 503(c)(1), such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 804(b) and knowingly fails to comply with a requirement of section 804(e) that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(c) No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301(a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c), or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 301(i)(2) if such person acted in

good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising.

(e)(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 505 and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, United States Code, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, United States Code, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under section 413 of such Act.

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f)(1)(A)[16] Except as provided in subparagraph (B), any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 704(g) who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this Act that relates to devices.

(B) Subparagraph (A) shall not apply—

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[16] The subsection is designated as subsection (f) to be consistent with the United States Code. Prior to the enactment of Public Law 103–322, the last three subsections in section 303 were a subsection (e) that related to anabolic steroids, a subsection (f) that related to human growth hormone, and a subsection (g) that related to civil money penalties. Section 330015 of Public Law 103–322 (108 Stat. 2146) amended the amendatory instructions of section 1904 of Public Law 101–647 with the result that the subsection (e) relating to anabolic steroids was struck, and the subsection (f) relating to human growth hormone was redesignated as subsection (e).

Section 330015 did not, as a conforming amendment, expressly redesignate the subsection (g) on civil money penalties as subsection (f). The United States Code, however, shows the subsection on civil money penalties as subsection (f), and that approach is taken above to be consistent with the Code.

(i) to any person who violates the requirements of section 519(a) or 520(f) unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 519(e) or 519(f) (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 501(a)(2)(A) which involve one or more devices which are not defective.

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B). The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.

(3)(A) A civil penalty under paragraph (1) or (2) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under

paragraph (1) or (2). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(4) Any person who requested, in accordance with paragraph (3)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

(5) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (4), or

(B) after a court in an action brought under paragraph (4) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (4) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

SEIZURE

SEC. 304. [21 U.S.C. 334] (a)(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial

to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, and (D) Any adulterated or misbranded device.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

(i) is misbranded under section 403(a)(2) because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(i)(I) the food's advertising which resulted in the food being misbranded under section 403(a)(2) was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

(b) The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause

to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d)(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 801(e) can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 402(a) (1), (2), or (6), section 501(a)(3), section 502(j), or section 601 (a) or (d). Where such exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 801(e)(1) and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 801(e) have been met. Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under subsection (a) may appeal to the Secretary a detention of such device under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary

shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2)(A) Except as authorized by subparagraph (B), a device subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

(i) released by the Secretary, or

(ii) the expiration of the detention period applicable to such order,

whichever occurs first.

(B) A device subject to a detention order under paragraph (1) may be moved—

(i) in accordance with regulations prescribed by the Secretary, and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.

(h) ADMINISTRATIVE DETENTION OF FOODS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(B) SECRETARY'S APPROVAL.—An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

(2) PERIOD OF DETENTION.—An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

(3) SECURITY OF DETAINED ARTICLE.—An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order,

and section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 302 regarding the article of food involved.

HEARING BEFORE REPORT OF CRIMINAL VIOLATION

SEC. 305. [21 U.S.C. 335] Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

DEBARMENT, TEMPORARY DENIAL OF APPROVAL, AND SUSPENSION

SEC. 306. [21 U.S.C. 335a] (a) MANDATORY DEBARMENT; CERTAIN DRUG APPLICATIONS.—

(1) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—If the Secretary finds that a person other than an individual has been convicted, after the date of the enactment of this section, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

(2) INDIVIDUALS.—If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct—

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this Act,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

(b) PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS; FOOD IMPORTS.—

(1) IN GENERAL.—The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2), debar—

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application,

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application, or

(C) a person from importing an article of food or offering such an article for import into the United States.

(2) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS.—The following persons are subject to debarment under subparagraph (A) or (B) of paragraph (1):

(A) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—Any person other than an individual that the Secretary finds has been convicted—

(i) for conduct that—

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before the date of the enactment of this section), a misdemeanor under Federal law, or a felony under State law, or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(B) INDIVIDUALS.—

(i) Any individual whom the Secretary finds has been convicted of—

(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this Act, or

(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(ii) Any individual whom the Secretary finds has been convicted of—

(I) a felony which is not described in subsection (a)(2) or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering,

blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

(II) a conspiracy to commit, or aiding or abetting, such felony,

if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products.

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products.

(iv) Any high managerial agent whom the Secretary finds—

(I) worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment under subsection (a)(2), or clause (i), of such other individual,

(II) had actual knowledge of the actions described in subclause (I) of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge,

(III) knew that the actions described in subclause (I) were violative of law, and

(IV) did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions,

if the Secretary finds that the type of conduct which served as the basis for such other individual's conviction undermines the process for the regulation of drugs.

(3) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; FOOD IMPORTATION.—A person is subject to debarment under paragraph (1)(C) if—

(A) the person has been convicted of a felony for conduct relating to the importation into the United States of any food; or

(B) the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

(4) STAY OF CERTAIN ORDERS.—An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

(c) DEBARMENT PERIOD AND CONSIDERATIONS.—

(1) EFFECT OF DEBARMENT.—The Secretary—

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) during the period such person is debarred,

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B), debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

(C) shall, if the Secretary makes the finding described in paragraph (6) or (7) of section 307(a), assess a civil penalty in accordance with section 307.

(2) DEBARMENT PERIODS.—

(A) IN GENERAL.—The Secretary shall debar a person under subsection (a) or (b) for the following periods:

(i) The period of debarment of a person (other than an individual) under subsection (a)(1) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) occurs within 10 years after such person has been debarred under subsection (a)(1), the period of debarment shall be permanent.

(ii) The debarment of an individual under subsection (a)(2) shall be permanent.

(iii) The period of debarment of any person under paragraph (2) or (3) of subsection (b) shall not be more than 5 years.

The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

(B) NOTIFICATION.—Upon a conviction for an offense described in subsection (a) or (b) or upon execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify the Secretary that the person acquiesces to debarment and such person's debarment shall commence upon such notification.

(3) CONSIDERATIONS.—In determining the appropriateness and the period of a debarment of a person under subsection (b) and any period of debarment beyond the minimum specified in

subparagraph (A)(i) of paragraph (2), the Secretary shall consider where applicable—

(A) the nature and seriousness of any offense involved,

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

(d) TERMINATION OF DEBARMENT.—

(1) APPLICATION.—Any person that is debarred under subsection (a) (other than a person permanently debarred) or any person that is debarred under subsection (b) may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(2) DEADLINE.—The Secretary shall grant or deny any application respecting a debarment which is submitted under paragraph (1) within 180 days of the date the application is submitted.

(3) ACTION BY THE SECRETARY.—

(A) CORPORATIONS.—

(i) CONVICTION REVERSAL.—If the conviction which served as the basis for the debarment of a person under subsection (a)(1) or paragraph (2)(A) or (3) of subsection (b) is reversed, the Secretary shall withdraw the order of debarment.

(ii) APPLICATION.—Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that—

(I) changes in ownership, management, or operations have fully corrected the causes of the offense involved and provide reasonable assurances that the offense will not occur in the future, and

(II) in applicable cases, sufficient audits, conducted by the Food and Drug Administration or by independent experts acceptable to the Food and Drug Administration, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements.

In the case of persons debarred under subsection (a)(1), such termination shall take effect no earlier than the expiration of one year from the date of the debarment.

(B) INDIVIDUALS.—

(i) CONVICTION REVERSAL.—If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) or clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) or subsection (b)(3) is reversed, the Secretary shall withdraw the order of debarment.

(ii) APPLICATION.—Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) or subsection (b)(3) if such termination serves the interests of justice and adequately protects the integrity of the drug approval process or the food importation process, as the case may be.

(4) SPECIAL TERMINATION.—

(A) APPLICATION.—Any person that is debarred under subsection (a)(1) (other than a person permanently debarred under subsection (c)(2)(A)(i)) or any individual who is debarred under subsection (a)(2) may apply to the Secretary for special termination of debarment under this subsection. Any information submitted to the Secretary under this subparagraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(B) CORPORATIONS.—Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that—

(i) the person making the application under subparagraph (A) has demonstrated that the felony conviction which was the basis for such person's debarment involved the commission of an offense which was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the board's or agent's office or employment,

(ii) all individuals who were involved in the commission of the offense or who knew or should have known

of the offense have been removed from employment involving the development or approval of any drug subject to sections [17] 505,

(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities, and

(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

(C) INDIVIDUALS.—Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that such individual has provided substantial assistance in the investigations or prosecutions of offenses which are described in subsection (a) or (b) or which relate to any matter under the jurisdiction of the Food and Drug Administration.

(D) SECRETARIAL ACTION.—The action referred to in subparagraphs (B) and (C) is—

(i) in the case of a person other than an individual—

(I) terminating the debarment immediately, or

(II) limiting the period of debarment to less than one year, and

(ii) in the case of an individual, limiting the period of debarment to less than permanent but to no less than 1 year,

whichever best serves the interest of justice and protects the integrity of the drug approval process.

(e) PUBLICATION AND LIST OF DEBARRED PERSONS.—The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b), the effective date of the debarment, and the period of the debarment. The Secretary shall also maintain and make available to the public a list, updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such debarments, and of the termination of debarments.

(f) TEMPORARY DENIAL OF APPROVAL.—

(1) IN GENERAL.—The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (3), refuse by order, for the period prescribed by paragraph (2), to approve any abbreviated drug application submitted by any person—

(A) if such person is under an active Federal criminal investigation in connection with an action described in subparagraph (B),

(B) if the Secretary finds that such person—

(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or

[17] So in law. See section 125(b)(2)(C) of Public Law 105–115 (111 Stat. 2325). Probably should be "section".

attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services or to any other Federal, State, or local official in connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, such actions, or

(ii) has knowingly made or caused to be made a pattern or practice of false statements or misrepresentations with respect to material facts relating to any abbreviated drug application, or the production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of the Department of Health and Human Services, or has conspired to commit, or aided or abetted, such actions, and

(C) if a significant question has been raised regarding—

(i) the integrity of the approval process with respect to such abbreviated drug application, or

(ii) the reliability of data in or concerning such person's abbreviated drug application.

Such an order may be modified or terminated at any time.

(2) APPLICABLE PERIOD.—

(A) IN GENERAL.—Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate such denial—

(i) if the investigation with respect to which the finding was made does not result in a criminal charge against such person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered, or

(ii) if the Secretary determines that such finding was in error.

(B) EXTENSION.—If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in subparagraph (B) of paragraph (1), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate such extension if the charges have been dismissed, if a judgment of acquittal has been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

(3) INFORMAL HEARING.—Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide such person with an opportunity for an informal hearing, to be held within such 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which such hearing is held, the Secretary shall notify the person given such hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. Such notification shall be final agency action.

(g) SUSPENSION AUTHORITY.—

(1) IN GENERAL.—If—

(A) the Secretary finds—

(i) that a person has engaged in conduct described in subparagraph (B) of subsection (f)(1) in connection with 2 or more drugs under abbreviated drug applications, or

(ii) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of one or more drugs approved under an abbreviated drug application during a 2-year period, and—

(I) such violations may undermine the safety and efficacy of such drugs, and

(II) the causes of such violations have not been corrected within a reasonable period of time following notice of such violations by the Secretary, and

(B) such person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in subparagraph (A),

the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to such conduct described in subparagraph (A) or suspending the distribution of all drugs approved under abbreviated drug applications of such person if the Secretary finds that such conduct may have affected the development or approval of a significant number of drugs which the Secretary is unable to identify. The Secretary shall exclude a drug from such order if the Secretary determines that such conduct was not likely to have influenced the safety or efficacy of such drug.

(2) PUBLIC HEALTH WAIVER.—The Secretary shall, on the Secretary's own initiative or in response to a petition, waive the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)) with respect to any drug if the Secretary finds that such waiver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available. The Secretary shall act on any petition seeking action under this paragraph within 180 days of the date the petition is submitted to the Secretary.

(h) TERMINATION OF SUSPENSION.—The Secretary shall withdraw an order of suspension of the distribution of a drug under subsection (g) if the person with respect to whom the order was issued demonstrates in a petition to the Secretary—

(1)(A) on the basis of an audit by the Food and Drug Administration or by experts acceptable to the Food and Drug Administration, or on the basis of other information, that the development, approval, manufacturing, and distribution of such drug is in substantial compliance with the applicable requirements of this Act, and

(B) changes in ownership, management, or operations—

(i) fully remedy the patterns or practices with respect to which the order was issued, and

(ii) provide reasonable assurances that such actions will not occur in the future, or

(2) the initial determination was in error.

The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding. Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

(i) PROCEDURE.—The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(j) JUDICIAL REVIEW.—

(1) IN GENERAL.—Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(2) EXCEPTION.—Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) may obtain a review of such decision by the United States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by filing in such court (within 30 days following the date the person is notified of the Secretary's decision) a complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

(k) CERTIFICATION.—Any application for approval of a drug product shall include—

(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b), in connection with such application, and

(2) if such application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) which occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of such application.

(l) APPLICABILITY.—

(1) CONVICTION.—For purposes of this section, a person is considered to have been convicted of a criminal offense—

(A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending,

(B) when a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court, or

(C) when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld.

(2) EFFECTIVE DATES.—Subsection (a), subparagraph (A) of subsection (b)(2), clauses (i) and (ii) of subsection (b)(2)(B), and subsection (b)(3)(A) shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b). Clauses (iii) and (iv) of subsection (b)(2)(B), subsection (b)(3)(B), and subsections (f) and (g) shall not apply to an act or action which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g). Clause (iv) of subsection (b)(2)(B) shall not apply to an action which occurred before June 1, 1992. Subsection (k) shall not apply to applications submitted to the Secretary before June 1, 1992.

(m) DEVICES; MANDATORY DEBARMENT REGARDING THIRD-PARTY INSPECTIONS AND REVIEWS.—

(1) IN GENERAL.—If the Secretary finds that a person has been convicted of a felony under section 301(gg), the Secretary shall debar such person from being accredited under section 523(b) or 704(g)(2) and from carrying out activities under an agreement described in section 803(b).

(2) DEBARMENT PERIOD.—The Secretary shall debar a person under paragraph (1) for the following periods:

(A) The period of debarment of a person (other than an individual) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under such paragraph occurs within 10 years after such person has been debarred under such paragraph, the period of debarment shall be permanent.

(B) The debarment of an individual shall be permanent.

(3) TERMINATION OF DEBARMENT; JUDICIAL REVIEW; OTHER MATTERS.—Subsections (c)(3), (d), (e), (i), (j), and (l)(1) apply with respect to a person (other than an individual) or an individual who is debarred under paragraph (1) to the same extent and in the same manner as such subsections apply with respect to a person who is debarred under subsection (a)(1), or an individual who is debarred under subsection (a)(2), respectively.

CIVIL PENALTIES

SEC. 307. [21 U.S.C. 335b] (a) IN GENERAL.—Any person that the Secretary finds—

(1) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application,

(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

(3) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application,

(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug application,

(6) is a person that has an approved or pending drug product application and has knowingly—

(A) employed or retained as a consultant or contractor, or

(B) otherwise used in any capacity the services of,

a person who was debarred under section 306, or

(7) is an individual debarred under section 306 and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application,

shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

(b) PROCEDURE.—

(1) IN GENERAL.—

(A) ACTION BY THE SECRETARY.—A civil penalty under subsection (a) shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) ACTION BY THE ATTORNEY GENERAL.—In lieu of a proceeding under subparagraph (A), the Attorney General may, upon request of the Secretary, institute a civil action to recover a civil money penalty in the amount and for any of the acts set forth in subsection (a). Such an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated by the Attorney General under this Act.

(2) AMOUNT.—In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into

account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

(3) LIMITATION ON ACTIONS.—No action may be initiated under this section—

(A) with respect to any act described in subsection (a) that occurred before the date of the enactment of this section, or

(B) more than 6 years after the date when facts material to the act are known or reasonably should have been known by the Secretary but in no event more than 10 years after the date the act took place.

(c) JUDICIAL REVIEW.—Any person that is the subject of an adverse decision under subsection (b)(1)(A) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(d) RECOVERY OF PENALTIES.—The Attorney General may recover any civil penalty (plus interest at the currently prevailing rates from the date the penalty became final) assessed under subsection (b)(1)(A) in an action brought in the name of the United States. The amount of such penalty may be deducted, when the penalty has become final, from any sums then or later owing by the United States to the person against whom the penalty has been assessed. In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

(e) INFORMANTS.—The Secretary may award to any individual (other than an officer or employee of the Federal Government or a person who materially participated in any conduct described in subsection (a)) who provides information leading to the imposition of a civil penalty under this section an amount not to exceed—

(1) $250,000, or

(2) one-half of the penalty so imposed and collected,

whichever is less. The decision of the Secretary on such award shall not be reviewable.

AUTHORITY TO WITHDRAW APPROVAL OF ABBREVIATED DRUG APPLICATIONS

SEC. 308. [21 U.S.C. 335c] (a) IN GENERAL.—The Secretary—

(1) shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or material false statement, and

(2) may withdraw approval of an abbreviated drug application if the Secretary finds that the applicant has repeatedly demonstrated a lack of ability to produce the drug for which the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated

drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce.

(b) PROCEDURE.—The Secretary may not take any action under subsection (a) with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(c) APPLICABILITY.—Subsection (a) shall apply with respect to offenses or acts regardless of when such offenses or acts occurred.

(d) JUDICIAL REVIEW.—Any person that is the subject of an adverse decision under subsection (a) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

REPORT OF MINOR VIOLATIONS

SEC. 309. [21 U.S.C. 336] Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

PROCEEDINGS IN NAME OF UNITED STATES; PROVISION AS TO SUBPOENAS

SEC. 310. [21 U.S.C. 337] (a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or

has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. [21 U.S.C. 341] Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. [21 U.S.C. 342] A food shall be deemed to be adulterated—[18]

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.[19]

(2)(A)[20] if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed

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[18] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

[19] So in law. See section 3(i)(1) of Public Law 103–80. Probably should be "; or".

[20] Subparagraph (2) appears so as to reflect the probable intent of the Congress. Section 404 of Public Law 104–170 (110 Stat. 1514) had amendatory instructions whose probable intended effect was to strike the existing subparagraph (2) and to insert a substitute subparagraph (2). These included instructions to strike "(2)(A) if it bears'" and all that follows through "(3) if it consists", but "(3) If it consists" was the language that actually appeared. (Previously, section 3(i) of Public Law 103–80 (107 Stat. 776) had amended subparagraph (3) by striking "if it" and inserting "If it".)

food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

(b)(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a).

(d) If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale; or

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this Act, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f)(1) If it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury under—

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code, to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph [21] (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(g)(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.

[21] So in law. Probably should be "subparagraph".

(h) If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 801(a), unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this Act, as determined by the Secretary.

MISBRANDED FOOD

SEC. 403. [21 U.S.C. 343] A food shall be deemed to be misbranded—[22]

(a) If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and

[22] See footnote for paragraph (h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

form as such regulations specify, a statement that it falls below such standard; or

(3) a food that is pasteurized unless—

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this Act; or

(B)(i) such food has been subjected to a safe process or treatment that—

(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

(ii) at least 120 days have passed after the date of receipt of such notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of subclauses (I) through (III) of clause (i)[23].

For purposes of paragraph (3)[24], a determination by the Secretary that a process or treatment has not been shown to meet the requirements of subclauses (I) through (III) of subparagraph (B)(i)[25] shall constitute final agency action under such subclauses.

(i) Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable

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[23] References are so in law. See section 10808(b)(3) of Public Law 107–171 (116 Stat. 530). In order to be consistent with other cross-references within section 403 above, each reference in section 403(h)(3) to a paragraph, subparagraph, clause, or subclause should be a reference to a subparagraph, clause, subclause, or item, respectively. See, for example, cross-references in paragraph (q) (relating to nutrition information) and paragraph (r) (relating to nutrient levels and health claims).

Section 403 was enacted in 1938 and has organizational units and cross-references that are not in accordance with modern practice. In modern practice, "(a)" is a subsection, "(1)" is a paragraph, "(A)" is a subparagraph, "(i)" is a clause, "(I)" is a subclause, "(aa)" is an item, and "(AA)" is a subitem. The references in section 403(h)(3) follow this practice.

In modern practice, all of the section 403 text would be considered an undesignated subsection, and the list that begins after "A food shall be deemed to be misbranded—" would consist of paragraphs (1), (2), etc.

In section 403, however, the original authors of the 1938 act used a list consisting of (a), (b), etc., and the authors referred to "(a)" as a paragraph, "(1)" as a subparagraph, "(A)" as a clause, and "(i)" as a subclause. (Express references to organizational units below the "(i)" level have been avoided.)

The original authors followed this approach in each section in this act whose text was a list consisting of (a), (b), etc. Such sections include sections 201, 301, 402, 403, 501, 502, 601, and 602.

Some of these sections have numerous internal cross-references. Rather than conforming each of these to the modern practice, the usual approach in making amendments to these sections has been to follow the approach used by the original authors of the 1938 act.

[24] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

[25] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 721(c)[26] unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical, except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721.

(n) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

[(o) Repealed by Public Law 106–554, December 21, 2000.]

[(p) Repealed by Public Law 104–124, April 1, 1996.]

(q)(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

[26] So in law. Probably should be followed by a comma.

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this Act before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

(2)(A) If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

(B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (D).

(B)(i) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990[27], the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities

[27] Public Law 101–535, which was enacted Nov. 8, 1990.

or raw fish to provide nutrition information specified in subparagraphs (1) and (2). Such guidelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply—

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990[28], the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

(C)(i) Upon the expiration of 30 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990[29], the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.

(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information

[28] Public Law 101–535, which was enacted Nov. 8, 1990.
[29] Public Law 101–535, which was enacted Nov. 8, 1990.

to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).

(iii) Regulations issued under subclause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

(E) For purposes of this subparagraph, the term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

(iii) which is an infant formula subject to section 412,

(iv) which is a medical food as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)), or

(v) which is described in section 405(2).

(B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.

(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the

amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

(E)(i) During the 12-month period for which an exemption from subparagraphs (1) and (2) is claimed pursuant to this subclause, the requirements of such subparagraphs shall not apply to any food product if—

(I) the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r),

(II) the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 100 full-time equivalent employees,

(III) such person provided the notice described in subclause (iii), and

(IV) in the case of a food product which was sold in the 12-month period preceding the period for which an exemption was claimed, fewer than 100,000 units of such product were sold in the United States during such preceding period, or in the case of a food product which was not sold in the 12-month period preceding the period for which such exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which such exemption is claimed.

(ii) During the 12-month period after the applicable date referred to in this sentence, the requirements of subparagraphs (1) and (2) shall not apply to any food product which was first introduced into interstate commerce before May 8, 1994, if the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r), if such person provided the notice described in subclause (iii), and if—

(I) during the 12-month period preceding May 8, 1994, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 600,000 units of such product were sold in the United States,

(II) during the 12-month period preceding May 8, 1995, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of such product were sold in the United States, or

(III) during the 12-month period preceding May 8, 1996, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of such product were sold in the United States.

(iii) The notice referred to in subclauses (i) and (ii) shall be given to the Secretary prior to the beginning of the period during which

the exemption under subclause (i) or (ii) is to be in effect, shall state that the person claiming such exemption for a food product has complied with the applicable requirements of subclause (i) or (ii), and shall—

(I) state the average number of full-time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption,

(II) state the approximate number of units the person claiming the exemption sold in the United States,

(III) if the exemption is claimed for a food product which was sold in the 12-month period preceding the period for which the exemption was claimed, state the approximate number of units of such product which were sold in the United States during such preceding period, and, if the exemption is claimed for a food product which was not sold in such preceding period, state the number of units of such product which such person reasonably anticipates will be sold in the United States during the period for which the exemption was claimed, and

(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subclause if the Secretary has questioned the validity of such information.

If a person is not an importer, has fewer than 10 full-time equivalent employees, and sells fewer than 10,000 units of any food product in any year, such person is not required to file a notice for such product under this subclause for such year.

(iv) In the case of a person who claimed an exemption under subclause (i) or (ii), if, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the number in such subclause or if the number of food products sold in the United States exceeds the number in such subclause, such exemption shall extend to the expiration of 18 months after the date the number of full-time equivalent employees or food products sold exceeded the applicable number.

(v) For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower the employee or units of food products requirement of subclause (i) if the Secretary determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to such lower requirement.

(vi) For purposes of subclauses (i), (ii), (iii), (iv), and (v)—

(I) the term "unit" means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers,

(II) the term "food product" means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods, and

(III) the term "person" in the case of a corporation includes all domestic and foreign affiliates of the corporation.

(F) A dietary supplement product (including a food to which section 411 applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product

and which is specified in regulations of the Secretary which shall provide that—

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

(G) Subparagraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

(r)(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)—

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless—

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices

and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless—

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and a requirement that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: ''See nutrition information for ____ content.'' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.

(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary

under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term "diet" was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).

(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(H) A claim submitted under the requirements of clause (G) may be made until—

(i) such time as the Secretary issues a regulation—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.

(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(ii) A regulation described in subclause (i) shall describe—

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and

(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(D) A claim submitted under the requirements of clause (C) may be made until—

(i) such time as the Secretary issues a regulation under the standard in clause (B)(i)—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary denies the petition or the petition is deemed to be denied, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision. If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 412(h) and medical foods as defined in section 5(b) of the Orphan Drug Act.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 401 shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.".

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

(i) enable consumers to develop and maintain healthy dietary practices;

(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

(s) If—

(1) it is a dietary supplement; and

(2)(A) the label or labeling of the supplement fails to list—

(i) the name of each ingredient of the supplement that is described in section 201(ff); and

(ii)(I) the quantity of each such ingredient; or

(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term "dietary supplement", which term may be modified with the name of such an ingredient;

(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

(D) the supplement—

(i) is covered by the specifications of an official compendium;

(ii) is represented as conforming to the specifications of an official compendium; and

(iii) fails to so conform; or

(E) the supplement—

(i) is not covered by the specifications of an official compendium; and

(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.

(t)[30] If it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.

(u)[31] If it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus Panax.

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[30] Section 403(t) was added by subsection (a)(2) of section 10806 of Public Law 107–171 (116 Stat. 526). Subsection (a)(1) of such section 10806 provides as follows:

"(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

"(A) the term "catfish" may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and

"(B) only labeling or advertising for fish classified within that family may include the term "catfish".".

[31] Section 403(u) was added by subsection (b)(2) of section 10806 of Public Law 107–171 (116 Stat. 527). Subsection (b)(1) of such section 10806 provides as follows:

"(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

"(A) the term "ginseng" may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus Panax; and

"(B) only labeling or advertising for herbs or herbal ingredients classified within that genus may include the term "ginseng".".

(v) If—

(1) it fails to bear a label required by the Secretary under section 801(n)(1) (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner or consignee involved that the label is required under section 801, the Secretary informs the owner or consignee that the food presents such a threat.

(w)[32] (1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either—

(A) the word "Contains", followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or

(B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when—

(i) the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or

(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under section 201(qq)(2)(A) or (B).

(2) As used in this subsection, the term "name of the food source from which the major food allergen is derived" means the name described in section 201(qq)(1); provided that in the case of a tree nut, fish, or Crustacean shellfish, the term "name of the food source from which the major food allergen is derived" means the name of the specific type of nut or species of fish or Crustacean shellfish.

(3) The information required under this subsection may appear in labeling in lieu of appearing on the label only if the Secretary finds that such other labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

(4) Notwithstanding subsection (g), (i), or (k), or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

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[32] Section 203(d) of Public Law 108–282 provides that this section shall apply to any food that is labeled on or after Jan. 1, 2006.

(5) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) is necessary to protect the public health.

(6)(A) Any person may petition the Secretary to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection.

(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

(D) A determination regarding a petition under this paragraph shall constitute final agency action.

(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary's response to each.

(7)(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification containing—

(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409.

(B) The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

(C) The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

(x)[33] Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that

[33] Section 203(d) of Public Law 108–282 provides that this section shall apply to any food that is labeled on or after Jan. 1, 2006.

bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.

SEC. 403A.[34] [21 U.S.C. 343–1] (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g), except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 401 and 403(g),

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), 403(i)(2), 403(w), or 403(x) that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(c) and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(h)(1) and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A), or

(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under section 403(r)(5)(B).

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).

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[34] Section 403A was enacted without a section heading. See section 6(a) of Public Law 101–535 (104 Stat. 2362).

DIETARY SUPPLEMENT LABELING EXEMPTIONS

SEC. 403B. [21 U.S.C. 343–2] (a) IN GENERAL.—A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

(4) if displayed in an establishment, is physically separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

(b) APPLICATION.—Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

(c) BURDEN OF PROOF.—In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.

DISCLOSURE

SEC. 403C. [21 U.S.C. 343–3] (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

(b) In this section, the term "radiation disclosure statement" means a written statement that discloses that a food has been intentionally subject to radiation.

EMERGENCY PERMIT CONTROL

SEC. 404. [21 U.S.C. 344] (a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality of permits to which shall be attached such conditions governing the manufacture, processing, or packaging of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured,

processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

REGULATIONS MAKING EXEMPTIONS

SEC. 405. [21 U.S.C. 345] The Secretary shall promulgate regulations exempting from any labeling requirement of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, or condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment. This section does not apply to the labeling requirements of sections 403(q) and 403(r).

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD

SEC. 406. [21 U.S.C. 346] Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer

may be affected by the same or other poisonous or deleterious substances.

OLEOMARGARINE OR MARGARINE

SEC. 407.[35] [21 U.S.C. 347] (a) Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this Act as if it had been introduced in interstate commerce.

(b) No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) such oleomargarine or margarine is packaged,

(2) the net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) there appears on the label of the package (A) the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on such label, and (B) a full and accurate statement of all the ingredients contained in such oleomargarine, or margarine, and

(4) each part of the contents of the package is contained in a wrapper which bears the word "oleomargarine" or "margarine" in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this Act.

(c) No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

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[35] Section 4 of Public Law 81–459 (64 Stat. 20) amended section 15 of the Federal Trade Commission Act by adding the following subsection:

"(f) For the purposes of this section and section 407 of the Federal Food, Drug, and Cosmetic Act, as amended, the term 'oleomargarine' or 'margarine' includes—

"(1) all substances, mixtures, and compounds known as oleomargarine or margarine;

"(2) all substances, mixtures, and compounds which have a consistence similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter.".

In repealing section 2301 of the Internal Revenue Code (relating to the tax on oleomargarine) Public Law 81–459 declared, in part: "The Congress hereby finds and declares that the sale, or the serving in public eating places, of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded, and constitutes a burden on interstate commerce in such articles. Such burden exists, irrespective of whether such oleomargarine or margarine originates from an interstate source or from the State in which it is sold.".

Section 6 of such public law states that "nothing in this Act shall be construed as authorizing the possession, sale, or serving of colored oleomargarine or colored margarine in any State or Territory in contravention of the laws of such State or Territory.".

(d) Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 403 (except (a) and 403 (f))[36] if it complies with the requirements of subsection (b) of this section.

(e) For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six-tenths degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent.

TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

SEC. 408.[37] [21 U.S.C. 346a] (a) REQUIREMENT FOR TOLERANCE OR EXEMPTION.—

(1) GENERAL RULE.—Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

(2) PROCESSED FOOD.—Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B).

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[36] So in law. Probably should be "(except paragraphs (a) and (f))".
[37] See footnote for section 406.

(3) RESIDUES OF DEGRADATION PRODUCTS.—If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) EFFECT OF TOLERANCE OR EXEMPTION.—While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1).

(b) AUTHORITY AND STANDARD FOR TOLERANCE.—

(1) AUTHORITY.—The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) STANDARD.—

(A) GENERAL RULE.—

(i) STANDARD.—The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) DETERMINATION OF SAFETY.—As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) TOLERANCES FOR ELIGIBLE PESTICIDE CHEMICAL RESIDUES.—

(i) DEFINITION.—As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) DETERMINATION OF TOLERANCE.—Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) CONDITIONS REGARDING USE.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) CONDITIONS REGARDING RISK.—For purposes of clause (ii), the conditions described in this clause with

respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) REVIEW.—Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(vi) INFANTS AND CHILDREN.—Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) EXPOSURE OF INFANTS AND CHILDREN.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) FACTORS.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced

by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E) DATA AND INFORMATION REGARDING ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

(i) AUTHORITY.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) REQUIREMENT.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

(F) PERCENT OF FOOD ACTUALLY TREATED.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) DETECTION METHODS.—

(A) GENERAL RULE.—A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) DETECTION LIMIT.—A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

(1) AUTHORITY.—The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's initiative under subsection (e).

(2) STANDARD.—

(A) GENERAL RULE.—

(i) STANDARD.—The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii) DETERMINATION OF SAFETY.—The term ''safe'', with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B) FACTORS.—In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the

Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) PETITION FOR TOLERANCE OR EXEMPTION.—

(1) PETITIONS AND PETITIONERS.—Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) PETITION CONTENTS.—

(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3) NOTICE.—A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) ACTIONS BY THE ADMINISTRATOR.—

(A) IN GENERAL.—The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

(B) PRIORITIES.—The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

(i) DATE CERTAIN FOR REVIEW.—If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii) REQUIRED DETERMINATIONS.—If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(e) ACTION ON ADMINISTRATOR'S OWN INITIATIVE.—

(1) GENERAL RULE.—The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (l)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) NOTICE.—Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) SPECIAL DATA REQUIREMENTS.—

(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act;

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act;

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(2) NONCOMPLIANCE.—If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g) EFFECTIVE DATE, OBJECTIONS, HEARINGS, AND ADMINISTRATIVE REVIEW.—

(1) EFFECTIVE DATE.—A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2) FURTHER PROCEEDINGS.—

(A) OBJECTIONS.—Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

(B) HEARING.—An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C) FINAL DECISION.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) JUDICIAL REVIEW.—

(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will

be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) RECORD AND JURISDICTION.—A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) ADDITIONAL EVIDENCE.—If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5) APPLICATION.—Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i) CONFIDENTIALITY AND USE OF DATA.—

(1) GENERAL RULE.—Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) EXCEPTIONS.—

(A) IN GENERAL.—Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this Act or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act or such statutes.

(B) CONGRESS.—This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(3) SUMMARIES.—Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

(2) REGULATIONS UNDER SECTION 409.—Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

(4) CERTAIN SUBSTANCES.—With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 201(q)(1) but was so included on the day before the date of the enactment of the Antimicrobial Regulation

Technical Corrections Act of 1998, the following applies as of such date of enactment:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before such date, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 409.

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before the date of the enactment of the Food Quality Protection Act of 1996) is deemed to have been issued under section 409.

(k) TRANSITIONAL PROVISION.—If, on the day before the date of the enactment of this subsection, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) as then in effect; or

(2) regarded by the Secretary as a substance described by section 201(s)(4);

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

(l) HARMONIZATION WITH ACTION UNDER OTHER LAWS.—

(1) COORDINATION WITH FIFRA.—To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) SUSPENSION OF TOLERANCE OR EXEMPTION FOLLOWING SUSPENSION OF ASSOCIATED REGISTRATIONS.—

(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4) TOLERANCES FOR UNAVOIDABLE RESIDUES.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide

chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m)[38] FEES.—

(1) AMOUNT.—The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A) the acceptance for filing of a petition submitted under subsection (d);

(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C) the acceptance for filing of objections under subsection (g); or

[38] Section 501(d)(2) of division G of Public Law 108–199 (118 Stat. 422) provides as follows: "(2) TOLERANCE FEES.—Notwithstanding section 408(m)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(m)(1)), during the period beginning on October 1, 2003, and ending on September 30, 2008, the Administrator of the Environmental Protection Agency shall not collect any tolerance fees under that section.".

(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h);

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) DEPOSIT.—All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(n) NATIONAL UNIFORMITY OF TOLERANCES.—

(1) QUALIFYING PESTICIDE CHEMICAL RESIDUE.—For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act on April 25, 1985; or

(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act on or after the date of enactment of this subsection.

(2) QUALIFYING FEDERAL DETERMINATION.—For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A) is issued under this section after the date of the enactment of this subsection and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption); or

(B)(i) pursuant to subsection (j) is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) as exempt from the requirement for a tolerance; and

(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption).

(3) LIMITATION.—The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h).

(4) STATE AUTHORITY.—Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5) PETITION PROCEDURE.—

(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B) PETITION REQUIREMENTS.—Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

(C) AUTHORIZATION.—The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be a violation of Federal law.

(D) TREATMENT.—In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d), the Administrator shall thereafter act on the petition pursuant to subsection (d).

(E) REVIEW.—Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h).

(6) URGENT PETITION PROCEDURE.—Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the

State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(7) RESIDUES FROM LAWFUL APPLICATION.—No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

(8) SAVINGS.—Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

(o) CONSUMER RIGHT TO KNOW.—Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing[39] in this subsection shall prevent retail grocers from providing additional information.

(p) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of this section, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine

[39] Indentation is so in law. Probably should be flush left.

whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) IMPLEMENTATION.—Not later than 3 years after the date of enactment of this section, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act or the science advisory board established by section 8 of the Environmental Research, Development, and Demonstration [40] Act of 1978 (42 U.S.C. 4365), the Administrator shall implement the program.

(3) SUBSTANCES.—In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

(4) EXEMPTION.—Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

(5) COLLECTION OF INFORMATION.—

(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

(B) PROCEDURES.—To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

(C) FAILURE OF REGISTRANTS TO SUBMIT INFORMATION.—

(i) SUSPENSION.—If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend

[40] So in law. The word "Authorization" probably should appear after "Demonstration".

the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

(ii) HEARING.—If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5, United States Code. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

(iii) TERMINATION OF SUSPENSIONS.—The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6) AGENCY ACTION.—In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this Act, as is necessary to ensure the protection of public health.

(7) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Administrator shall prepare and submit to Congress a report containing—

(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

(q) SCHEDULE FOR REVIEW.—

(1) IN GENERAL.—The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protection Act of 1996, as expeditiously as practicable, assuring that—

(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of the date of enactment of such Act;

(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of the date of enactment of such Act; and

(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of the date of enactment of such Act.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections[41] (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

(2) PRIORITIES.—In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

(3) PUBLICATION OF SCHEDULE.—Not later than 12 months after the date of the enactment of the Food Quality Protection Act of 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to the date of the enactment of the Food Quality Protection Act of 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

(r) TEMPORARY TOLERANCE OR EXEMPTION.—The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

(s) SAVINGS CLAUSE.—Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act or the Federal Insecticide, Fungicide, and Rodenticide Act.

FOOD ADDITIVES

Unsafe Food Additives

SEC. 409. [21 U.S.C. 348] (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (j) of this section;

[41] So in law. Probably should be "subsection".

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

(B) a notification submitted under subsection (h) that is effective.

While such a regulation relating to a food additive, or such a notification under subsection (h)(1) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).

Petition To Establish Safety

(b)(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner), a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

Action on the Petition

(c)(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

Regulation Issued on Secretary's Initiative

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

Publication and Effective Date of Orders

(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

Objections and Public Hearing

(f)(1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after

completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Judicial Review

(g)(1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section

shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

Notification Relating to a Food Contact Substance

(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

(C) In this paragraph, the term "food contact substance" means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

(5)(A)(i) Except as provided in clause (ii), the notification program established under this subsection shall not operate in any fiscal year unless—

(I) an appropriation equal to or exceeding the applicable amount under clause (iv) is made for such fiscal year for carrying out such program in such fiscal year; and

(II) the Secretary certifies that the amount appropriated for such fiscal year for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subclause (I)) equals or exceeds the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

(ii) The Secretary shall, not later than April 1, 1999, begin accepting and reviewing notifications submitted under the notification program established under this subsection if—

(I) an appropriation equal to or exceeding the applicable amount under clause (iii) is made for the last six months of fiscal year 1999 for carrying out such program during such period; and

(II) the Secretary certifies that the amount appropriated for such period for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subclause (I)) equals or exceeds an amount equivalent to one-half the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

(iii) For the last six months of fiscal year 1999, the applicable amount under this clause is $1,500,000, or the amount specified in the budget request of the President for the six-month period involved for carrying out the notification program in fiscal year 1999, whichever is less.

(iv) For fiscal year 2000 and subsequent fiscal years, the applicable amount under this clause is $3,000,000, or the amount specified in the budget request of the President for the fiscal year involved for carrying out the notification program under this subsection, whichever is less.

(B) For purposes of carrying out the notification program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through fiscal year 2003, except that such authorization of appropriations is not effective for a fiscal year for any amount that is less than the applicable amount under clause (iii) or (iv) of subparagraph (A), whichever is applicable.

(C) Not later than April 1 of fiscal year 1998 and February 1 of each subsequent fiscal year, the Secretary shall submit a report to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate that provides an estimate of the Secretary of the costs of carrying out the notification program established under this subsection for the next fiscal year.

(6) In this section, the term ''food contact substance'' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

Amendment or Repeal of Regulations

(i) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations. The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective.

Exemptions for Investigational Use

(j) Without regard to subsections (b) to (i), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

BOTTLED DRINKING WATER STANDARDS

SEC. 410. [21 U.S.C. 349] (a) Except as provided in subsection (b), whenever the Administrator of the Environmental Protection Agency prescribes interim or revised national primary drinking water regulations under section 1412 of the Public Health Service Act, the Secretary shall consult with the Administrator and within 180 days after the promulgation of such drinking water regulations either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal Register his reasons for not making such amendments.

(b)(1) Not later than 180 days before the effective date of a national primary drinking water regulation promulgated by the Administrator of the Environmental Protection Agency for a contaminant under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the Secretary shall promulgate a standard of quality regulation under this subsection for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems (as defined under section 1401(4) of such Act (42 U.S.C. 300f(4))) but not in water used for bottled drinking water. The effective date for any such standard of quality regulation shall be the same as the effective date for such national primary drinking water regulation, except for any standard of quality of regulation promulgated by the Secretary before the date of enactment of the Safe Drinking Water Act Amendments of 1996 for which (as of such date of enactment) an effective date had not been established. In the case of a standard of quality regulation to which such exception applies, the Secretary shall promulgate monitoring requirements for the contaminants covered by the regulation not later than 2 years after such date of enactment.

(2) A regulation issued by the Secretary as provided in this subsection shall include any monitoring requirements that the Secretary determines appropriate for bottled water.

(3) A regulation issued by the Secretary as provided in this subsection shall require the following:

(A) In the case of contaminants for which a maximum contaminant level is established in a national primary drinking water regulation under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the regulation under this subsection shall establish a maximum contaminant level for the contaminant in bottled water which is no less stringent than the maximum contaminant level provided in the national primary drinking water regulation.

(B) In the case of contaminants for which a treatment technique is established in a national primary drinking water regulation under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the regulation under this subsection shall require that bottled water be subject to requirements no less protective of the public health than those applicable to water provided by public water systems using the treatment technique required by the national primary drinking water regulation.

(4)(A) If the Secretary does not promulgate a regulation under this subsection within the period described in paragraph (1), the national primary drinking water regulation referred to in paragraph (1) shall be considered, as of the date on which the Secretary is required to establish a regulation under paragraph (1), as the regulation applicable under this subsection to bottled water.

(B) In the case of a national primary drinking water regulation that pursuant to subparagraph (A) is considered to be a standard of quality regulation, the Secretary shall, not later than the applicable date referred to in such subparagraph, publish in the Federal Register a notice—

(i) specifying the contents of such regulation, including monitoring requirements; and

(ii) providing that for purposes of this paragraph the effective date for such regulation is the same as the effective date for the regulation for purposes of the Safe Drinking Water Act (or, if the exception under paragraph (1) applies to the regulation, that the effective date for the regulation is not later than 2 years and 180 days after the date of enactment of the Safe Drinking Water Act Amendments of 1996).

VITAMINS AND MINERALS

SEC. 411. [21 U.S.C. 350] (a)(1) Except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of any synthetic or natural—

(i) vitamin,

(ii) mineral, or

(iii) other ingredient of food,

within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph[42], the term "children" means individuals who are under the age of twelve years.

(b)(1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403(i)(2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2) The labeling for any food to which this section applies may not list its ingredients which are not dietary supplement ingredients described in section 201(ff) (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 403. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(c)(1) For purposes of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or

(ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 403 (j) insofar as that section is applicable to food to which this section applies, the term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

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[42] So in law. Probably should be "paragraph".

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

REQUIREMENTS FOR INFANT FORMULAS

SEC. 412. [21 U.S.C. 350a] (a) An infant formula, including an infant formula powder, shall be deemed to be adulterated if—

(1) such infant formula does not provide nutrients as required by subsection (i),

(2) such infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1), or

(3) the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary under subsection (b)(2).

(b)(1) The Secretary shall by regulation establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i).

(2)(A) The Secretary shall by regulation establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to assure that an infant formula provides nutrients in accordance with this subsection and subsection (i) and is manufactured in a manner designed to prevent adulteration of the infant formula.

(B) The good manufacturing practices and quality control procedures prescribed by the Secretary under subparagraph (A) shall include requirements for—

(i) the testing, in accordance with paragraph (3) and by the manufacturer of an infant formula or an agent of such manufacturer, of each batch of infant formula for each nutrient required by subsection (i) before the distribution of such batch,

(ii) regularly scheduled testing, by the manufacturer of an infant formula or an agent of such manufacturer, of samples of infant formulas during the shelf life of such formulas to ensure that such formulas are in compliance with this section,

(iii) in-process controls including, where necessary, testing required by good manufacturing practices designed to prevent adulteration of each batch of infant formula, and

(iv) the conduct by the manufacturer of an infant formula or an agent of such manufacturer of regularly scheduled audits to determine that such manufacturer has complied with the regulations prescribed under subparagraph (A).

In prescribing requirements for audits under clause (iv), the Secretary shall provide that such audits be conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula.

(3)(A) At the final product stage, each batch of infant formula shall be tested for vitamin A, vitamin B1, vitamin C, and vitamin E to ensure that such infant formula is in compliance with the requirements of this subsection and subsection (i) relating to such vitamins.

(B) Each nutrient premix used in the manufacture of an infant formula shall be tested for each relied upon nutrient required by

subsection (i) which is contained in such premix to ensure that such premix is in compliance with its specifications or certifications by a premix supplier.

(C) During the manufacturing process or at the final product stage and before distribution of an infant formula, an infant formula shall be tested for all nutrients required to be included in such formula by subsection (i) for which testing has not been conducted pursuant to subparagraph (A) or (B). Testing under this subparagraph shall be conducted to—

(i) ensure that each batch of such infant formula is in compliance with the requirements of subsection (i) relating to such nutrients, and

(ii) confirm that nutrients contained in any nutrient premix used in such infant formula are present in each batch of such infant formula in the proper concentration.

(D) If the Secretary adds a nutrient to the list of nutrients in the table in subsection (i), the Secretary shall by regulation require that the manufacturer of an infant formula test each batch of such formula for such new nutrient in accordance with subparagraph (A), (B), or (C).

(E) For purposes of this paragraph, the term "final product stage" means the point in the manufacturing process, before distribution of an infant formula, at which an infant formula is homogenous and is not subject to further degradation.

(4)(A) The Secretary shall by regulation establish requirements respecting the retention of records. Such requirements shall provide for—

(i) the retention of all records necessary to demonstrate compliance with the good manufacturing practices and quality control procedures prescribed by the Secretary under paragraph (2), including records containing the results of all testing required under paragraph (2)(B),

(ii) the retention of all certifications or guarantees of analysis by premix suppliers,

(iii) the retention by a premix supplier of all records necessary to confirm the accuracy of all premix certifications and guarantees of analysis,

(iv) the retention of—

(I) all records pertaining to the microbiological quality and purity of raw materials used in infant formula powder and in finished infant formula, and

(II) all records pertaining to food packaging materials which show that such materials do not cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C),

(v) the retention of all records of the results of regularly scheduled audits conducted pursuant to the requirements prescribed by the Secretary under paragraph (2)(B)(iv), and

(vi) the retention of all complaints and the maintenance of files with respect to, and the review of, complaints concerning infant formulas which may reveal the possible existence of a hazard to health.

(B)(i) Records required under subparagraph (A) with respect to an infant formula shall be retained for at least one year after the

expiration of the shelf life of such infant formula. Except as provided in clause (ii), such records shall be made available to the Secretary for review and duplication upon request of the Secretary.

(ii) A manufacturer need only provide written assurances to the Secretary that the regularly scheduled audits required by paragraph (2)(B)(iv) are being conducted by the manufacturer, and need not make available to the Secretary the actual written reports of such audits.

(c)(1) No person shall introduce or deliver for introduction into interstate commerce any new infant formula unless—

(A) such person has, before introducing such new infant formula, or delivering such new infant formula for introduction, into interstate commerce, registered with the Secretary the name of such person, the place of business of such person, and all establishments at which such person intends to manufacture such new infant formula, and

(B) such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by subsection (c)(1).

(2) For purposes of paragraph (1), the term "new infant formula" includes—

(A) an infant formula manufactured by a person which has not previously manufactured an infant formula, and

(B) an infant formula manufactured by a person which has previously manufactured infant formula and in which there is a major change, in processing or formulation, from a current or any previous formulation produced by such manufacturer.

For purposes of this paragraph, the term "major change" has the meaning given to such term in section 106.30(c)(2) of title 21, Code of Federal Regulations (as in effect on August 1, 1986), and guidelines issued thereunder.

(d)(1) A person shall, with respect to any infant formula subject to subsection (c), make a submission to the Secretary which shall include—

(A) the quantitative formulation of the infant formula,

(B) a description of any reformulation of the formula or change in processing of the infant formula,

(C) assurances that the infant formula will not be marketed unless it meets the requirements of subsections (b)(1) and (i), as demonstrated by the testing required under subsection (b)(3), and

(D) assurances that the processing of the infant formula complies with subsection (b)(2).

(2) After the first production of an infant formula subject to subsection (c), and before the introduction into interstate commerce of such formula, the manufacturer of such formula shall submit to the Secretary, in such form as may be prescribed by the Secretary, a written verification which summarizes test results and records demonstrating that such formula complies with the requirements of subsections (b)(1), (b)(2)(A), (b)(2)(B)(i), (b)(2)(B)(iii), (b)(3)(A), (b)(3)(C), and (i).

(3) If the manufacturer of an infant formula for commercial or charitable distribution for human consumption determines that a

change in the formulation of the formula or a change in the processing of the formula may affect whether the formula is adulterated under subsection (a), the manufacturer shall, before the first processing of such formula, make the submission to the Secretary required by paragraph (1).

(e)(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer—

(A) may not provide the nutrients required by subsection (i), or

(B) may be otherwise adulterated or misbranded,

the manufacturer shall promptly notify the Secretary of such knowledge. If the Secretary determines that the infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

(2) For purposes of paragraph (1), the term "knowledge" as applied to a manufacturer means (A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(f)(1) If a recall of infant formula is begun by a manufacturer, the recall shall be carried out in accordance with such requirements as the Secretary shall prescribe under paragraph (2) and—

(A) the Secretary shall, not later than the 15th day after the beginning of such recall and at least once every 15 days thereafter until the recall is terminated, review the actions taken under the recall to determine whether the recall meets the requirements prescribed under paragraph (2), and

(B) the manufacturer shall, not later than the 14th day after the beginning of such recall and at least once every 14 days thereafter until the recall is terminated, report to the Secretary the actions taken to implement the recall.

(2) The Secretary shall by regulation prescribe the scope and extent of recalls of infant formulas necessary and appropriate for the degree of risks to human health presented by the formula subject to the recall.

(3) The Secretary shall by regulation require each manufacturer of an infant formula who begins a recall of such formula because of a risk to human health to request each retail establishment at which such formula is sold or available for sale to post at the point of purchase of such formula a notice of such recall at such establishment for such time that the Secretary determines necessary to inform the public of such recall.

(g)(1) Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least one year after the expiration of the shelf life of the infant formula.

(2) To the extent that the Secretary determines that records are not being made or maintained in accordance with paragraph (1),

the Secretary may by regulation prescribe the records required to be made under paragraph (1) and requirements respecting the retention of such records under such paragraph. Such regulations shall take effect on such date as the Secretary prescribes but not sooner than the 180th day after the date such regulations are promulgated. Such regulations shall apply only with respect to distributions of infant formulas made after such effective date.

(h)(1) Any infant formula which is represented and labeled for use by an infant—

(A) who has an inborn error of metabolism or a low birth weight, or

(B) who otherwise has an unusual medical or dietary problem,

is exempt from the requirements of subsections (a), (b), and (c). The manufacturer of an infant formula exempt under this paragraph shall, in the case of the exempt formula, be required to provide the notice required by subsection (e)(1) only with respect to adulteration or misbranding described in subsection (e)(1)(B) and to comply with the regulations prescribed by the Secretary under paragraph (2).

(2) The Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a), (b), and (c). An exemption of an infant formula under paragraph (1) may be withdrawn by the Secretary if such formula is not in compliance with applicable terms and conditions prescribed under this paragraph.

(i)(1) An infant formula shall contain nutrients in accordance with the table set out in this subsection or, if revised by the Secretary under paragraph (2), as so revised.

(2) The Secretary may by regulation—

(A) revise the list of nutrients in the table in this subsection, and

(B) revise the required level for any nutrient required by the table.

NUTRIENTS

Nutrient	Minimum [1]	Maximum [1]
Protein (gm)	1.8 [2]	4.5.
Fat:		
gm	3.3	6.0.
percent cal	30.0	54.0.
Essential fatty acids (linoleate):		
percent cal	2.7	
mg	300.0	
Vitamins:		
A (IU)	250.0 (75 µg) [3]	750.0 (225 µg).[3]
D (IU)	40.0	100.0.
K (µg)	4.0	
E (IU)	0.7 (with 0.7 IU/gm linoleic acid).	
C (ascorbic acid) (mg)	8.0	
B_1 (thiamine) (µg)	40.0	
B_2 (riboflavin) (µg)	60.0	
B_6 (pyridoxine) (µg)	35.0 (with 15 µg/gm of protein in formula).	
B_{12} (µg)	0.15	
Niacin (µg)	250.0	
Folic acid (µg)	4.0	
Pantothenic acid (µg)	300.0	
Biotin (µg)	1.5 [4]	
Choline (mg)	7.0 [4]	
Inositol (mg)	4.0 [4]	
Minerals:		
Calcium (mg)	50.0 [5]	
Phosphorus (mg)	25.0 [5]	
Magnesium (mg)	6.0	
Iron (mg)	0.15	
Iodine (µg)	5.0	
Zinc (mg)	0.5	
Copper (µg)	60.0	
Manganese (µg)	5.0	
Sodium (mg)	20.0	60.0.
Potassium (mg)	80.0	200.0.
Chloride (mg)	55.0	150.0.

[1] Stated per 100 kilocalories.
[2] The source of protein shall be at least nutritionally equivalent to casein.
[3] Retinol equivalents.
[4] Required to be included in this amount only in formulas which are not milk-based.
[5] Calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0.

NEW DIETARY INGREDIENTS

SEC. 413. [21 U.S.C. 350b] (a) IN GENERAL.—A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of

the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

(b) PETITION.—Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, United States Code, the decision of the Secretary shall be considered final agency action.

(c) DEFINITION.—For purposes of this section, the term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.

SEC. 414. [21 U.S.C. 350c] MAINTENANCE AND INSPECTION OF RECORDS.

(a) RECORDS INSPECTION.—If the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The requirement under the preceding sentence applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health

consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

(c) PROTECTION OF SENSITIVE INFORMATION.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

(d) LIMITATIONS.—This section shall not be construed—

(1) to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this Act;

(2) to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

(3) to have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code; or

(4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

SEC. 415. [21 U.S.C. 350d] REGISTRATION OF FOOD FACILITIES.

(a) REGISTRATION.—

(1) IN GENERAL.—The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. To be registered—

(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and

(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

(2) REGISTRATION.—An entity (referred to in this section as the "registrant") shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed, or held at such facility. The registrant shall notify the Secretary in a timely manner of changes to such information.

(3) PROCEDURE.—Upon receipt of a completed registration described in paragraph (1), the Secretary shall notify the registrant of the receipt of such registration and assign a registration number to each registered facility.

(4) LIST.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section.

Such list and any registration documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code. Information derived from such list or registration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered person.

(b) FACILITY.—For purposes of this section:

(1) The term "facility" includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).

(2) The term "domestic facility" means a facility located in any of the States or Territories.

(3)(A) The term "foreign facility" means a facility that manufacturers, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States.

(B) A food may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the food.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process.

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. [21 U.S.C. 351] A drug or device shall be deemed to be adulterated—[43]

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and

[43] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a), or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a); or (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

(e)(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514, unless such device is in all respects in conformity with such standard.

(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.

(f)(1) If it is a class III device—

(A)(i) which is required by a regulation promulgated under subsection (b) of section 515 to have an approval under such section of an application for premarket approval and which is not exempt from section 515 under section 520(g), and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g), and

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 520(l) into class III, which under such section is required to have in effect an approved application under section 515, and which has an application which has been suspended or is otherwise not in effect.

(2)(A) In the case of a device classified under section 513(f) into class III and intended solely for investigational use, paragraph [44] (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g)(2).

(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 515, paragraph [45] (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or

(ii) on the ninetieth day after the date of the promulgation of such regulation,

whichever occurs later.

(g) If it is a banned device.

(h) If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section

[44] So in law. Probably should be "subparagraph".
[45] So in law. Probably should be "subparagraph".

520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).

(i) If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

MISBRANDED DRUGS AND DEVICES

SEC. 502. [21 U.S.C. 352] A drug or device shall be deemed to be misbranded—[46]

(a) If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term ''health care economic information'' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(e)(1)(A)[47] If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

[46] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of ''(a)'', ''(b)'', etc.

[47] Paragraph (d) was struck by section 126(6) of Public Law 105–115 (111 Stat. 2327).

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under

different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

(4) As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States, it shall be subject to the requirements of the United States Pharmacopeia with respect to packaging, and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States, and not to those of the United States Pharmacopeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(m)[48] If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 721.

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e)[49], printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e)[50], and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act, except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57). This paragraph (n)[51] shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers.[52]

(o) If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 510, if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires.

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[48] Paragraph (k) was struck by section 125(a)(2)(B) of Public Law 105–115 (111 Stat. 2325). Paragraph (l) was struck by section 125(b)(2)(D) of such public law.

[49] So in law. Probably should be "paragraph (e)".

[50] So in law. Probably should be "paragraph (e)".

[51] So in law. Probably should be "This paragraph".

[52] Sentence was added by title I of Public Law 95–633. Section 112 of such Public Law provided as follows: "This title shall take effect on the date the Convention on Psychotropic Substances, signed at Vienna, Austria on February 21, 1971, enters into force in respect to the United States.". The Convention entered into force in respect to the United States on July 15, 1980.

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(q) In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e).

(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52–55). This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m).

(s) If it is a device subject to a performance standard established under section 514, unless it bears such labeling as may be prescribed in such performance standard.

(t) If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 518 respecting the device, (2) to furnish any material or information required by or under section 519 respecting the device, or (3) to comply with a requirement under section 522.

(u)[53] If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this paragraph for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would

[53] Paragraph (u) was added by section 301(a) of Public Law 107–250 (116 Stat. 1616), which was enacted Oct. 26, 2002. Subsection (b) of such section (as amended by section 2(c)(1) of Public Law 108–214; 118 Stat. 575) provides as follows:

"(b) EFFECTIVE DATE.—The amendment made by subsection (a) takes effect 36 months after the date of the enactment of this Act, and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date.".

compromise the provision of reasonable assurance of the safety or effectiveness of the device.

(v)[54] If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use. Reprocessed by ____." The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

(w) If it is a new animal drug—

(1) that is conditionally approved under section 571 and its labeling does not conform with the approved application or section 571(f), or that is not conditionally approved under section 571 and its label bears the statement set forth in section 571(f)(1)(A); or

(2) that is indexed under section 572 and its labeling does not conform with the index listing under section 572(e) or 572(h), or that has not been indexed under section 572 and its label bears the statement set forth in section 572(h).

EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS

SEC. 503. [21 U.S.C. 353] (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded, under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b)(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

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[54] Paragraph (v) was added by section 302(a)(1) of Public Law 107–250 (116 Stat. 1616), which was enacted Oct. 26, 2002. Paragraph (2) of such subsection provides as follows:

"(2) EFFECTIVE DATE.—The amendment made by paragraph (1) takes effect 15 months after the date of the enactment of this Act, and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date.".

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U.S.C. 3220), or to marihuana as defined in section 3238(b) of the Internal Revenue Code (26 U.S.C. 3238(b)).

(c)(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b).

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b), and

(ii)(I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Subparagraph (A) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b).

For purposes of this paragraph, the term ''entity'' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term ''emergency medical reasons'' includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d)(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term ''distribute'' does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(e)(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

(B) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B).

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

(3) For the purposes of this subsection and subsection (d)—

(A) the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

(B) the term "wholesale distribution" means distribution of drugs subject to subsection (b) to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B).

(f)(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 512, a conditionally-approved application under section 571, or an index listing under section 572 to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) Shall be exempt from the requirements of section 502, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filing, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512, 571, or 572 from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.". A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g)(1) The Secretary shall in accordance with this subsection assign an agency center to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product.

If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market clearance procedures in accordance with paragraphs (1) and (2) not later than 1 year after the date of enactment of this subsection.[55]

(4)(A) Not later than 60 days after the date of the enactment of this paragraph[56], the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely and effective premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of Food and Drugs that is responsible for such determinations. Such office (referred to in this paragraph as the "Office") shall have appropriate scientific and medical expertise, and shall be headed by a director.

(B) In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.

(C)(i) In carrying out this subsection, the Office shall ensure timely and effective premarket reviews by overseeing the timeliness of and coordinating reviews involving more than one agency center.

(ii) In order to ensure the timeliness of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness of the premarket review.

(D) In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

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[55] The subsection was added by section 16(a)(2) of Public Law 101–692, which was enacted Nov. 28, 1990. The subsection was added as subsection (f), and was redesignated as subsection (g) by section 2(d)(4) of Public Law 102–108.

[56] Paragraph (4) was added by section 204(3) of Public Law 107–250 (116 Stat. 1611), which was enacted Oct. 26, 2002.

(E)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the dispute is clearly premature.

(ii) During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

(F) The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

(G) Not later than one year after the date of the enactment of this paragraph and annually thereafter, the Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions—

(i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;

(ii) identifying the number of premarket reviews of such products that involved a consulting agency center; and

(iii) describing improvements in the consistency of postmarket regulation of combination products.

(H) Nothing in this paragraph shall be construed to limit the regulatory authority of any agency center.

(5) As used in this subsection:

(A) The term "agency center" means a center or alternative organizational component of the Food and Drug Administration.

(B) The term "biological product" has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(C) The term "market clearance" includes—

(i) approval of an application under section 505, 507, 515, or 520(g),

(ii) a finding of substantial equivalence under this subchapter, and

(iii) approval of a biologics license application under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 503A. [21 U.S.C. 353a] PHARMACY COMPOUNDING.

(a) IN GENERAL.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii)(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) COMPOUNDED DRUG.—

(1) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);

(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) DEFINITION.—For purposes of paragraph (1)(D), the term ''essentially a copy of a commercially available drug product'' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) DRUG PRODUCT.—A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

(c) ADVERTISING AND PROMOTION.—A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or

licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

(d) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) LIMITING COMPOUNDING.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(e) APPLICATION.—This section shall not apply to—

(1) compounded positron emission tomography drugs as defined in section 201(ii); or

(2) radiopharmaceuticals.

(f) DEFINITION.—As used in this section, the term ''compounding'' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

VETERINARY FEED DIRECTIVE DRUGS

SEC. 504. [21 U.S.C. 354] (a)(1) A drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b), a conditionally-approved application filed pursuant to section 571, or an index listing pursuant to section 572 to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug. Any animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from section 502(f).

(2) A veterinary feed directive is lawful if it—

(A) contains such information as the Secretary may by general regulation or by order require; and

(B) is in compliance with the conditions and indications for use of the drug set forth in the notice published pursuant to section 512(i), or the index listing pursuant to section 572(e).

(3)(A) Any persons involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug and the licensed veterinarian issuing the veterinary feed directive shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing such feed to another person for further distribution. Such person distributing the feed shall maintain a written acknowledgment from the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to its immediate supplier.

(B) Every person required under subparagraph (A) to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(C) Any person who distributes animal feed bearing or containing a veterinary feed directive drug shall upon first engaging in such distribution notify the Secretary of that person's name and place of business. The failure to provide such notification shall be deemed to be an act which results in the drug being misbranded.

(b) A veterinary feed directive drug and any feed bearing or containing a veterinary feed directive drug shall be deemed to be misbranded if their labeling fails to bear such cautionary statement and such other information as the Secretary may by general regulation or by order prescribe, or their advertising fails to conform to the conditions and indications for use published pursuant to section 512(i), or the index listing pursuant to section 572(e) or fails to contain the general cautionary statement prescribed by the Secretary.

(c) Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any Federal or State law.

NEW DRUGS

SEC. 505. [21 U.S.C. 355] (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;[57] (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such

[57] The amendments made to this act by the Drug Amendments of 1962 (Public Law 87–781) included amendments establishing the requirement that new drugs be effective. Section 107(c) of such Public Law concerned the applicability of the amendments.

drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 505B. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug. If a application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in

the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant

makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(c)(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited

basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary, the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence[58], and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

[58] Provision was added by title I of Public Law 98–417, which was enacted Sept. 24, 1984.

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B)[59] relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access

[59] So in law. See section 1101(b)(2)(D) of Public Law 108–173 (117 Stat. 2454). Probably should be "subsection (b)(3)".

shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection [60], the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has

[60] See footnote for subsection (c)(2).

not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this

clause and the supplement contains reports of new clinical investigations (other than bioavailabilty[61] studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions;

[61] So in law. Probably should be "bioavailability".

or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under

this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 510(k)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court

unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i)(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D)[62] the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of

[62] Indentation is so in law. See section 15(c) of Public Law 107–109 (115 Stat. 1420).

a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims

the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in

the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[63] the Secretary shall issue guidance defining the term ''listed drug'' for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this

[63] Public Law 108–173, enacted Dec. 8, 2003.

paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug

under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term ''180-day exclusivity period'' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term ''first applicant'' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application

that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought

such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the

applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term ''forfeiture event'', with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final

judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection[64], the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection[65], no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time

[64] This subsection was added by title I of Public Law 98–417, which was enacted Sept. 24, 1984.

[65] See footnote for clause (i).

(if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection [66] and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection [67] and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection [68], the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection [69].

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

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[66] See footnote for clause (i).
[67] See footnote for clause (i).
[68] See footnote for clause (i).
[69] See footnote for clause (i).

(7)(A)(i) Within sixty days of the date of the enactment of this subsection [70], the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection [71];

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment [72], whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) [73] For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

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[70] See footnote for paragraph (5)(F)(i).
[71] See footnote for paragraph (5)(F)(i).
[72] See footnote for paragraph (5)(F)(i).
[73] Subsection (a) of section 1103 of Public Law 108–173 (117 Stat. 2460) amended subparagraph (A) of paragraph (8) to read as provided above, and also added to such paragraph subparagraph (C) above. Subsection (b) of such section 1103 provides as follows: "The amendment made by subsection (a) does not alter the standards for approval of drugs under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j))."

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(k)(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for

the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(l) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(m) For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 904 to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

(5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

SEC. 505A. [21 U.S.C. 355a] PEDIATRIC STUDIES OF DRUGS.[74]

(a) DEFINITIONS.—As used in this section, the term "pediatric studies" or "studies" means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used.

(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

(2)(A) if the drug is the subject of—

(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a

[74] Section 16 of Public Law 107–109 (115 Stat. 1421) requires the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, to submit to Congress a report that relates to section 505A and to section 409I of the Public Health Service Act. The report is required to be submitted not later than Oct. 1, 2006.

period of six months after the date the patent expires (including any patent extensions).

(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

(2)(A) if the drug is the subject of—

(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

(d) CONDUCT OF PEDIATRIC STUDIES.—

(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request from the Secretary under subsection (b) or (c), after consultation with—

(A) the sponsor of an application for an investigational new drug under section 505(i);

(B) the sponsor of an application for a new drug under section 505(b)(1); or

(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug. Such agreement shall be in writing and shall include a timeframe for such studies.

(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (b) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). In reaching an agreement regarding written protocols, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (b) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

(4) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.—

(A) REQUEST AND RESPONSE.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (c) to the holder of an application approved under section 505(b)(1), the holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the holder to act on the request by—

(i) indicating when the pediatric studies will be initiated, if the holder agrees to the request; or

(ii) indicating that the holder does not agree to the request.

(B) NO AGREEMENT TO REQUEST.—

(i) REFERRAL.—If the holder does not agree to a written request within the time period specified in

subparagraph (A), and if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall refer the drug to the Foundation for the National Institutes of Health established under section 499 of the Public Health Service Act (42 U.S.C. 290b) (referred to in this paragraph as the "Foundation") for the conduct of the pediatric studies described in the written request.

(ii) PUBLIC NOTICE.—The Secretary shall give public notice of the name of the drug, the name of the manufacturer, and the indications to be studied made in a referral under clause (i).

(C) LACK OF FUNDS.—On referral of a drug under subparagraph (B)(i), the Foundation shall issue a proposal to award a grant to conduct the requested studies unless the Foundation certifies to the Secretary, within a timeframe that the Secretary determines is appropriate through guidance, that the Foundation does not have funds available under section 499(j)(9)(B)(i)[75] to conduct the requested studies. If the Foundation so certifies, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of the studies.

(D) EFFECT OF SUBSECTION.—Nothing in this subsection (including with respect to referrals from the Secretary to the Foundation) alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(E) NO REQUIREMENT TO REFER.—Nothing in this subsection shall be construed to require that every declined written request shall be referred to the Foundation.

(F) WRITTEN REQUESTS UNDER SUBSECTION (b).—For drugs under subsection (b) for which written requests have not been accepted, if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall issue a written request under subsection (c) after the date of approval of the drug.

(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATION.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a new drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or the applicable period under clauses (ii) through (iv) of section 505(c)(3)(D) or clauses (ii) through (iv) of section 505(j)(5)(F), but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j) until the determination under subsection (d) is

[75] So in law. There is no section 499 in this act. The probable intent of the Congress was to refer to section 499 of the Public Health Service Act, which provides for a Foundation.

made, but any such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable six-month period under subsection (b) or (c) shall be deemed to have been running during the period of delay.

(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.

(g) LIMITATIONS.—A drug to which the six-month period under subsection (b) or (c) has already been applied—

(1) may receive an additional six-month period under subsection (c)(1)(A)(ii) for a supplemental application if all other requirements under this section are satisfied, except that such a drug may not receive any additional such period under subsection (c)(2); and

(2) may not receive any additional such period under subsection (c)(1)(B).

(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Notwithstanding any other provision of law, if any pediatric study is required by a provision of law (including a regulation) other than this section and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

(i) LABELING SUPPLEMENTS.—

(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENTS.—Any supplement to an application under section 505 proposing a labeling change pursuant to a report on a pediatric study under this section—

(A) shall be considered to be a priority supplement; and

(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

(2) DISPUTE RESOLUTION.—

(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that an application with respect to which a pediatric study is conducted under this section is approvable and that the only open issue for final action on the application is the reaching of an agreement between the sponsor of the application and the Commissioner on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application—

(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

(ii) if the sponsor of the application does not agree to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under

subparagraph (A)(ii), the Pediatric Advisory Committee shall—

(i) review the pediatric study reports; and

(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate.

(D) MISBRANDING.—If the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.

(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(j) DISSEMINATION OF PEDIATRIC INFORMATION.—

(1) IN GENERAL.—Not later than 180 days after the date of submission of a report on a pediatric study under this section, the Commissioner shall make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement, including by publication in the Federal Register.

(2) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(k) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—

(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or

(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period would, but for the application of this subsection, expire during the six-month exclusivity period.

(l) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING.—

(1) GENERAL RULE.—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).

(2) LABELING.—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—

(A) a statement that, because of marketing exclusivity for a manufacturer—

(i) the drug is not labeled for pediatric use; or

(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and

(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.

(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS.—This subsection does not affect—

(A) the availability or scope of exclusivity under this section;

(B) the availability or scope of exclusivity under section 505 for pediatric formulations;

(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or

(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.

(m) REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program established under this section. The study and report shall examine all relevant issues, including—

(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

(2) the adequacy of the incentive provided under this section;

(3) the economic impact of the program on taxpayers and consumers, including the impact of the lack of lower cost generic drugs on patients, including on lower income patients; and

(4) any suggestions for modification that the Secretary determines to be appropriate.

(n) SUNSET.—A drug may not receive any 6-month period under subsection (a) or (c)[76] unless—

(1) on or before October 1, 2007, the Secretary makes a written request for pediatric studies of the drug;

(2) on or before October 1, 2007, an application for the drug is accepted for filing under section 505(b); and

(3) all requirements of this section are met.

SEC. 505B.[77] [21 U.S.C. 355c] RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—A person that submits an application (or supplement to an application)—

(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration;

shall submit with the application the assessments described in paragraph (2).

(2) ASSESSMENTS.—

(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate

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[76] Probably should be "subsection (b) or (c)". Section 19(4) of Public Law 107–109 (115 Stat. 1424) provided in part that subsection (m) is amended by striking "subsection (a) or (c)" and inserting "subsection (b) or (c)". The language to be struck does not appear in subsection (m), but does appear in subsection (n). (Subsections (m) and (n) were two of 10 subsections redesignated by section 19(2) of such Public Law.)

[77] Section 2 of Public Law 108–155 (117 Stat. 1936) added section 505B above. Section 4 of such act (117 Stat. 1942) provides as follows:

"SEC. 4. EFFECTIVE DATE.

"(a) IN GENERAL.—Subject to subsection (b), this Act and the amendments made by this Act take effect on the date of enactment of this Act.

"(b) APPLICABILITY TO NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—Subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall apply to an application described in paragraph (1) of that subsection submitted to the Secretary of Health and Human Services on or after April 1, 1999.

"(2) WAIVERS AND DEFERRALS.—

"(A) WAIVER OR DEFERRAL GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, a waiver or deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the waiver or deferral shall be a waiver or deferral under subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act, except that any date specified in such a deferral shall be extended by the number of days that is equal to the number of days between October 17, 2002, and the date of enactment of this Act.

"(B) WAIVER AND DEFERRAL NOT GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, neither a waiver nor deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the person that submitted the application shall be required to submit assessments under subsection (a)(2) of section 505B of the Federal Food, Drug, and Cosmetic Act on the date that is the later of—

"(i) the date that is 1 year after the date of enactment of this Act; or

"(ii) such date as the Secretary may specify under subsection (a)(3) of that section;

"unless the Secretary grants a waiver under subsection (a)(4) of that section.

"(c) NO LIMITATION OF AUTHORITY.—Neither the lack of guidance or regulations to implement this Act or the amendments made by this Act nor the pendency of the process for issuing guidance or regulations shall limit the authority of the Secretary of Health and Human Services under, or defer any requirement under, this Act or those amendments.".

formulations for each age group for which the assessment is required, that are adequate—

(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.

(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

(A) the Secretary finds that—

(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

(iii) there is another appropriate reason for deferral; and

(B) the applicant submits to the Secretary—

(i) certification of the grounds for deferring the assessments;

(ii) a description of the planned or ongoing studies; and

(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.

(4) WAIVERS.—

(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—After providing notice in the form of a letter and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) if the Secretary finds that—

(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or

(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for one or more of the claimed indications; and

(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

(2) WAIVERS.—

(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

(iii)(I) the drug or biological product—

(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(3) RELATIONSHIP TO OTHER PEDIATRIC PROVISIONS.—

(A) NO ASSESSMENT WITHOUT WRITTEN REQUEST.—No assessment may be required under paragraph (1) for a drug subject to an approved application under section 505 unless—

(i) the Secretary has issued a written request for a related pediatric study under section 505A(c) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m);

(ii)(I) if the request was made under section 505A(c)—

(aa) the recipient of the written request does not agree to the request; or

(bb) the Secretary does not receive a response as specified under section 505A(d)(4)(A); or

(II) if the request was made under section 409I of the Public Health Service Act (42 U.S.C. 284m)—

(aa) the recipient of the written request does not agree to the request; or

(bb) the Secretary does not receive a response as specified under section 409I(c)(2) of that Act; and

(iii)(I) the Secretary certifies under subparagraph (B) that there are insufficient funds under sections 409I and 499 of the Public Health Service Act (42 U.S.C. 284m, 290b) to conduct the study; or

(II) the Secretary publishes in the Federal Register a certification that certifies that—

(aa) no contract or grant has been awarded under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b); and

(bb) not less than 270 days have passed since the date of a certification under subparagraph (B) that there are sufficient funds to conduct the study.

(B) NO AGREEMENT TO REQUEST.—Not later than 60 days after determining that no holder will agree to the written request (including a determination that the Secretary has not received a response specified under section 505A(d) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m), the Secretary shall certify whether the Secretary has sufficient funds to conduct the study under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b), taking into account the prioritization under section 409I.

(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B)(i) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary estimates that—

(1) if approved, the drug or biological product would represent a significant improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit an assessment described in subsection (a)(2), or a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

(2) the failure to submit the assessment or request shall not be the basis for a proceeding—

(A) to withdraw approval for a drug under section 505(e); or

(B) to revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

(e) MEETINGS.—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—

(1) information that the sponsor submits on plans and timelines for pediatric studies; or

(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

(f) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

(g) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.

(h) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(n).

SEC. 506. [21 U.S.C. 356] FAST TRACK PRODUCTS.

(a) DESIGNATION OF DRUG AS A FAST TRACK PRODUCT.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition. (In this section, such a drug is referred to as a ''fast track product''.)

(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application

for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

(b) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—

(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track product under section 505(c) or section 351 of the Public Health Service Act upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

(2) LIMITATION.—Approval of a fast track product under this subsection may be subject to the requirements—

(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the effect on the clinical endpoint; and

(B) that the sponsor submit copies of all promotional materials related to the fast track product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

(B) a post-approval study of the fast track product fails to verify clinical benefit of the product;

(C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

(A) provides a schedule for submission of information necessary to make the application complete; and

(B) pays any fee that may be required under section 736.

(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

(d) AWARENESS EFFORTS.—The Secretary shall—

(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to fast track products; and

(2) establish a program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.

SEC. 506A. [21 U.S.C. 356a] MANUFACTURING CHANGES.

(a) IN GENERAL.—With respect to a drug for which there is in effect an approved application under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (referred to in this section as a ''holder'') has validated the effects of the change in accordance with subsection (b); and

(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).

(b) VALIDATION OF EFFECTS OF CHANGES.—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

(c) MAJOR MANUFACTURING CHANGES.—

(1) REQUIREMENT OF SUPPLEMENTAL APPLICATION.—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(2) CHANGES QUALIFYING AS MAJOR CHANGES.—For purposes of subsection (a)(2)(A), a major manufacturing change is a

manufacturing change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug. Such a change includes a change that—

(A) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in subsection (a) for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection);

(B) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

(C) is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

(d) OTHER MANUFACTURING CHANGES.—

(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

(A) The Secretary may in accordance with paragraph (2) authorize holders to distribute such drugs without submitting a supplemental application for such changes.

(B) The Secretary may in accordance with paragraph (3) require that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications for such changes.

(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

(2) CHANGES NOT REQUIRING SUPPLEMENTAL APPLICATION.—

(A) SUBMISSION OF REPORT.—A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information developed under subsection (b) by the holder in validating the effects of the change. The report shall be submitted by such date as the Secretary may specify.

(B) AUTHORITY REGARDING ANNUAL REPORTS.—In the case of a holder that during a single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph by submitting a single report for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

(3) CHANGES REQUIRING SUPPLEMENTAL APPLICATION.—

(A) SUBMISSION OF SUPPLEMENTAL APPLICATION.—The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information

as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(B) AUTHORITY FOR DISTRIBUTION.—In the case of a manufacturing change to which paragraph (1)(B) applies:

(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph, unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced.

(ii) The Secretary may designate a category of such changes for the purpose of providing that, in the case of a change that is in such category, the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change.

(iii) If the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change.

SEC. 506B. [21 U.S.C. 356b] REPORTS OF POSTMARKETING STUDIES.

(a) SUBMISSION.—

(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

(2) AGREEMENTS PRIOR TO EFFECTIVE DATE.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Administration Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

(b) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—Any information pertaining to a report described in subsection (a) shall be considered to be public information to the extent that the information is necessary—

(1) to identify the sponsor; and

(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides information on the status of the postmarketing studies—

(1) that sponsors have entered into agreements to conduct; and

(2) for which reports have been submitted under subsection (a)(1).

(d) DISCLOSURE.—If a sponsor fails to complete an agreed upon study required by this section by its original or otherwise negotiated deadline, the Secretary shall publish a statement on the Internet site of the Food and Drug Administration stating that the study was not completed and, if the reasons for such failure to complete the study were not satisfactory to the Secretary, a statement that such reasons were not satisfactory to the Secretary.

(e) NOTIFICATION.—With respect to studies of the type required under section 506(b)(2)(A) or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as each of such sections was in effect on the day before the effective date[78] of this subsection, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of such sections of such type for a drug or biological product (including such a study conducted after such effective date) notify practitioners who prescribe such drug or biological product of the failure to complete such study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete such study. Nothing in this subsection shall be construed as altering the requirements of the types of studies required under section 506(b)(2)(A) or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as so in effect, or as prohibiting the Secretary from modifying such sections of title 21 of such Code to provide for studies in addition to those of such type.

SEC. 506C. [21 U.S.C. 356c] DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug—

(1) that is—

(A) life-supporting;

(B) life-sustaining; or

(C) intended for use in the prevention of a debilitating disease or condition;

(2) for which an application has been approved under section 505(b) or 505(j); and

(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product,

shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

(b) REDUCTION IN NOTIFICATION PERIOD.—The notification period required under subsection (a) for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation in which—

[78] Subsection (e) was added by section 506 of Public Law 107–188 (116 Stat. 693). Section 506 was contained in subtitle A of title V of the Public Law, and section 508 of that subtitle provided that "The amendments made by this subtitle take effect October 1, 2002."

(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;

(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code; or

(6) the manufacturer can continue the distribution of the drug involved for 6 months.

(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs described in subsection (a) to appropriate physician and patient organizations.

AUTHORITY TO DESIGNATE OFFICIAL NAMES

SEC. 508.[79] [21 U.S.C. 358] (a) The Secretary may designate an official name for any drug or device if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug or device shall be the only official name of that drug or device used in any official compendium published after such name has been prescribed or for any other purpose of this Act. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

(b) Within a reasonable time after the effective date of this section, and at such other times as he may deem necessary, the Secretary shall cause a review to be made of the official names by which drugs are identified in the official United States Pharmacopeia, the official Homeopathic Pharmacopeia of the United States, and the official National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto) to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

(c) Whenever he determines after any such review that (1) any such official name is unduly complex or is not useful for any other reason, (2) two or more official names have been applied to a single drug or device, or to two or more drugs which are identical in chemical structure and pharmacological action and which are substantially identical in strength, quality, and purity, or to two or more devices which are substantially equivalent in design and purpose or (3) no official name has been applied to a medically useful drug or device, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs or device are identified and recognized his request for the recommendation of a single official name for such drug or drugs or device which will have usefulness and simplicity. Whenever such a single official name

[79] Section 507 was struck by section 125(b)(1) of Public Law 105–115 (111 Stat. 2325).

has not been recommended within one hundred and eighty days after such request, or the Secretary determines that any name so recommended is not useful for any reason, he shall designate a single official name for such drug or drugs or device. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs or device. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 553 of title 5, United States Code.

(d) After each such review, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall cause to be compiled, published, and publicly distributed a list which shall list all revised official names of drugs or devices designated under this section and shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

(e) Upon a request in writing by any compiler of any official compendium that the Secretary exercise the authority granted to him under section 508(a), he shall upon public notice and in accordance with the procedure set forth in section 553 of title 5, United States Code designate the official name of the drug or device for which the request is made.

NONAPPLICABILITY TO COSMETICS

SEC. 509. [21 U.S.C. 359] This chapter, as amended by the Drug Amendments of 1962, shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof.

REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES [80]

SEC. 510. [21 U.S.C. 360] (a) As used in this section—

(1) the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

(2) the term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing

[80] The purpose of section 510 was stated in section 301 of Public Law 82–781 as follows:

"SEC. 301. The Congress hereby finds and declares that in order to make regulation of interstate commerce in drugs effective, it is necessary to provide for registration and inspection of all establishments in which drugs are manufactured, prepared, propagated, compounded, or processed; that the products of all such establishments are likely to enter the channels of interstate commerce and directly affect such commerce; and that the regulation of interstate commerce in drugs without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such drugs would discriminate against and depress interstate commerce in such drugs, and adversely burden, obstruct, and affect such interstate commerce.".

of a drug or drugs or a device or devices shall register with the Secretary his name, places of business, and all such establishments.

(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment.

(d) Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

(e) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j). Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.

(f) The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section; except that any list submitted pursuant to paragraph (3) of subsection (j) and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.

(g) The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or

(5) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a

finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

In this subsection, the term "wholesale distributor" means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

(h) Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 704 and every such establishment engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

(i)(1) On or before December 31 of each year, any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation.

(2) The establishment shall also provide the information required by subsection (j).

(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

(j)(1) Every person who registers with the Secretary under subsection (b), (c), (d), or (i) shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name (as defined in section 502(e)) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a drug contained in the applicable list and subject to section 505 or 512, or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 514 or which is subject to section 515, a reference to the authority for the marketing of such drug or device and a copy of all labeling for such drug or device;

(B) in the case of any other drug or device contained in an applicable list—

(i) which drug is subject to section 503(b)(1), or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or

(ii) which drug is not subject to section 503(b)(1) or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

(C) in the case of any drug contained in an applicable list which is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product the Secretary may require the submission of a quantitative listing of all ingredients if he finds that such submission is necessary to carry out the purposes of this Act; and

(D) if the registrant filing a list has determined that a particular drug product or device contained in such list is not subject to section 505 or 512, or the particular device contained in such list is not subject to a performance standard established under section 514 or to section 515 or is not a restricted device, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular drug product or device.

(2) Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following information:

(A) A list of each drug or device introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a drug or device by its established name (as defined in section 502(e)) and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if he has not made a report under this paragraph, since the effective date of this subsection [81]) he has discontinued the manufacture, preparation, propagation,

[81] The effective date is Feb. 1, 1973. This subsection was added by Public Law 92–387, which was enacted Aug. 16, 1972. Section 5 of such Public Law provided that the amendments made

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compounding, or processing for commercial distribution of a drug or device included in a list filed by him under subparagraph (A) or paragraph (1); notice of such discontinuance, the date of such discontinuance, and the identity (by established name (as defined in section 502(e)) and by any proprietary name) of such drug or device.

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug or device (by established name (as defined in section 502(e)) and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(3) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient. The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this Act.

(k) Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 523(a) (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.

(l) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

(m)(1) Not later than 60 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of

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by the Public Law "shall take effect on the first day of the sixth month beginning after the date of the enactment of this Act.".

class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary as not requiring the report shall be exempt from the requirement to provide a report under subsection (k) as of the date of the publication of the list in the Federal Register. The Secretary shall publish such list on the Internet site of the Food and Drug Administration. The list so published shall be updated not later than 30 days after each revision of the list by the Secretary.

(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(n) The Secretary shall review the report required in subsection (k) and make a determination under section 513(f)(1) not later than 90 days after receiving the report.

(o)(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. Within six months after enactment of this subsection, the Secretary shall publish in the Federal Register a list of the types so identified, and shall revise the list as appropriate. Reports under subsection (k) for devices or types of devices within a type included on the list are, upon publication of the list, required to include such validation data.

(B) In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this Act against such device solely on the basis that the validation data for the device have not been

submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 502(o) or adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission of the report under subsection (k); (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii) the Secretary determines that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

(C) In the case of a report under subsection (k) for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under subparagraph (A) to include such type, require that the report include the validation data specified in subparagraph (A).

(D) Section 502(o) applies with respect to the failure of a report under subsection (k) to include validation data required under subparagraph (A).

(2) With respect to critical or semi-critical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices. The Secretary shall publish in the Federal Register a list of the devices or types of devices so identified, and shall revise the list as appropriate. The exemption for each device or type included on the list is terminated upon the publication of the list. For each report under subsection (k) submitted pursuant to this subparagraph the Secretary shall require the validation data described in paragraph (1)(A).

(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this Act against such device solely on the basis that such report has not been submitted to the Secretary. After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 502(o) or adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device.

Upon a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

(C) In the case of semi-critical devices, the initial list under subparagraph (A) shall be published not later than 18 months after the effective date of this subsection. In the case of critical devices, the initial list under such subparagraph shall be published not later than six months after such effective date.

(D) Section 502(o) applies with respect to the failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or semi-critical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

(p) Registrations under subsections (b), (c), (d), and (i) (including the submission of updated information) shall be submitted to the Secretary by electronic means, upon a finding by the Secretary that the electronic receipt of such registrations is feasible, unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

NEW ANIMAL DRUGS

SEC. 512.[82,83] [21 U.S.C. 360b] (a)(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for purposes of section 501(a)(5) and section 402(a)(2)(C)(ii) unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to such approved application;

(B) there is in effect a conditional approval of an application filed pursuant to section 571 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to such conditionally approved application; or

(C) there is in effect an index listing pursuant to section 572 with respect to such use or intended use of such drug in a minor species, and such drug, its labeling, and such use conform to such index listing.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee (i) holds a license issued under subsection (m) and has in its possession current approved labeling for

[82] Section 511 was repealed by section 701(a) of Public Law 91–513.

[83] Section 512 was added by Public Law 90–399, which was enacted July 13, 1968. Section 108 of such Public Law concerned the effective date and applicability of the amendment.

such drug in animal feed; or (ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of a license issued under subsection (m).

(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed be deemed unsafe for purposes of section 501(a)(6) unless—

(A) there is in effect—

(i) an approval of an application filed pursuant to subsection (b) with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution, holding, and use conform to such approved application;

(ii) a conditional approval of an application filed pursuant to section 571 with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution, holding, and use conform to such conditionally approved application; or

(iii) an index listing pursuant to section 572 with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution, holding, and use conform to such index listing; and

(B) such animal feed is manufactured at a site for which there is in effect a license issued pursuant to subsection (m)(1) to manufacture such animal feed.

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 501(a)(5) or (6) if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under section 512(j).

(4)(A) Except as provided in subparagraph (B), if an approval of an application filed under subsection (b) is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for the purposes of paragraph (1) and shall be exempt from the requirements of section 502(f) with respect to a different use or intended use of the drug, other than a use in or on animal feed, if such use or intended use—

(i) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

(ii) is in compliance with regulations promulgated by the Secretary that establish the conditions for such different use or intended use.

The regulations promulgated by the Secretary under clause (ii) may prohibit particular uses of an animal drug and shall not permit such different use of an animal drug if the labeling of another animal drug that contains the same active ingredient and which is in the same dosage form and concentration provides for such different use.

(B) If the Secretary finds that there is a reasonable probability that a use of an animal drug authorized under subparagraph (A) may present a risk to the public health, the Secretary may—

(i) establish a safe level for a residue of an animal drug when it is used for such different use authorized by subparagraph (A); and

(ii) require the development of a practical, analytical method for the detection of residues of such drug above the safe level established under clause (i).

The use of an animal drug that results in residues exceeding a safe level established under clause (i) shall be considered an unsafe use of such drug under paragraph (1). Safe levels may be established under clause (i) either by regulation or order.

(C) The Secretary may by general regulation provide access to the records of veterinarians to ascertain any use or intended use authorized under subparagraph (A) that the Secretary has determined may present a risk to the public health.

(D) If the Secretary finds, after affording an opportunity for public comment, that a use of an animal drug authorized under subparagraph (A) presents a risk to the public health or that an analytical method required under subparagraph (B) has not been developed and submitted to the Secretary, the Secretary may, by order, prohibit any such use.

(5) If the approval of an application filed under section 505 is in effect, the drug under such application shall not be deemed unsafe for purposes of paragraph (1) and shall be exempt from the requirements of section 502(f) with respect to a use or intended use of the drug in animals if such use or intended use—

(A) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

(B) is in compliance with regulations promulgated by the Secretary that establish the conditions for the use or intended use of the drug in animals.

(6) For purposes of section 402(a)(2)(D), a use or intended use of a new animal drug shall not be deemed unsafe under this section if the Secretary establishes a tolerance for such drug and any edible portion of any animal imported into the United States does not contain residues exceeding such tolerance. In establishing such tolerance, the Secretary shall rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar food safety criteria used by the Secretary to establish tolerances for applications for new animal drugs filed under subsection (b)(1). The Secretary may consider and rely on data submitted by the drug manufacturer, including data submitted to appropriate regulatory authorities in any country where the new animal drug is lawfully used or data available from a relevant international organization, to the extent such data are not inconsistent with the criteria used by the Secretary to establish a tolerance for applications for new animal drugs filed under subsection (b)(1). For purposes of this paragraph, "relevant international organization" means the Codex Alimenterius Commission or other international organization deemed appropriate by the Secretary. The Secretary may, under procedures specified by regulation, revoke a tolerance established under this paragraph if information demonstrates that the use of the new animal drug under actual use conditions results in food

being imported into the United States with residues exceeding the tolerance or if scientific evidence shows the tolerance to be unsafe.

(b)(1) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; (G) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (H) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe. The applicant shall file with the application the patent number and the expiration date of any patent which claims the new animal drug for which the applicant filed the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.

(2) Any person may file with the Secretary an abbreviated application for the approval of a new animal drug. An abbreviated application shall contain the information required by subsection (n).

(3) Any person intending to file an application under paragraph (1), section 571, or a request for an investigational exemption under subsection (j) shall be entitled to one or more conferences prior to such submission to reach an agreement acceptable to the Secretary establishing a submission or an investigational requirement, which may include a requirement for a field investigation. A decision establishing a submission or an investigational requirement shall bind the Secretary and the applicant or requestor unless (A) the Secretary and the applicant or requestor mutually agree to modify the requirement, or (B) the Secretary by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the animal

drug involved has appeared after the conference. No later than 25 calendar days after each such conference, the Secretary shall provide a written order setting forth a scientific justification specific to the animal drug and intended uses under consideration if the agreement referred to in the first sentence requires more than one field investigation as being essential to provide substantial evidence of effectiveness for the intended uses of the drug. Nothing in this paragraph shall be construed as compelling the Secretary to require a field investigation.

(c)(1) Within one hundred and eighty days after the filing of an application pursuant to subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (A) issue an order approving the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for a hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2)(A) Subject to subparagraph (C), the Secretary shall approve an abbreviated application for a drug unless the Secretary finds—

(i) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(ii) the conditions of use prescribed, recommended, or suggested in the proposed labeling are not reasonably certain to be followed in practice or, except as provided in subparagraph (B), information submitted with the application is insufficient to show that each of the proposed conditions of use or similar limitations (whether in the labeling or published pursuant to subsection (i)) have been previously approved for the approved new animal drug referred to in the application;

(iii) information submitted with the application is insufficient to show that the active ingredients are the same as those of the approved new animal drug referred to in the application;

(iv)(I) if the application is for a drug whose active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed is the same as the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed of the approved new animal drug referred to in the application, information submitted in the application is insufficient to show that the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed is the same as that of the approved new animal drug, or

(II) if the application is for a drug whose active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed is different from that of the

approved new animal drug referred to in the application, no petition to file an application for the drug with the different active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed was approved under subsection (n)(3);

(v) if the application was filed pursuant to the approval of a petition under subsection (n)(3), the application did not contain the information required by the Secretary respecting the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed which is not the same;

(vi) information submitted in the application is insufficient to show that the drug is bioequivalent to the approved new animal drug referred to in the application, or if the application is filed under a petition approved pursuant to subsection (n)(3), information submitted in the application is insufficient to show that the active ingredients of the new animal drug are of the same pharmacological or therapeutic class as the pharmacological or therapeutic class of the approved new animal drug and that the new animal drug can be expected to have the same therapeutic effect as the approved new animal drug when used in accordance with the labeling;

(vii) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the approved new animal drug referred to in the application except for changes required because of differences approved under a petition filed under subsection (n)(3), because of a different withdrawal period, or because the drug and the approved new animal drug are produced or distributed by different manufacturers;

(viii) information submitted in the application or any other information available to the Secretary shows that (I) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, (II) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included, or (III) in the case of a drug for food producing animals, the inactive ingredients of the drug or its composition may be unsafe with respect to human food safety;

(ix) the approval under subsection (b)(1) of the approved new animal drug referred to in the application filed under subsection (b)(2) has been withdrawn or suspended for grounds described in paragraph (1) of subsection (e), the Secretary has published a notice of a hearing to withdraw approval of the approved new animal drug for such grounds, the approval under this paragraph of the new animal drug for which the application under subsection (b)(2) was filed has been withdrawn or suspended under subparagraph (G) for such grounds, or the Secretary has determined that the approved new animal drug has been withdrawn from sale for safety or effectiveness reasons;

(x) the application does not meet any other requirement of subsection (n); or

(xi) the application contains an untrue statement of material fact.

(B) If the Secretary finds that a new animal drug for which an application is submitted under subsection (b)(2) is bioequivalent to the approved new animal drug referred to in such application and that residues of the new animal drug are consistent with the tolerances established for such approved new animal drug but at a withdrawal period which is different than the withdrawal period approved for such approved new animal drug, the Secretary may establish, on the basis of information submitted, such different withdrawal period as the withdrawal period for the new animal drug for purposes of the approval of such application for such drug.

(C) Within 180 days of the initial receipt of an application under subsection (b)(2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(D) The approval of an application filed under subsection (b)(2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in clause (i) or (ii) of subsection (n)(1)(G) or in both such clauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in clause (iii) of subsection (n)(1)(G), the approval may be made effective on the date certified under clause (iii).

(iii) If the applicant made a certification described in clause (iv) of subsection (n)(1)(G), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of 45 days from the date the notice provided under subsection (n)(2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the 30 month period beginning on the date of the receipt of the notice provided under subsection (n)(2)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that if before the expiration of such period—

(I) the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

(III) the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of 45 days from the date the notice made under subsection (n)(2)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in clause (iv) of subsection (n)(1)(G) and is for a drug for which a previous application has been filed under this subsection containing such a certification, the application shall be made effective not earlier than 180 days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in subclause (III)[84] holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within 30 days after such notice, such hearing shall commence not more than 90 days after the expiration of such 30 days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within 90 days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application submitted under subsection (b)(1) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b)(1), is approved after the date of the enactment of this paragraph[85], no application may be submitted under subsection (b)(2) which refers to the drug for which the subsection (b)(1) application was submitted before the expiration of 5 years from the date of the approval of the application under subsection (b)(1), except that such an application may be submitted under subsection (b)(2) after the expiration of 4 years from the date of the approval of the subsection (b)(1) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (n)(1)(G). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning 48 months after the date of the approval of the subsection (b) application, the 30 month period referred to in subparagraph (D)(iii) shall be extended by such amount of time

[84] So in law. Probably should be "clause (iii)(III)".

[85] The reference to "this paragraph" is a reference to paragraph (2) of subsection (c). Paragraph (2) was added by title I of Public Law 100–670, which was enacted Nov. 16, 1988.

(if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(ii) If an application submitted under subsection (b)(1) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under such subsection, is approved after the date of enactment of this paragraph[86] and if such application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species) required for the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b)(2) for the conditions of approval of such drug in the subsection (b)(1) application effective before the expiration of 3 years from the date of the approval of the application under subsection (b)(1) for such drug.

(iii) If a supplement to an application approved under subsection (b)(1) is approved after the date of enactment of this paragraph[87] and the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species) required for the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b)(2) for a change approved in the supplement effective before the expiration of 3 years from the date of the approval of the supplement.

(iv) An applicant under subsection (b)(1) who comes within the provisions of clause (i) of this subparagraph as a result of an application which seeks approval for a use solely in non-food producing animals, may elect, within 10 days of receiving such approval, to waive clause (i) of this subparagraph, in which event the limitation on approval of applications submitted under subsection (b)(2) set forth in clause (ii) of this subparagraph shall be applicable to the subsection (b)(1) application.

(v) If an application (including any supplement to a new animal drug application) submitted under subsection (b)(1) for a new animal drug for a food-producing animal use, which includes an active ingredient (including any ester or salt of the active ingredient) which has been the subject of a waiver under clause (iv) is approved after the date of enactment of this paragraph[88], and if the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or human food safety studies (other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species) required for the new approval of the application and conducted or sponsored by the applicant, the Secretary may not make

[86] See footnote for subparagraph (F)(i).
[87] See footnote for subparagraph (F)(i).
[88] See footnote for subparagraph (F)(i).

the approval of an application (including any supplement to such application) submitted under subsection (b)(2) for the new conditions of approval of such drug in the subsection (b)(1) application effective before the expiration of five years from the date of approval of the application under subsection (b)(1) for such drug. The provisions of this paragraph shall apply only to the first approval for a food-producing animal use for the same applicant after the waiver under clause (iv).

(G) If an approved application submitted under subsection (b)(2) for a new animal drug refers to a drug the approval of which was withdrawn or suspended for grounds described in paragraph (1) or (2) of subsection (e) or was withdrawn or suspended under this subparagraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this paragraph shall be withdrawn or suspended—

(i) for the same period as the withdrawal or suspension under subsection (e) or this subparagraph, or

(ii) if the approved new animal drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(H) For purposes of this paragraph:

(i) The term "bioequivalence" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a new animal drug and becomes available at the site of drug action.

(ii) A new animal drug shall be considered to be bioequivalent to the approved new animal drug referred to in its application under subsection (n) if—

(I) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the approved new animal drug referred to in the application when administered at the same dose of the active ingredient under similar experimental conditions in either a single dose or multiple doses;

(II) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the approved new animal drug referred to in the application when administered at the same dose of the active ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the approved new animal drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective drug concentrations in use, and is considered scientifically insignificant for the drug in attaining the intended purposes of its use and preserving human food safety; or

(III) in any case in which the Secretary determines that the measurement of the rate and extent of absorption or excretion of the new animal drug in biological fluids is inappropriate or impractical, an appropriate acute pharmacological effects test or other test of the new animal drug

and, when deemed scientifically necessary, of the approved new animal drug referred to in the application in the species to be tested or in an appropriate animal model does not show a significant difference between the new animal drug and such approved new animal drug when administered at the same dose under similar experimental conditions.

If the approved new animal drug referred to in the application for a new animal drug under subsection (n) is approved for use in more than one animal species, the bioequivalency information described in subclauses (I), (II), and (III) shall be obtained for one species, or if the Secretary deems appropriate based on scientific principles, shall be obtained for more than one species. The Secretary may prescribe the dose to be used in determining bioequivalency under subclause (I), (II), or (III). To assure that the residues of the new animal drug will be consistent with the established tolerances for the approved new animal drug referred to in the application under subsection (b)(2) upon the expiration of the withdrawal period contained in the application for the new animal drug, the Secretary shall require bioequivalency data or residue depletion studies of the new animal drug or such other data or studies as the Secretary considers appropriate based on scientific principles. If the Secretary requires one or more residue studies under the preceding sentence, the Secretary may not require that the assay methodology used to determine the withdrawal period of the new animal drug be more rigorous than the methodology used to determine the withdrawal period for the approved new animal drug referred to in the application. If such studies are required and if the approved new animal drug, referred to in the application for the new animal drug for which such studies are required, is approved for use in more than one animal species, such studies shall be conducted for one species, or if the Secretary deems appropriate based on scientific principles, shall be conducted for more than one species.

(3) If the patent information described in subsection (b)(1) could not be filed with the submission of an application under subsection (b)(1) because the application was filed before the patent information was required under subsection (b)(1) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the new animal drug for which the application was filed or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b)(1) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than 30 days after the date of the enactment of this sentence [89], and if the holder of an approved application could not file patent information under

[89] The sentence was added by title I of Public Law 100–670, which was enacted Nov. 16, 1988.

subsection (b)(1) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than 30 days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(d)(1) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that—

(A) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(B) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

(C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

(D) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions;

(E) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(F) upon the basis of information submitted to the Secretary as part of the application or any other information before the Secretary with respect to such drug, any use prescribed, recommended, or suggested in labeling proposed for such drug will result in a residue of such drug in excess of a tolerance found by the Secretary to be safe for such drug;

(G) the application failed to contain the patent information prescribed by subsection (b)(1);

(H) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; or

(I) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and

reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (I) do not apply, he shall issue an order approving the application.

(2) In determining whether such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the Secretary shall consider, among other relevant factors, (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug, (B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, (C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and (D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice. Any order issued under this subsection refusing to approve an application shall state the findings upon which it is based.

(3) As used in this section, the term "substantial evidence" means evidence consisting of one or more adequate and well controlled investigations, such as—

(A) a study in a target species;

(B) a study in laboratory animals;

(C) any field investigation that may be required under this section and that meets the requirements of subsection (b)(3) if a presubmission conference is requested by the applicant;

(D) a bioequivalence study; or

(E) an in vitro study;

by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(4) In a case in which an animal drug contains more than one active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with one or more other animal drugs, and the active ingredients or drugs intended for use in the combination have previously been separately approved pursuant to an application submitted under section 512(b)(1) for particular uses and conditions of use for which they are intended for use in the combination—

(A) the Secretary shall not issue an order under paragraph (1)(A), (1)(B), or (1)(D) refusing to approve the application for such combination on human food safety grounds unless the Secretary finds that the application fails to establish that—

(i) none of the active ingredients or drugs intended for use in the combination, respectively, at the longest withdrawal time of any of the active ingredients or drugs in the combination, respectively, exceeds its established tolerance; or

(ii) none of the active ingredients or drugs in the combination interferes with the methods of analysis for another of the active ingredients or drugs in the combination, respectively;

(B) the Secretary shall not issue an order under paragraph (1)(A), (1)(B), or (1)(D) refusing to approve the application for such combination on target animal safety grounds unless the Secretary finds that—

(i)(I) there is a substantiated scientific issue, specific to one or more of the active ingredients or animal drugs in the combination, that cannot adequately be evaluated based on information contained in the application for the combination (including any investigations, studies, or tests for which the applicant has a right of reference or use from the person by or for whom the investigations, studies, or tests were conducted); or

(II) there is a scientific issue raised by target animal observations contained in studies submitted to the Secretary as part of the application; and

(ii) based on the Secretary's evaluation of the information contained in the application with respect to the issues identified in clauses (i) (I) and (II), paragraph (1) (A), (B), or (D) apply;

(C) except in the case of a combination that contains a nontopical antibacterial ingredient or animal drug, the Secretary shall not issue an order under paragraph (1)(E) refusing to approve an application for a combination animal drug intended for use other than in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that—

(i) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to labeled effectiveness;

(ii) each active ingredient or animal drug intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population; or

(iii) where based on scientific information the Secretary has reason to believe the active ingredients or animal drugs may be physically incompatible or have disparate dosing regimens, such active ingredients or animal drugs are physically compatible or do not have disparate dosing regimens; and

(D) the Secretary shall not issue an order under paragraph (1)(E) refusing to approve an application for a combination animal drug intended for use in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that—

(i) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the labeled effectiveness;

(ii) each of the active ingredients or animal drugs intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population;

(iii) where a combination contains more than one nontopical antibacterial ingredient or animal drug, there is substantial evidence that each of the nontopical antibacterial ingredients or animal drugs makes a contribution to the labeled effectiveness, except that for purposes of this clause, antibacterial ingredient or animal drug does not include the ionophore or arsenical classes of animal drugs; or

(iv) where based on scientific information the Secretary has reason to believe the active ingredients or animal drugs intended for use in drinking water may be physically incompatible, such active ingredients or animal drugs intended for use in drinking water are physically compatible.

(5) In reviewing an application that proposes a change to add an intended use for a minor use or a minor species to an approved new animal drug application, the Secretary shall reevaluate only the relevant information in the approved application to determine whether the application for the minor use or minor species can be approved. A decision to approve the application for the minor use or minor species is not, implicitly or explicitly, a reaffirmation of the approval of the original application.

(e)(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) with respect to any new animal drug if the Secretary finds—

(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved or the condition of use authorized under subsection (a)(4)(A);

(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) applies to such drug;

(C) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that such drug will have the effect it

purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(D) the patent information prescribed by subsection (c)(3) was not filed within 30 days after the receipt of written notice from the Secretary specifying the failure to file such information;

(E) that the application contains any untrue statement of a material fact; or

(F) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

(2) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this section if the Secretary finds—

(A) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under subsection (l), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection;

(B) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(C) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(3) Any order under this subsection shall state the findings upon which it is based.

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d), (e), or (m), or

section 571 (c), (d), or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section, or section 571 (other than orders issuing, amending, or repealing regulations) shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application filed under subsection (b) or (m) of this section. The provisions of subsection (h) of section 505 of this Act shall govern any such appeal.

(i) When a new animal drug application filed pursuant to subsection (b) or section 571 is approved, the Secretary shall by notice, which upon publication shall be effective as a regulation, publish in the Federal Register the name and address of the applicant and the conditions and indications of use of the new animal drug covered by such application, including any tolerance and withdrawal period or other use restrictions and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements and any requirement that an animal feed bearing or containing the new animal drug be limited to use under the professional supervision of a licensed veterinarian) applicable to any animal feed for use in which such drug is approved, and such other information, upon the basis of which such application was approved, as the Secretary deems necessary to assure the safe and effective use of such drug. Upon withdrawal of approval of such new animal drug application or upon its suspension or upon failure to renew a conditional approval under section 571, the Secretary shall forthwith revoke or suspend, as the case may be, the regulation published pursuant to this subsection (i)[90] insofar as it is based on the approval of such application.

(j) To the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of this section new animal drugs, and animal feeds bearing or containing new animal drugs, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. Such regulations may, in the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such article, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of such article, as the Secretary finds will enable him to evaluate the safety and effectiveness of such article in the event of the filing of an application pursuant to this section. Such regulations, among other

[90] So in law. Probably should be "this subsection".

things, shall set forth the conditions (if any) upon which animals treated with such articles, and any products of such animals (before or after slaughter), may be marketed for food use.

(k) While approval of an application for a new animal drug is effective, a food shall not, by reason of bearing or containing such drug or any substance formed in or on the food because of its use in accordance with such application (including the conditions and indications of use prescribed pursuant to subsection (i)), be considered adulterated within the meaning of clause (1) of section 402(a).

(l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) or section 571 is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(m)(1) Any person may file with the Secretary an application for a license to manufacture animal feeds bearing or containing new animal drugs. Such person shall submit to the Secretary as part of the application (A) a full statement of the business name and address of the specific facility at which the manufacturing is to take place and the facility's registration number, (B) the name and signature of the responsible individual or individuals for that facility, (C) a certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published pursuant to subsection (i) or for indexed new animal drugs in accordance with the index listing published pursuant to section 572(e)(2) and the labeling requirements set forth in section 572(h), and (D) a certification that the methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds are in conformity with current good manufacturing practice as described in section 501(a)(2)(B).

(2) Within 90 days after the filing of an application pursuant to paragraph (1), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall (A) issue an order approving the application if the Secretary then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a

hearing before the Secretary under paragraph (3) on the question whether such application is approvable. The procedure governing such a hearing shall be the procedure set forth in the last two sentences of subsection (c)(1).

(3) If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving the applicant an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to the Secretary as part of the application, on the basis of a preapproval inspection, or on the basis of any other information before the Secretary—

(A) that the application is incomplete, false, or misleading in any particular;

(B) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(C) that the facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published pursuant to subsection (i) or an index listing pursuant to section 572(e),

the Secretary shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (C) do not apply, the Secretary shall issue an order approving the application. An order under this subsection approving an application for a license to manufacture animal feeds bearing or containing new animal drugs shall permit a facility to manufacture only those animal feeds bearing or containing new animal drugs for which there are in effect regulations pursuant to subsection (i) or an index listing pursuant to section 572(e) relating to the use of such drugs in or on such animal feed.

(4)(A) The Secretary shall, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feeds bearing or containing new animal drugs under this subsection if the Secretary finds—

(i) that the application for such license contains any untrue statement of a material fact; or

(ii) that the applicant has made changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application.

If the Secretary (or in the Secretary's absence the officer acting as the Secretary) finds that there is an imminent hazard to the health of humans or of the animals for which such animal feed is intended, the Secretary may suspend the license immediately, and

give the applicant prompt notice of the action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence shall not be delegated.

(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feed under this subsection if the Secretary finds—

(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under paragraph (5)(A) of this subsection or section 504(a)(3)(A), or the applicant has refused to permit access to, or copying or verification of, such records as required by subparagraph (B) of such paragraph or section 504(a)(3)(B);

(ii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary, specifying the matter complained of;

(iii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(iv) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(C) The Secretary may also revoke a license to manufacture animal feeds under this subsection if an applicant gives notice to the Secretary of intention to discontinue the manufacture of all animal feed covered under this subsection and waives an opportunity for a hearing on the matter.

(D) Any order under this paragraph shall state the findings upon which it is based.

(5) When a license to manufacture animal feeds bearing or containing new animal drugs has been issued—

(A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b), as the Secretary

may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or paragraph (4); and

(B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(6) To the extent consistent with the public health, the Secretary may promulgate regulations for exempting from the operation of this subsection facilities that manufacture, process, pack, or hold animal feeds bearing or containing new animal drugs.

(n)(1) An abbreviated application for a new animal drug shall contain—

(A)(i) except as provided in clause (ii), information to show that the conditions of use or similar limitations (whether in the labeling or published pursuant to subsection (i)) prescribed, recommended, or suggested in the labeling proposed for the new animal drug have been previously approved for a new animal drug listed under paragraph (4) (hereinafter in this subsection referred to as an ''approved new animal drug''), and

(ii) information to show that the withdrawal period at which residues of the new animal drug will be consistent with the tolerances established for the approved new animal drug is the same as the withdrawal period previously established for the approved new animal drug or, if the withdrawal period is proposed to be different, information showing that the residues of the new animal drug at the proposed different withdrawal period will be consistent with the tolerances established for the approved new animal drug;

(B)(i) information to show that the active ingredients of the new animal drug are the same as those of the approved new animal drug, and

(ii) if the approved new animal drug has more than one active ingredient, and if one of the active ingredients of the new animal drug is different from one of the active ingredients of the approved new animal drug and the application is filed pursuant to the approval of a petition filed under paragraph (3)—

(I) information to show that the other active ingredients of the new animal drug are the same as the active ingredients of the approved new animal drug,

(II) information to show either that the different active ingredient is an active ingredient of another approved new animal drug or of an animal drug which does not meet the requirements of section 201(v), and

(III) such other information respecting the different active ingredients as the Secretary may require;

(C)(i) if the approved new animal drug is permitted to be used with one or more animal drugs in animal feed, information to show that the proposed uses of the new animal drug

with other animal drugs in animal feed are the same as the uses of the approved new animal drug, and

(ii) if the approved new animal drug is permitted to be used with one or more other animal drugs in animal feed, and one of the other animal drugs proposed for use with the new animal drug in animal feed is different from one of the other animal drugs permitted to be used in animal feed with the approved new animal drug, and the application is filed pursuant to the approval of a petition filed under paragraph (3)—

(I) information to show either that the different animal drug proposed for use with the approved new animal drug in animal feed is an approved new animal drug permitted to be used in animal feed or does not meet the requirements of section 201(v) when used with another animal drug in animal feed,

(II) information to show that other animal drugs proposed for use with the new animal drug in animal feed are the same as the other animal drugs permitted to be used with the approved new animal drug, and

(III) such other information respecting the different animal drug or combination with respect to which the petition was filed as the Secretary may require,

(D) information to show that the route of administration, the dosage form, and the strength of the new animal drug are the same as those of the approved new animal drug or, if the route of administration, the dosage form, or the strength of the new animal drug is different and the application is filed pursuant to the approval of a petition filed under paragraph (3), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(E) information to show that the new animal drug is bioequivalent to the approved new animal drug, except that if the application is filed pursuant to the approval of a petition filed under paragraph (3) for the purposes described in subparagraph (B) or (C), information to show that the active ingredients of the new animal drug are of the same pharmacological or therapeutic class as the pharmacological or therapeutic class of the approved new animal drug and that the new animal drug can be expected to have the same therapeutic effect as the approved new animal drug when used in accordance with the labeling;

(F) information to show that the labeling proposed for the new animal drug is the same as the labeling approved for the approved new animal drug except for changes required because of differences approved under a petition filed under paragraph (3), because of a different withdrawal period, or because the new animal drug and the approved new animal drug are produced or distributed by different manufacturers;

(G) the items specified in clauses (B) through (F) of subsection (b)(1);

(H) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the approved new animal drug or which claims a use for such

approved new animal drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b)(1) or (c)(3)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new animal drug for which the application is filed; and

(I) if with respect to the approved new animal drug information was filed under subsection (b)(1) or (c)(3) for a method of use patent which does not claim a use for which the applicant is seeking approval of an application under subsection (c)(2), a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by subparagraphs (A) through (I).

(2)(A) An applicant who makes a certification described in paragraph (1)(G)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved application under subsection (c)(1) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application, which contains data from bioequivalence studies, has been filed under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (1)(G)(iv), the notice required by subparagraph (B) shall be given when the amended application is filed.

(3) If a person wants to submit an abbreviated application for a new animal drug—

(A) whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or

(B) whose use with other animal drugs in animal feed differs from that of an approved new animal drug,

such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve a petition for a new animal drug unless the Secretary finds that—

(C) investigations must be conducted to show the safety and effectiveness, in animals to be treated with the drug, of the active ingredients, route of administration, dosage form,

strength, or use with other animal drugs in animal feed which differ from the approved new animal drug, or

(D) investigations must be conducted to show the safety for human consumption of any residues in food resulting from the proposed active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed for the new animal drug which is different from the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed of the approved new animal drug.

The Secretary shall approve or disapprove a petition submitted under this paragraph within 90 days of the date the petition is submitted.

(4)(A)(i) Within 60 days of the date of the enactment of this subsection [91], the Secretary shall publish and make available to the public a list in alphabetical order of the official and proprietary name of each new animal drug which has been approved for safety and effectiveness before the date of the enactment of this subsection [91].

(ii) Every 30 days after the publication of the first list under clause (i) the Secretary shall revise the list to include each new animal drug which has been approved for safety and effectiveness under subsection (c) during the 30 day period.

(iii) When patent information submitted under subsection (b)(1) or (c)(3) respecting a new animal drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A new animal drug approved for safety and effectiveness before the date of the enactment of this subsection [92] or approved for safety and effectiveness under subsection (c) shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

(C) If the approval of a new animal drug was withdrawn or suspended under subsection (c)(2)(G) or for grounds described in subsection (e) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (c)(2)(G) or (e), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(5) If an application contains the information required by clauses (A), (G), and (H) of subsection (b)(1) and such information—

(A) is relied on by the applicant for the approval of the application, and

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[91] The reference to "this subsection" is a reference to subsection (n). That subsection was added by title I of Public Law 100–670, which was enacted Nov. 16, 1988.

[92] See footnote for paragraph (4)(A)(i).

(B) is not information derived either from investigations, studies, or tests conducted by or for the applicant or for which the applicant had obtained a right of reference or use from the person by or for whom the investigations, studies, or tests were conducted,

such application shall be considered to be an application filed under subsection (b)(2).

(o) For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(p)(1) Safety and effectiveness data and information which has been submitted in an application filed under subsection (b)(1) or section 571(a) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application filed under subsection (b)(2) which refers to such drug or upon the date upon which the approval of an application filed under subsection (b)(2) which refers to such drug could be made effective if such an application had been filed.

(2) Any request for data and information pursuant to paragraph (1) shall include a verified statement by the person making the request that any data or information received under such paragraph shall not be disclosed by such person to any other person—

(A) for the purpose of, or as part of a plan, scheme, or device for, obtaining the right to make, use, or market, or making, using, or marketing, outside the United States, the drug identified in the application filed under subsection (b)(1) or section 571(a), and

(B) without obtaining from any person to whom the data and information are disclosed an identical verified statement, a copy of which is to be provided by such person to the Secretary, which meets the requirements of this paragraph.

CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Device Classes

SEC. 513. [21 U.S.C. 360c] (a)(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 514 and 515, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

(i) which is sufficient to determine the effectiveness of a device, and

(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 514 and 515, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

(D)(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a

reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

(iii) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.

Classification; Classification Panels

(b)(1) For purposes of—

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f)) into the classes established by subsection (a). For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this section, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–

18 of the General Schedule[93], for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code) as the Secretary;

(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

(iii) the same opportunity as the Secretary to participate in meetings of the panel.

(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.

(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

Classification Panel Organization and Operation

(c)(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews

[93] The General Schedule under section 5332 of title 5, United States Code, no longer includes the grade GS–18. The grades are GS–1 through GS–15.

and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 514 or 515 to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 510, 519, or 520(f).

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section.

Classification

(d)(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such

device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 510, 519 or 520(f) shall not apply to the device. A regulation which makes a requirement of section 510, 519, or 520(f) inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 515(b)(1) the Secretary may establish priorities which, in his discretion, shall be used in applying sections 514 and 515, as appropriate, to such devices.

Classification Changes

(e)(1) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

(2) By regulation promulgated under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

Initial Classification and Reclassification of Certain Devices

(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.

(3)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be used under subsection (b). A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

(ii) The requirements of paragraphs (1) and (2) of subsection (c) (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 510, 519, and 520(f)) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B). In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

(ii) The requirements of paragraphs (1) and (2)(A) of subsection (d) (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 510, 519, and 520(f)) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(4) If a manufacturer reports to the Secretary under section 510(k) that a device is substantially equivalent to another device—

(A) which the Secretary has classified as a class III device under subsection (b),

(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been promulgated under section 515(b),

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 510(k) a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 510(k) report is being made and which has not been submitted to the Secretary under section 519. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health).

Information

(g) Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.

Definitions

(h) For purposes of this section and sections 501, 510, 514, 515, 516, 519, and 520—

(1) a reference to "general controls" is a reference to the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520,

(2) a reference to "class I," "class II," or "class III" is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

(3) a reference to a "panel under section 513" is a reference to a panel established or authorized to be used under this section.

Substantial Equivalence

(i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term ''different technological characteristics'' means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

(D) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the ''Director'') may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the

Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 510(k) respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

PERFORMANCE STANDARDS

Provisions of Standards

SEC. 514. [21 U.S.C. 360d] (a)(1) The special controls required by section 513(a)(1)(B) shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under subsection (b) if the device has been reclassified as a class II device under a regulation under section 513(e) but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

(2) A performance standard established under subsection (b) for a device—

(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

(iii) provisions for the measurement of the performance characteristics of the device,

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e); and

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

(3) The Secretary shall provide for periodic evaluation of performance standards established under subsection (b) to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(4) In carrying out his duties under this subsection and subsection (b), the Secretary shall, to the maximum extent practicable—

(A) use personnel, facilities, and other technical support available in other Federal agencies,

(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

Establishment of a Standard

(b)(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,

(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 513(e) based on new information relevant to the classification, and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of not less than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 513, either deny the request or give notice of an intent to initiate such change under section 513(e).

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B) for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule[94], for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

[94] The General Schedule under section 5332 of title 5, United States Code, no longer includes the grade GS–18. The grades are GS–1 through GS–15.

Recognition of a Standard

(c)(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable.

(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.

(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this Act.

(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

(C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.

PREMARKET APPROVAL

General Requirement

SEC. 515. [21 U.S.C. 360e] (a) A class III device—

(1) which is subject to a regulation promulgated under subsection (b); or

(2) which is a class III device because of section 513(f),

is required to have, unless exempt under section 520(g), an approval under this section of an application for premarket approval or, as applicable, an approval under subsection (c)(2) of a report seeking premarket approval.

Regulation To Require Premarket Approval

(b)(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type;

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—

(i) the proposed regulation;

(ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(iii) opportunity for the submission of comments on the proposed regulation and the proposed findings; and

(iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(B) If, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 513, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e).

(3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2)(A)(ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

(4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.

Application for Premarket Approval

(c)(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.

(2)(A) Any person may file with the Secretary a report seeking premarket approval for a class III device referred to in subsection (a) that is a reprocessed single-use device. Such a report shall contain the following:

(i) The device name, including both the trade or proprietary name and the common or usual name.

(ii) The establishment registration number of the owner or operator submitting the report.

(iii) Actions taken to comply with performance standards under section 514.

(iv) Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use.

(v) Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective.

(vi) A description of the device's components, ingredients, and properties.

(vii) A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device.

(viii) Such samples of the device that the Secretary may reasonably require.

(ix) A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations.

(x) A statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report.

(xi) Any additional data and information, including information of the type required in paragraph (1) for an application under such paragraph, that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device.

(xii) Validation data described in section 510(o)(1)(A) that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting such report.

(B) In the case of a class III device referred to in subsection (a) that is a reprocessed single-use device:

(i) Subparagraph (A) of this paragraph applies in lieu of paragraph (1).

(ii) Subject to clause (i), the provisions of this section apply to a report under subparagraph (A) to the same extent and in the same manner as such provisions apply to an application under paragraph (1).

(iii) Each reference in other sections of this Act to an application under this section, other than such a reference in section 737 or 738, shall be considered to be a reference to a report under subparagraph (A).

(iv) Each reference in other sections of this Act to a device for which an application under this section has been approved, or has been denied, suspended, or withdrawn, other than such a reference in section 737 or 738, shall be considered to be a reference to a device for which a report under subparagraph (A) has been approved, or has been denied, suspended, or withdrawn, respectively.

(3) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513,

refer such application to the appropriate panel under section 513 for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.

(4)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the

application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept and review such portion, during any period in which, under section 738(g), the Secretary does not have the authority to collect fees under section 738(a).

(B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless a significant issue of safety or effectiveness provides the Secretary reason to review such accepted portion.

(C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall, in writing, provide to the applicant a description of any deficiencies in such portion and identify the information that is required to correct these deficiencies, unless the applicant is no longer pursuing the application.

Action on an Application for Premarket Approval

(d)(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in section 520(l)(3)(D)(ii) or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e).

(iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 520(f);

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

(iii) The Secretary shall notify the applicant promptly of—

(I) any additional deficiency identified in the application, or

(II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

(4) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

(A) representing breakthrough technologies,

(B) for which no approved alternatives exist,

(C) which offer significant advantages over existing approved alternatives, or

(D) the availability of which is in the best interest of the patients.

(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.

Withdrawal and Temporary Suspension of Approval of Application

(e)(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a), (ii) has refused to permit access to, or copying or verification of, such records as required by section 704, or (iii) has not complied with the requirements of section 510;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 520(f) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 514 compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

Product Development Protocol

(f)(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c), such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, the Secretary—

(A) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or

(B) shall so refer such protocol upon the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data which would be reviewed by such panel substantially duplicate a product development protocol and accompanying data which have previously been reviewed by such a panel.

(3) A proposed product development protocol for a device may be approved only if—

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c); and

(B) the Secretary determines that the proposed protocol provides—

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 514 to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 513, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5, United States Code.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

Review

(g)(1) Upon petition for review of—

(A) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(B) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5 of the United States Code, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of—

(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary which rates may not exceed the daily equivalent for grade GS–18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United

States Code for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

Service of Orders

(h) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

Revision

(i)(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before December 1, 1995, the Secretary shall publish a regulation in the Federal Register for each device—

(A) which the Secretary has classified as a class III device, and

(B) for which no final regulation has been promulgated under section 515(b),

revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this paragraph and provide reasonable opportunity for the submission of comments on any such regulation. No regulation requiring a device to remain in class III or revising its classification may

take effect before the expiration of 90 days from the date of its publication in the Federal Register as a proposed regulation.

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the regulation requiring a device to remain in class III, establish a schedule for the promulgation of a section 515(b) regulation for each device which is subject to the regulation requiring the device to remain in class III.

BANNED DEVICES

General Rule

SEC. 516. [21 U.S.C. 360f] (a) Whenever the Secretary finds, on the basis of all available data and information, that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

Special Effective Date

(b) The Secretary may declare a proposed regulation under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

JUDICIAL REVIEW

Application of Section

SEC. 517. [21 U.S.C. 360g] (a) Not later than thirty days after—

(1) the promulgation of a regulation under section 513 classifying a device in class I or changing the classification of

a device to class I or an order under subsection (f)(2) of such section reclassifying a device or denying a petition for reclassification of a device,

(2) the promulgation of a regulation under section 514 establishing, amending, or revoking a performance standard for a device,

(3) the issuance of an order under section 514(b)(2) or 515(b)(2)(B) denying a request for reclassification of a device,

(4) the promulgation of a regulation under paragraph (3) of section 515(b) requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 515(g)(1) or 515(g)(2)(C),

(5) the promulgation of a regulation under section 516 (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

(6) the issuance of an order under section 520(f)(2),

(7) an order under section 520(g)(4) disapproving an application for an exemption of a device for investigational use or an order under section 520(g)(5) withdrawing such an exemption for a device,

(8) an order pursuant to section 513(i), or

(9) a regulation under section 515(i)(2) or 520(l)(5)(B),

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28, United States Code. For purposes of this section, the term "record" means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

Additional Data, Views, and Arguments

(b) If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make

new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

Standard for Review

(c) Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) and an order issued after the review provided by section 515(g) shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

Finality of Judgments

(d) The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28 of the United States Code.

Other Remedies

(e) The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

Statement of Reasons

(f) To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 513, 514, 515, 516, 518, 519, 520, or 521 each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

NOTIFICATION AND OTHER REMEDIES

Notification

SEC. 518. [21 U.S.C. 360h] (a) If the Secretary determines that—

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by

the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

Repair, Replacement, or Refund

(b)(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

(i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health.

(ii) there are reasonable grounds to believe that the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design or manufacture,

(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

(iv) the notification authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

(A) To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

(B) To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this Act.

(C) To refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more—

(i) at the time of notification ordered under subsection (a), or

(ii) at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1),

whichever first occurs).

(3) No charge shall be made to any person (other than a manufacturer, importer, distributor or retailer) for availing himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

Reimbursement

(c) An order issued under subsection (b) with respect to a device may require any person who is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, importer, distributor, or retailer of such device for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health.

Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

Effect on Other Liability

(d) Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

Recall Authority

(e)(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)—

(A) to immediately cease distribution of such device, and

(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) An amended order under subparagraph (A)—

(i) shall—

(I) not include recall of a device from individuals, and

(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use, and

(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).

(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

RECORDS AND REPORTS ON DEVICES

General Rule

SEC. 519. [21 U.S.C. 360i] (a) Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

(1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

(A) may have caused or contributed to a death or serious injury, or

(B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;

(2) shall define the term "serious injury" to mean an injury that—

(A) is life threatening,

(B) results in permanent impairment of a body function or permanent damage to a body structure, or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

(4) shall not impose requirements unduly burdensome to a device manufacturer or importer taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this Act;

(5) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(6) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

(7) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this Act; and

(8) may not require a manufacturer or importer of a class I device to—

(A) maintain for such a device records respecting information not in the possession of the manufacturer or importer, or

(B) to submit for such a device to the Secretary any report or information—

(i) not in the possession of the manufacturer or importer, or

(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded. and[95]

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (7) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient. The Secretary shall by regulation require distributors to keep records and make such records available to the Secretary upon request. Paragraphs (4) and (8) apply to distributors to the same extent and in the same manner as such paragraphs apply to manufacturers and importers.

User Reports

(b)(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

(B) Whenever a device user facility receives or otherwise becomes aware of—

(i) information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility, or

(ii) other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported,

shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

(C) Each device user facility shall submit to the Secretary on an annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 of each year. The summary shall be in such form and contain such

[95] So in law. See section 213(a)(1)(D)(ii) of Public Law 105–115 (111 Stat. 2347). That section struck former paragraph (9), and amended paragraph (8) "by striking the semicolon at the end and inserting a period", rather than by striking "; and" and inserting a period.

information from such reports as the Secretary may require and shall include—

(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

(ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

(iii) the name and the address of the manufacturer of such device, and

(iv) a brief description of the event reported to the manufacturer.

(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

(2) The Secretary may not disclose the identity of a device user facility which makes a report under paragraph (1) except in connection with—

(A) an action brought to enforce section 301(q), or

(B) a communication to a manufacturer of a device which is the subject of a report under paragraph (1).

This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (1) or any information in such a report to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

(3) No report made under paragraph (1) by—

(A) a device user facility,

(B) an individual who is employed by or otherwise formally affiliated with such a facility, or

(C) a physician who is not required to make such a report, shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a).

(5) With respect to device user facilities:

(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply.

(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply except to the extent that the Secretary determines otherwise.

(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to a user

facility unless the facility is included in the subset referred to in subparagraph (A).

(E) Not later than 2 years after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.

(6) For purposes of this subsection:

(A) The term "device user facility" means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. The Secretary may by regulation include an outpatient diagnostic facility which is not a physician's office in such term.

(B) The terms "serious illness" and "serious injury" mean illness or injury, respectively, that—

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Persons Exempt

(c) Subsection (a) shall not apply to—

(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 520(g)); and

(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

[(d) Repealed by Public Law 105–115, November 21, 1997.]

Device Tracking

(e)(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is—

(i) intended to be implanted in the human body for more than one year, or

(ii) a life sustaining or life supporting device used outside a device user facility.

(2) Any patient receiving a device subject to tracking under paragraph (1) may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.

Reports of Removals and Corrections

(f)(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer or importer of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer or importer if the removal or correction was undertaken—

(A) to reduce a risk to health posed by the device, or

(B) to remedy a violation of this Act caused by the device which may present a risk to health.

A manufacturer or importer of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

(3) For purposes of paragraphs (1) and (2), the terms "correction" and "removal" do not include routine servicing.

GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

General Rule

SEC. 520. [21 U.S.C. 360j] (a) Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by or under section 501, 502, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

Custom Devices

(b) Sections 514 and 515 do not apply to any device which, in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 515 if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device—

(A)(i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

(ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and

(B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

Trade Secrets

(c) Any information reported to or otherwise obtained by the Secretary or his representative under section 513, 514, 515, 516, 518, 519, or 704 or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 514 for a device reclassified from class III to class II, except (1) in accordance with subsection (h), and (2) that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act (other than section 513 or 514 thereof).

Notices and Findings

(d) Each notice of proposed rulemaking under section 513, 514, 515, 516, 518, or 519, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

Restricted Devices

(e)(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

Good Manufacturing Practice Requirements

(f)(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated;

(ii) afford opportunity for an oral hearing; and

(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act,

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of

the methods, facilities, and controls prescribed by the requirement, and

(iii) contain such other information as the Secretary shall prescribe.

(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A), or

(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) The Secretary may approve—

(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act, and

(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this Act.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this Act.

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule[96], for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

Exemption for Devices for Investigational Use

(g)(1) It is the purpose of this subsection to encourage to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 721 or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

[96] The General Schedule under section 5332 of title 5, United States Code, no longer includes the grade GS–18. The grades are GS–1 through GS–15.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if—

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 516) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(6)(A) Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(ii) changes or modifications to clinical protocols that do not affect—

(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

(III) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.

Release of Safety and Effectiveness Information

(h)(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for—

(A) an order under section 515(d)(1)(A) approving an application for premarket approval for the device or denying approval of such an application or an order under section 515(e) withdrawing approval of such an application for the device,

(B) an order under section 515(f)(6)(A) revoking an approved protocol for the device, an order under section 515(f)(6)(B) declaring a protocol for the device completed or not completed, or an order under section 515(f)(7) revoking the approval of the device, or

(C) an order approving an application under subsection (g) for an exemption for the device from section 516 or an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

(2) The Secretary shall promulgate regulations under which each advisory committee established under section 515(g)(2)(B) shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 515(g)(2)(A). A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order.

(3) Except as provided in paragraph (4), any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

(i) approving another device;

(ii) determining whether a product development protocol has been completed, under section 515 for another device;

(iii) establishing a performance standard or special control under this Act; or

(iv) classifying or reclassifying another device under section 513 and subsection (l)(2).

(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

Proceedings of Advisory Panels and Committees

(i) Each panel under section 513 and each advisory committee established under section 514(b)(5)(B) or 515(g) or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

Traceability Requirements

(j) Except as provided in section 519(e), no regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

Research and Development

(k) The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5)[97].

Transitional Provisions for Devices Considered as New Drugs

(l)(1) Any device intended for human use—

(A) for which on the date of enactment of the Medical Device Amendments of 1976[98] (hereinafter in this subsection referred to as the "enactment date") an approval of an application submitted under section 505(b) was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which enforces a requirement of section 505 or for an alleged violation of section 505(a),

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

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[97] Section 3648 of the Revised Statutes has been superseded by subsections (a) and (b) of section 3324 of title 31, United States Code. See Public Law 97–258.

[98] Public Law 94–295, enacted May 28, 1976.

(2) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appropriate panel under section 513, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 513(a)(1)(A) or 513(a)(1)(B), of the device in class I or class II.

(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

(i) such device shall on the enactment date be considered a device with an approved application under section 515, and

(ii) the requirements applicable to such device before the enactment date under section 505 shall continue to apply to such device until changed by the Secretary as authorized by this Act.

(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 515 on the enactment date. The period in which the Secretary shall act on such application in accordance with section 515(d)(1) shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 515(d)(1)(B)(i)) less the number of days in the period beginning on the date an application for such device was filed under section 505 and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 515.

(ii) If—

(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 515(d)(1)(B), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 505, and which is in class III—

(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 515 unless exempt under subsection (g) of this section, and

(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

[(4) Repealed by Public Law 105–115, November 21, 1997.**]**

(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the

Secretary shall apply the criteria set forth in section 513(a). Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

Humanitarian Device Exemption

(m)(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 514 and 515 for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The request shall be in the form of an application submitted to the Secretary. Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.

(3) No person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) Devices granted an exemption under paragraph (2) may only be used—

(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to supervise clinical testing of devices in the facilities, and

(B) if, before the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A), unless a physician determines in an emergency situation that approval from a local institutional review committee can not be obtained in time to prevent serious harm or death to a patient.

In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the local institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.

(6) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.

STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES

General Rule

SEC. 521. [21 U.S.C. 360k] (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Exempt Requirements

(b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.

POSTMARKET SURVEILLANCE

SEC. 522.[99] [21 U.S.C. 360l] (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

(1) implanted in the human body for more than one year, or

(2) a life sustaining or life supporting device used outside a device user facility.

(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562.

SEC. 523. [21 U.S.C. 360m] ACCREDITED PERSONS.

(a) IN GENERAL.—

(1) REVIEW AND CLASSIFICATION OF DEVICES.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing reports submitted under section 510(k) and making recommendations to the Secretary regarding the initial classification of devices under section 513(f)(1).

(2) REQUIREMENTS REGARDING REVIEW.—

(A) IN GENERAL.—In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

[99] Section 212 of Public Law 107–250 (116 Stat. 1614), as amended by section 2(d)(3)(C) of Public Law 108–214 (118 Stat. 577), provides for a study whose purpose is determining whether the system under the Federal Food, Drug, and Cosmetic Act for the postmarket surveillance of medical devices provides adequate safeguards regarding the use of devices in pediatric populations. The study is required to be submitted not later than 4 years after the date of the enactment of Public Law 107–250, which was enacted Oct. 26, 2002.

(C) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended under paragraph (1) by an accredited person, and in such case shall provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the change.

(3) CERTAIN DEVICES.—

(A) IN GENERAL.—An accredited person may not be used to perform a review of—

(i) a class III device;

(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting; or

(iii) a class II device which requires clinical data in the report submitted under section 510(k) for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.

(B) ADJUSTMENT.—In determining for a year the ratio described in subparagraph (A)(iii), the Secretary shall not include in the numerator class III devices that the Secretary reclassified into class II, and the Secretary shall include in the denominator class II devices for which reports under section 510(k) were not required to be submitted by reason of the operation of section 510(m).

(b) ACCREDITATION.—

(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

(2) ACCREDITATION.—

(A) IN GENERAL.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or poses a threat to public health or fails to

act in a manner that is consistent with the purposes of this section.

(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

(ii) take such additional measures as the Secretary determines to be appropriate.

(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

(i) certify that reported information accurately reflects data reviewed;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as proprietary information;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person

to receive a section 510(k) report a panel of at least two or more accredited persons from which the regulated person may select one for a specific regulatory function.

(5) COMPENSATION OF ACCREDITED PERSONS.—Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(c) DURATION.—The authority provided by this section terminates October 1, 2007.

(d) REPORT.—Not later than January 10, 2007, the Secretary shall conduct a study based on the experience under the program under this section and submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the findings of the study. The objectives of the study shall include determining—

(1) the number of devices reviewed under this section;

(2) the number of devices reviewed under this section that were ultimately cleared by the Secretary;

(3) the number of devices reviewed under this section that were ultimately not cleared by the Secretary;

(4) the average time period for a review under this section (including the time it takes for the Secretary to review a recommendation of an accredited person under subsection (a) and determine the initial device classification);

(5) the average time period identified in paragraph (4) compared to the average time period for review of devices solely by the Secretary pursuant to section 510(k);

(6) if there is a difference in the average time period under paragraph (4) and the average time period under paragraph (5), the reasons for such difference;

(7) whether the quality of reviews under this section for devices for which no guidance has been issued is qualitatively inferior to reviews by the Secretary for devices for which no guidance has been issued;

(8) whether the quality of reviews under this section of devices for which no guidance has been issued is qualitatively inferior to reviews under this section of devices for which guidance has been issued;

(9) whether this section has in any way jeopardized or improved the public health;

(10) any impact of this section on resources available to the Secretary to review reports under section 510(k); and

(11) any suggestions for continuation, modification (including contraction or expansion of device eligibility), or termination of this section that the Secretary determines to be appropriate.

SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

RECOMMENDATIONS FOR INVESTIGATIONS OF DRUGS FOR RARE DISEASES OR CONDITIONS [100]

SEC. 525. [21 U.S.C. 360aa] (a) The sponsor of a drug for a disease or condition which is rare in the States may request the Secretary to provide written recommendations for the nonclinical and clinical investigations which must be conducted with the drug before—

(1) it may be approved for such disease or condition under section 505, or

(2) if the drug is a biological product, it may be licensed for such disease or condition under section 351 of the Public Health Service Act.

If the Secretary has reason to believe that a drug for which a request is made under this section is a drug for a disease or condition which is rare in the States, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request under this section, would be necessary for approval of such drug for such disease or condition under section 505 or licensing of such drug for such disease or condition under section 351 of the Public Health Service Act.

(b) The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

DESIGNATION OF DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 526. [21 U.S.C. 360bb] (a)(1) The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition. A request for designation of a drug shall be made before the submission of an application under section 505(b) for the drug, or the submission of an application for licensing of the drug under section 351 of the Public Health Service Act. If the Secretary finds that a drug for which a request is submitted under this subsection is being or will be investigated for a rare disease or condition and—

(A) if an application for such drug is approved under section 505, or

(B) if a license for such drug is issued under section 351 of the Public Health Service Act,

the approval, certification, or license would be for use for such disease or condition, the Secretary shall designate the drug as a drug for such disease or condition. A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (b) respecting the designation of the drug.

(2) For purposes of paragraph (1), the term rare disease or condition" means any disease or condition which (A) affects less than

[100] Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) (Public Law 97–414) establishes a program to make grants and enter into contracts regarding the development of drugs for rare diseases and conditions. Authorizations of appropriations for this program are currently provided through fiscal year 2006. See section 3 of Public Law 107–281 (116 Stat. 1993).

200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

(b) A designation of a drug under subsection (a) shall be subject to the condition that—

(1) if an application was approved for the drug under section 505(b) or a license was issued for the drug under section 351 of the Public Health Service Act, the manufacturer of the drug will notify the Secretary of any discontinuance of the production of the drug at least one year before discontinuance, and

(2) if an application has not been approved for the drug under section 505(b) or a license has not been issued for the drug under section 351 of the Public Health Service Act and if preclinical investigations or investigations under section 505(i) are being conducted with the drug, the manufacturer or sponsor of the drug will notify the Secretary of any decision to discontinue active pursuit of approval of an application under section 505(b) or approval of a license under section 351 of the Public Health Service Act.

(c) Notice respecting the designation of a drug under subsection (a) shall be made available to the public.

(d) The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

PROTECTION FOR DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 527. [21 U.S.C. 360cc] (a) Except as provided in subsection (b), if the Secretary—

(1) approves an application filed pursuant to section 505, or

(2) issues a license under section 351 of the Public Health Service Act

for a drug designated under section 526 for a rare disease or condition, the Secretary may not approve another application under section 505 or issue another license under section 351 of the Public Health Service Act for such drug for such disease or condition for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

(b) If an application filed pursuant to section 505 is approved for a drug designated under section 526 for a rare disease or condition or if a license is issued under section 351 of the Public Health Service Act for such a drug, the Secretary may, during the seven-year period beginning on the date of the application approval or of the issuance of the license, approve another application under section 505 or issue a license under section 351 of the Public Health Service Act, for such drug for such disease or condition for a person

who is not the holder of such approved application or of such license if—

(1) the Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or

(2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such seven-year period.

OPEN PROTOCOLS FOR INVESTIGATIONS OF DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 528. [21 U.S.C. 360dd] If a drug is designated under section 526 as a drug for a rare disease or condition and if notice of a claimed exemption under section 505(i) or regulations issued thereunder is filed for such drug, the Secretary shall encourage the sponsor of such drug to design protocols for clinical investigations of the drug which may be conducted under the exemption to permit the addition to the investigations of persons with the disease or condition who need the drug to treat the disease or condition and who cannot be satisfactorily treated by available alternative drugs.

SUBCHAPTER C—ELECTRONIC PRODUCT RADIATION CONTROL

DEFINITIONS

SEC. 531. [21 U.S.C. 360hh] As used in this subchapter—

(1) the term "electronic product radiation" means—

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

(2) the term "electronic product" means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation;

(3) the term "manufacturer" means any person engaged in the business of manufacturing, assembling, or importing of electronic products;

(4) the term "commerce" means (A) commerce between any place in any State and any place outside thereof; and (B) commerce wholly within the District of Columbia; and

(5) the term "State" includes the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, and American Samoa.

ELECTRONIC PRODUCT RADIATION CONTROL PROGRAM

SEC. 532. [21 U.S.C. 360ii] (a) The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—

(1) pursuant to section 534, develop and administer performance standards for electronic products;

(2) plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation;

(3) maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry and labor associations, and other organizations on present and future potential electronic product radiation;

(4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation; and

(6) consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) techniques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 534 to control such radiation emissions.

(b) In carrying out the purposes of subsection (a), the Secretary is authorized to—

(1)(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation; and (B) make such recommendations relating to such hazards and control as he considers appropriate;

(2) make grants to public and private agencies, organizations, and institutions, and to individuals for the purposes stated in paragraphs (2), (4), and (5) of subsection (a) of this section;

(3) contract with public or private agencies, institutions, and organizations, and with individuals, without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes of the United States (41 U.S.C. 5); and

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products.

(c)(1) Each recipient of assistance under this subchapter pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance,

the total cost of the project or undertaking in connection with which such assistance is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient that are pertinent to the grants or contracts entered into under this subchapter under other than competitive bidding procedures.

STUDIES BY THE SECRETARY

SEC. 533. [21 U.S.C. 360jj] (a) The Secretary shall conduct the following studies, and shall make a report or reports of the results of such studies to the Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate:

(1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to—

(A) control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954;

(B) any gaps and inconsistencies in present controls;

(C) the need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading such products to meet the standards for new products or separate standards for used products;

(D) measures to assure consistent and effective control of the aforementioned health hazards;

(E) measures to strengthen radiological health programs of State governments; and

(F) the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation;

(2) A study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes; and

(3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation which may be emitted from electronic products manufactured or imported prior to the effective date of any applicable standard established pursuant to this subchapter.

(b) In carrying out these studies, the Secretary shall invite the participation of other Federal departments and agencies having related responsibilities and interests, State governments—particularly those of States which regulate radioactive materials under section 274 of the Atomic Energy Act of 1954, as amended, and interested professional, labor, and industrial organizations. Upon request from congressional committees interested in these studies, the Secretary shall keep these committees currently informed as to

the progress of the studies and shall permit the committees to send observers to meetings of the study groups.

(c) The Secretary or his designee shall organize the studies and the participation of the invited participants as he deems best. Any dissent from the findings and recommendations of the Secretary shall be included in the report if so requested by the dissenter.

PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS

SEC. 534. [21 U.S.C. 360kk] (a)(1) The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products. Such standards may be prescribed from time to time whenever such determinations are made, but the first of such standards shall be prescribed prior to January 1, 1970. In the development of such standards, the Secretary shall consult with Federal and State departments and agencies having related responsibilities or interests and with appropriate professional organizations and interested persons, including representatives of industries and labor organizations which would be affected by such standards, and shall give consideration to—

(A) the latest available scientific and medical data in the field of electronic product radiation;

(B) the standards currently recommended by (i) other Federal agencies having responsibilities relating to the control and measurement of electronic product radiation, and (ii) public or private groups having an expertise in the field of electronic product radiation;

(C) the reasonableness and technical feasibility of such standards as applied to a particular electronic product;

(D) the adaptability of such standards to the need for uniformity and reliability of testing and measuring procedures and equipment; and

(E) in the case of a component, or accessory described in paragraph (2)(B) of section 531, the performance of such article in the manufactured or assembled product for which it is designed.

(2) The Secretary may prescribe different and individual performance standards, to the extent appropriate and feasible, for different electronic products so as to recognize their different operating characteristics and uses.

(3) The performance standards prescribed under this section shall not apply to any electronic product which is intended solely for export if (A) such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and (B) such product meets all the applicable requirements of the country to which such product is intended for export.

(4) The Secretary may by regulation amend or revoke any performance standard prescribed under this section.

(5) The Secretary may exempt from the provisions of this section any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

(b) The provisions of subchapter II of chapter 5 of title 5 of the United States Code (relating to the administrative procedure for rulemaking), and of chapter 7 of such title (relating to judicial review), shall apply with respect to any regulation prescribing, amending, or revoking any standard prescribed under this section.

(c) Each regulation prescribing, amending, or revoking a standard shall specify the date on which it shall take effect which, in the case of any regulation prescribing, or amending any standard, may not be sooner than one year or not later than two years after the date on which such regulation is issued, unless the Secretary finds, for good cause shown, that an earlier or later effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier or later date shall apply.

(d)(1) In a case of actual controversy as to the validity of any regulation issued under this section prescribing, amending, or revoking a performance standard, any person who will be adversely affected by such regulation when it is effective may at any time prior to the sixtieth day after such regulation is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such regulation. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based the regulation, as provided in section 2112 of title 28 of the United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original regulation, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to review the regulation in accordance with chapter 7 of title 5 of the United States Code and to grant appropriate relief as provided in such chapter.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such regulation of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code.

(5) Any action instituted under this subsection shall survive, notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(e) A certified copy of the transcript of the record and administrative proceedings under this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, exclusion of imports, or other proceeding arising under or in respect of this subchapter, irrespective of whether proceedings with respect to the regulation have previously been initiated or become final under this section.

(f)(1)(A) The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this subchapter referred to as the Committee") which he shall consult before prescribing any standard under this section. The Committee shall be appointed by the Secretary, after consultation with public and private agencies concerned with the technical aspect of electronic product radiation safety, and shall be composed of fifteen members each of whom shall be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(i) Five members shall be selected from governmental agencies, including State and Federal Governments;

(ii) Five members shall be selected from the affected industries after consultation with industry representatives; and

(iii) Five members shall be selected from the general public, of which at least one shall be a representative of organized labor.

(B) The Committee may propose electronic product radiation safety standards to the Secretary for his consideration. All proceedings of the Committee shall be recorded and the record of each such proceeding shall be available for public inspection.

(2) Payments to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 208 of the Public Health Service Act shall not render members of the Committee officers or employees of the United States for any purpose.

(g) The Secretary shall review and evaluate on a continuing basis testing programs carried out by industry to assure the adequacy of safeguards against hazardous electronic product radiation and to assure that electronic products comply with standards prescribed under this section.

(h) Every manufacturer of an electronic product to which is applicable a standard in effect under this section shall furnish to the distributor or dealer at the time of delivery of such product, in the form of a label or tag permanently affixed to such product or in

such manner as approved by the Secretary, the certification that such product conforms to all applicable standards under this section. Such certification shall be based upon a test, in accordance with such standard, of the individual article to which it is attached or upon a testing program which is in accord with good manufacturing practice and which has not been disapproved by the Secretary (in such manner as he shall prescribe by regulation) on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this section.

NOTIFICATION OF DEFECTS IN, AND REPAIR OR REPLACEMENT OF, ELECTRONIC PRODUCTS

SEC. 535. [21 U.S.C. 360*ll*] (a)(1) Every manufacturer of electronic products, who discovers that an electronic product produced, assembled, or imported by him has a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, or that an electronic product produced, assembled, or imported by him on or after the effective date of an applicable standard prescribed pursuant to section 534 fails to comply with such standard, shall immediately notify the Secretary of such defect or failure to comply if such product has left the place of manufacture and shall (except as authorized by paragraph (2)) with reasonable promptness furnish notification of such defect or failure to the persons (where known to the manufacturer) specified in subsection (b) of this section.

(2) If, in the opinion of such manufacturer, the defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he may, at the time of giving notice to the Secretary of such defect or failure to comply, apply to the Secretary for an exemption from the requirement of notice to the persons specified in subsection (b). If such application states reasonable grounds for such exemption, the Secretary shall afford such manufacturer an opportunity to present his views and evidence in support of the application, the burden of proof being on the manufacturer. If, after such presentation, the Secretary is satisfied that such defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he shall exempt such manufacturer from the requirement of notice to the persons specified in subsection (b) of this section and from the requirements of repair or replacement imposed by subsection (f) of this section.

(b) The notification (other than to the Secretary) required by paragraph (1) of subsection (a) of this section shall be accomplished—

(1) by certified mail to the first purchaser of such product for purposes other than resale, and to any subsequent transferee of such product; and

(2) by certified mail or other more expeditious means to the dealers or distributors of such manufacturer to whom such product was delivered.

(c) The notifications required by paragraph (1) of subsection (a) of this section shall contain a clear description of such defect or

failure to comply with an applicable standard, an evaluation of the hazard reasonably related to such defect or failure to comply, and a statement of the measures to be taken to repair such defect. In the case of a notification to a person referred to in subsection (b) of this section, the notification shall also advise the person of his rights under subsection (f) of this section.

(d) Every manufacturer of electronic products shall furnish to the Secretary a true or representative copy of all notices, bulletins, and other communications to the dealers or distributors of such manufacturer or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any such defect in such product or any such failure to comply with a standard applicable to such product. The Secretary shall disclose to the public so much of the information contained in such notice or other information obtained under section 537 as he deems will assist in carrying out the purposes of this subchapter, but he shall not disclose any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code unless he determines that it is necessary to carry out the purposes of this subchapter.

(e) If through testing, inspection, investigation, or research carried out pursuant to this subchapter, or examination of reports submitted pursuant to section 537, or otherwise, the Secretary determines that any electronic product—

(1) does not comply with an applicable standard prescribed pursuant to section 534; or

(2) contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation;

he shall immediately notify the manufacturer of such product of such defect or failure to comply. The notice shall contain the findings of the Secretary and shall include all information upon which the findings are based. The Secretary shall afford such manufacturer an opportunity to present his views and evidence in support thereof, to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of such radiation hazard. If after such presentation by the manufacturer the Secretary determines that such product does not comply with an applicable standard prescribed pursuant to section 534, or that it contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, the Secretary shall direct the manufacturer to furnish the notification specified in subsection (c) of this section to the persons specified in paragraphs (1) and (2) of subsection (b) of this section (where known to the manufacturer), unless the manufacturer has applied for an exemption from the requirement of such notification on the ground specified in paragraph (2) of subsection (a) and the Secretary is satisfied that such noncompliance or defect is not such as to create a significant risk of injury, including genetic injury, to any person.

(f) If any electronic product is found under subsection (a) or (e) to fail to comply with an applicable standard prescribed under this subchapter or to have a defect which relates to the safety of use of such product, and the notification specified in subsection (c) is

required to be furnished on account of such failure or defect, the manufacturer of such product shall (1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied, (2) replace such product with a like or equivalent product which complies with each applicable standard prescribed under this subchapter and which has no defect relating to the safety of its use, or (3) make a refund of the cost of such product. The manufacturer shall take the action required by this subsection in such manner, and with respect to such persons, as the Secretary by regulations shall prescribe.

(g) This section shall not apply to any electronic product that was manufactured before the date of the enactment of this subchapter [101].

IMPORTS

SEC. 536. [21 U.S.C. 360mm] (a) Any electronic product offered for importation into the United States which fails to comply with an applicable standard prescribed under this subchapter, or to which is not affixed a certification in the form of a label or tag in conformity with section 534(h) shall be refused admission into the United States. The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon the latter's request, samples of electronic products which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may have a hearing before the Secretary of Health and Human Services. If it appears from an examination of such samples or otherwise that any electronic product fails to comply with applicable standards prescribed pursuant to section 534, then, unless subsection (b) of this section applies and is complied with, (1) such electronic product shall be refused admission, and (2) the Secretary of the Treasury shall cause the destruction of such electronic product unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days after the date of notice of refusal of admission or within such additional time as may be permitted by such regulations.

(b) If it appears to the Secretary of Health and Human Services that any electronic product refused admission pursuant to subsection (a) of this section can be brought into compliance with applicable standards prescribed pursuant to section 534, final determination as to admission of such electronic product may be deferred upon filing of timely written application by the owner or consignee and the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as the Secretary of Health and Human Services may by regulation prescribe. If such application is filed and such bond is

[101] This subchapter was enacted by Public Law 90–602, which was enacted Oct. 18, 1968. (The subchapter was originally enacted as part of the Public Health Service Act, and was transferred to this act by section 19 of Public Law 101–629.)

executed the Secretary of Health and Human Services may, in accordance with rules prescribed by him, permit the applicant to perform such operations with respect to such electronic product as may be specified in the notice of permission.

(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of operations provided for in subsection (b) of this section, and all expenses in connection with the storage, cartage, or labor with respect to any electronic product refused admission pursuant to subsection (a) of this section, shall be paid by the owner or consignee, and, in event of default, shall constitute a lien against any future importations made by such owner or consignee.

(d) It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this subchapter or any standards prescribed pursuant to this subchapter may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

INSPECTION AND REPORTS

SEC. 537. [21 U.S.C. 360nn] (a) If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times, any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 534(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic

product which does not comply with an applicable standard prescribed under this subchapter and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 535(a)(2) or 535(e).

(b) Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subchapter and standards prescribed pursuant to this subchapter and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to this subchapter.

(c) Every manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out the purposes of this subchapter. The Secretary is authorized to require the manufacturer to give such notification of such performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product, as he determines necessary to carry out the purposes of this subchapter after consulting with the affected industry.

(d) Accident and investigation reports made under this subchapter by any officer, employee, or agent of the Secretary shall be available for use in any civil, criminal, or other judicial proceeding arising out of such accident. Any such officer, employee, or agent may be required to testify in such proceedings as to the fact developed in such investigations. Any such report shall be made available to the public in a manner which need not identify individuals. All reports on research projects, demonstration projects, and other related activities shall be public information.

(e) The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to subsection (a) or (b) of this section, which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of other agencies concerned with carrying out this subchapter or when relevant in any proceeding under this subchapter. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

(f) The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subchapter and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 535, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer, to hold

and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 535, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefor for the purposes of section 535, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 535(a).

PROHIBITED ACTS

SEC. 538. [21 U.S.C. 360oo] (a) It shall be unlawful—

(1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 534;

(2) for any person to fail to furnish any notification or other material or information required by section 535 or 537; or to fail to comply with the requirements of section 535(f);

(3) for any person to fail or to refuse to establish or maintain records required by this subchapter or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 537;

(4) for any person to fail or to refuse to make any report required pursuant to section 537(b) or to furnish or preserve any information required pursuant to section 537(f); or

(5) for any person (A) to fail to issue a certification as required by section 534(h), or (B) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 534(h) or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.

(b) The Secretary may exempt any electronic product, or class thereof, from all or part of subsection (a), upon such conditions as he may find necessary to protect the public health or welfare, for the purpose of research, investigations, studies, demonstrations, or training, or for reasons of national security.

ENFORCEMENT

SEC. 539. [21 U.S.C. 360pp] (a) The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of section 538 and to restrain dealers and distributors of electronic products from selling or otherwise disposing of electronic products which do not conform to an applicable standard prescribed pursuant to section 534 except when such products are disposed of

by returning them to the distributor or manufacturer from whom they were obtained. The district courts of the United States shall also have jurisdiction in accordance with section 1355 of title 28 of the United States Code to enforce the provisions of subsection (b) of this section.

(b)(1) Any person who violates section 538 shall be subject to a civil penalty of not more than $1,000. For purposes of this subsection, any such violation shall with respect to each electronic product involved, or with respect to each act or omission made unlawful by section 538, constitute a separate violation, except that the maximum civil penalty imposed on any person under this subsection for any related series of violations shall not exceed $300,000.

(2) Any such civil penalty may on application be remitted or mitigated by the Secretary. In determining the amount of such penalty, or whether it should be remitted or mitigated and in what amount, the appropriateness of such penalty to the size of the business of the person charged and the gravity of the violation shall be considered. The amount of such penalty, when finally determined, may be deducted from any sums owing by the United States to the person charged.

(c) Actions under subsections (a) and (b) of this section may be brought in the district court of the United States for the district wherein any act or omission or transaction constituting the violation occurred, or in such court for the district where the defendant is found or transacts business, and process in such cases may be served in any other district of which the defendant is an inhabitant or wherever the defendant may be found.

(d) Nothing in this subchapter shall be construed as requiring the Secretary to report for the institution of proceedings minor violations of this subchapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(e) Except as provided in the first sentence of section 542, compliance with this subchapter or any regulations issued thereunder shall not relieve any person from liability at common law or under statutory law.

(f) The remedies provided for in this subchapter shall be in addition to and not in substitution for any other remedies provided by law.

[Sec. 540 repealed by Public Law 105–362, § 601(a)(2)(A).]

FEDERAL-STATE COOPERATION

SEC. 541. [21 U.S.C. 360rr] The Secretary is authorized (1) to accept from State and local authorities engaged in activities related to health or safety or consumer protection, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of this subchapter which he may request and which they may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance, and (2) he may, for the purpose of conducting examinations, investigations, and inspections, commission any officer or employee of any such authority as an officer of the Department.

EFFECT ON STATE STANDARDS

SEC. 542. [21 U.S.C. 360ss] Whenever any standard prescribed pursuant to section 534 with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard. Nothing in this subchapter shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.

SUBCHAPTER D—DISSEMINATION OF TREATMENT INFORMATION [102]

SEC. 551. [21 U.S.C. 360aaa] REQUIREMENTS FOR DISSEMINATION OF TREATMENT INFORMATION ON DRUGS OR DEVICES.

(a) IN GENERAL.—Notwithstanding sections 301(d), 502(f), and 505, and section 351 of the Public Health Service Act (42 U.S.C. 262), a manufacturer may disseminate to—

(1) a health care practitioner;

(2) a pharmacy benefit manager;

(3) a health insurance issuer;

(4) a group health plan; or

(5) a Federal or State governmental agency;

written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device if the manufacturer meets the requirements of subsection (b).

(b) SPECIFIC REQUIREMENTS.—A manufacturer may disseminate information under subsection (a) on a new use only if—

(1)(A) in the case of a drug, there is in effect for the drug an application filed under subsection (b) or (j) of section 505 or a biologics license issued under section 351 of the Public Health Service Act; or

(B) in the case of a device, the device is being commercially distributed in accordance with a regulation under subsection (d) or (e) of section 513, an order under subsection (f) of such section, or the approval of an application under section 515;

(2) the information meets the requirements of section 552;

(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

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[102] This subchapter was added by section 401(a) of Public Law 105–115. Subsections (d) and (e) of such section provides as follows:

"(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

"(e) SUNSET.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.".

(4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary—

(A) a copy of the information to be disseminated; and

(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

(5) the manufacturer has complied with the requirements of section 554 (relating to a supplemental application for such use);

(6) the manufacturer includes along with the information to be disseminated under this subsection—

(A) a prominently displayed statement that discloses—

(i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;

(ii) if applicable, that the information is being disseminated at the expense of the manufacturer;

(iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

(iv) the official labeling for the drug or device and all updates with respect to the labeling;

(v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated; and

(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

(c) ADDITIONAL INFORMATION.—If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and balanced, the Secretary may require the manufacturer to disseminate—

(1) additional objective and scientifically sound information that pertains to the safety or effectiveness of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary or, where appropriate, a summary of such information or any other information that the Secretary has authority to make available to the public; and

(2) an objective statement of the Secretary, based on data or other scientifically sound information available to the Secretary, that bears on the safety or effectiveness of the new use of the drug or device.

SEC. 552. [21 U.S.C. 360aaa–1] INFORMATION AUTHORIZED TO BE DISSEMINATED.

(a) AUTHORIZED INFORMATION.—A manufacturer may disseminate information under section 551 on a new use only if the information—

(1) is in the form of an unabridged—

(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal (as defined in section 556(5)), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or

(B) reference publication, described in subsection (b), that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation; and

(2) is not false or misleading and would not pose a significant risk to the public health.

(b) REFERENCE PUBLICATION.—A reference publication referred to in subsection (a)(1)(B) is a publication that—

(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug or device;

(2) has not been edited or significantly influenced by such a manufacturer;

(3) is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold;

(4) does not focus on any particular drug or device of a manufacturer that disseminates information under section 551 and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

(5) presents materials that are not false or misleading.

SEC. 553. [21 U.S.C. 360aaa–2] ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.

(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the manufacturer prepares and submits to the Secretary biannually—

(1) a list containing the titles of the articles and reference publications relating to the new use of drugs or devices that were disseminated by the manufacturer to a person described

in section 551(a) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

(2) a list that identifies the categories of providers (as described in section 551(a)) that received the articles and reference publications for the 6-month period described in paragraph (1).

(b) RECORDS.—A manufacturer that disseminates information under section 551 shall keep records that may be used by the manufacturer when, pursuant to section 555, such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to such section. Such records, at the Secretary's discretion, may identify the recipient of information provided pursuant to section 551 or the categories of such recipients.

SEC. 554. [21 U.S.C. 360aaa–3] REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT.

(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if—

(1)(A) the manufacturer has submitted to the Secretary a supplemental application for such use; or

(B) the manufacturer meets the condition described in subsection (b) or (c) (relating to a certification that the manufacturer will submit such an application); or

(2) there is in effect for the manufacturer an exemption under subsection (d) from the requirement of paragraph (1).

(b) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF COMPLETED STUDIES.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary an application containing a certification that—

(1) the studies needed for the submission of a supplemental application for the new use have been completed; and

(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of information under section 551.

(c) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF PLANNED STUDIES.—

(1) IN GENERAL.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if—

(A) the manufacturer has submitted to the Secretary an application containing—

(i) a proposed protocol and schedule for conducting the studies needed for the submission of a supplemental application for the new use; and

(ii) a certification that the supplemental application will be submitted to the Secretary not later than 36 months after the date of the initial dissemination of information under section 551 (or, as applicable, not later than such date as the Secretary may specify pursuant to an extension under paragraph (3)); and

(B) the Secretary has determined that the proposed protocol is adequate and that the schedule for completing such studies is reasonable.

(2) PROGRESS REPORTS ON STUDIES.—A manufacturer that submits to the Secretary an application under paragraph (1) shall submit to the Secretary periodic reports describing the status of the studies involved.

(3) EXTENSION OF TIME REGARDING PLANNED STUDIES.—The period of 36 months authorized in paragraph (1)(A)(ii) for the completion of studies may be extended by the Secretary if—

(A) the Secretary determines that the studies needed to submit such an application cannot be completed and submitted within 36 months; or

(B) the manufacturer involved submits to the Secretary a written request for the extension and the Secretary determines that the manufacturer has acted with due diligence to conduct the studies in a timely manner, except that an extension under this subparagraph may not be provided for more than 24 additional months.

(d) EXEMPTION FROM REQUIREMENT OF SUPPLEMENTAL APPLICATION.—

(1) IN GENERAL.—For purposes of subsection (a)(2), a manufacturer may disseminate information on a new use if—

(A) the manufacturer has submitted to the Secretary an application for an exemption from meeting the requirement of subsection (a)(1); and

(B)(i) the Secretary has approved the application in accordance with paragraph (2); or

(ii) the application is deemed under paragraph (3)(A) to have been approved (unless such approval is terminated pursuant to paragraph (3)(B)).

(2) CONDITIONS FOR APPROVAL.—The Secretary may approve an application under paragraph (1) for an exemption if the Secretary makes a determination described in subparagraph (A) or (B), as follows:

(A) The Secretary makes a determination that, for reasons defined by the Secretary, it would be economically prohibitive with respect to such drug or device for the manufacturer to incur the costs necessary for the submission of a supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate)—

(i) the lack of the availability under law of any period during which the manufacturer would have exclusive marketing rights with respect to the new use involved; and

(ii) the size of the population expected to benefit from approval of the supplemental application.

(B) The Secretary makes a determination that, for reasons defined by the Secretary, it would be unethical to conduct the studies necessary for the supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate) whether the new use involved is the standard of medical care for a health condition.

(3) TIME FOR CONSIDERATION OF APPLICATION; DEEMED APPROVAL.—

(A) IN GENERAL.—The Secretary shall approve or deny an application under paragraph (1) for an exemption not later than 60 days after the receipt of the application. If the Secretary does not comply with the preceding sentence, the application is deemed to be approved.

(B) TERMINATION OF DEEMED APPROVAL.—If pursuant to a deemed approval under subparagraph (A) a manufacturer disseminates written information under section 551 on a new use, the Secretary may at any time terminate such approval and under section 555(b)(3) order the manufacturer to cease disseminating the information.

(e) REQUIREMENTS REGARDING APPLICATIONS.—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

SEC. 555. [21 U.S.C. 360aaa–4] CORRECTIVE ACTIONS; CESSATION OF DISSEMINATION.

(a) POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.—

(1) CORRECTIVE ACTIONS.—With respect to data received by the Secretary after the dissemination of information under section 551 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the data indicate that the new use involved may not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such action regarding the dissemination of the information as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease the dissemination of the information.

(2) RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.—After a manufacturer disseminates information under section 551, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

(b) CESSATION OF DISSEMINATION.—

(1) FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only after the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and (unless paragraph (2)(B) applies) has provided an opportunity for a meeting with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the Secretary shall delay

issuing the order and provide to the manufacturer an opportunity to correct the violation.

(2) SUPPLEMENTAL APPLICATIONS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if—

(A) in the case of a manufacturer that has submitted a supplemental application for a new use pursuant to section 554(a)(1), the Secretary determines that the supplemental application does not contain adequate information for approval of the new use for which the application was submitted;

(B) in the case of a manufacturer that has submitted a certification under section 554(b), the manufacturer has not, within the 6-month period involved, submitted the supplemental application referred to in the certification; or

(C) in the case of a manufacturer that has submitted a certification under section 554(c) but has not yet submitted the supplemental application referred to in the certification, the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies involved.

(3) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—If under section 554(d)(3) the Secretary terminates a deemed approval of an exemption, the Secretary may order the manufacturer involved to cease disseminating the information. A manufacturer shall comply with an order under the preceding sentence not later than 60 days after the receipt of the order.

(c) CORRECTIVE ACTIONS BY MANUFACTURERS.—

(1) IN GENERAL.—In any case in which under this section the Secretary orders a manufacturer to cease disseminating information, the Secretary may order the manufacturer to take action to correct the information that has been disseminated, except as provided in paragraph (2).

(2) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may not order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

SEC. 556. [21 U.S.C. 360aaa–5] DEFINITIONS.

For purposes of this subchapter:

(1) The term "health care practitioner" means a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs or devices.

(2) The terms "health insurance issuer" and "group health plan" have the meaning given such terms under section 2791 of the Public Health Service Act.

(3) The term "manufacturer" means a person who manufactures a drug or device, or who is licensed by such person to distribute or market the drug or device.

(4) The term ''new use''—

(A) with respect to a drug, means a use that is not included in the labeling of the approved drug; and

(B) with respect to a device, means a use that is not included in the labeling for the approved or cleared device.

(5) The term ''scientific or medical journal'' means a scientific or medical publication—

(A) that is published by an organization—

(i) that has an editorial board;

(ii) that utilizes experts, who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles; and

(iii) that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

(B) whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

(C) that is generally recognized to be of national scope and reputation;

(D) that is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health; and

(E) that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers.

SEC. 557. [21 U.S.C. 360aaa–6] RULES OF CONSTRUCTION.

(a) UNSOLICITED REQUEST.—Nothing in section 551 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

(b) DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 551, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

(c) PATENT PROTECTION.—Nothing in section 551 shall affect patent rights in any manner.

(d) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 551 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 556(5)) from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles from such entity.

SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

SEC. 561. [21 U.S.C. 360bbb] EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

(a) EMERGENCY SITUATIONS.—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(b) INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition if—

(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition;

(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

(4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) or 520(g), including any regulations promulgated under section 505(i) or 520(g), describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

(c) TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS AND TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS.—Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an "expanded access protocol"), the Secretary shall permit such investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

(1) under the treatment investigational new drug application or treatment investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an investigational drug application in effect under section 505(i) or investigational device exemption in effect under section 520(g); or

(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

(5) in the case of an investigational drug or investigational device described in paragraph (3)(A), the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i) or 520(g);

(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 505(i) or 520(g), including regulations promulgated under section 505(i) or 520(g). The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be the same type of information that is required by section 402(j)(3) of the Public Health Service Act.

(d) TERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug or investigational device if the requirements under this section are no longer met.

(e) DEFINITIONS.—In this section, the terms ''investigational drug'', ''investigational device'', ''treatment investigational new drug application'', and ''treatment investigational device exemption'' shall have the meanings given the terms in regulations prescribed by the Secretary.

SEC. 562. [21 U.S.C. 360bbb–1] DISPUTE RESOLUTION.

If, regarding an obligation concerning drugs or devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate scientific advisory panel described in section 505(n) or an advisory committee described in section 515(g)(2)(B). Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997.

SEC. 563. [21 U.S.C. 360bbb–2] CLASSIFICATION OF PRODUCTS.

(a) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 503(g) or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the product under subsection (a), or the component of the Food and Drug Administration that will regulate the product, and shall provide to the person a written statement that identifies such classification or such component, and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.

SEC. 564. [21 U.S.C. 360bbb–3] AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

(a) IN GENERAL.—

(1) EMERGENCY USES.—Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for

use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) APPROVAL STATUS OF PRODUCT.—An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under a provision of law referred to in such paragraph (referred to in this section as an "unapproved product"); or

(B) is approved, licensed, or cleared under such a provision, but which use is not under such provision an approved, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product").

(3) RELATION TO OTHER USES.—An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a provision of law referred to in such paragraph.

(4) DEFINITIONS.—For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act.

(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).

(C) The term "product" means a drug, device, or biological product.

(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).

(E) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).

(b) DECLARATION OF EMERGENCY.—

(1) IN GENERAL.—The Secretary may declare an emergency justifying the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or

(C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

(2) TERMINATION OF DECLARATION.—

(A) IN GENERAL.—A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) the expiration of the one-year period beginning on the date on which the declaration is made.

(B) RENEWAL.—Notwithstanding subparagraph (A), the Secretary may renew a declaration under this subsection, and this paragraph shall apply to any such renewal.

(C) DISPOSITION OF PRODUCT.—If an authorization under this section with respect to an unapproved product ceases to be effective as a result of a termination under subparagraph (A) of this paragraph, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

(3) ADVANCE NOTICE OF TERMINATION.—The Secretary shall provide advance notice that a declaration under this subsection will be terminated. The period of advance notice shall be a period reasonably determined to provide—

(A) in the case of an unapproved product, a sufficient period for disposition of the product, including the return of such product (except such quantities of product as are necessary to provide for continued use consistent with subsection (f)(2)) to the manufacturer (in the case of a manufacturer that chooses to have such product returned); and

(B) in the case of an unapproved use of an approved product, a sufficient period for the disposition of any labeling, or any information under subsection (e)(2)(B)(ii), as the case may be, that was provided with respect to the emergency use involved.

(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register each declaration, determination, advance notice of termination, and renewal under this subsection.

(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved), the Secretary concludes—

(1) that an agent specified in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

(A) the product may be effective in diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this Act, or licensed under section 351 of the Public Health Service Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and

(4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

(d) SCOPE OF AUTHORIZATION.—An authorization of a product under this section shall state—

(1) each disease or condition that the product may be used to diagnose, prevent, or treat within the scope of the authorization;

(2) the Secretary's conclusions, made under subsection (c)(2)(B), that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and

(3) the Secretary's conclusions, made under subsection (c), concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating such diseases or conditions, including an assessment of the available scientific evidence.

(e) CONDITIONS OF AUTHORIZATION.—

(1) UNAPPROVED PRODUCT.—

(A) REQUIRED CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the circumstances of the emergency, shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

(ii) Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use.

(iii) Appropriate conditions with respect to the collection and analysis of information, during the period when the authorization is in effect, concerning the safety and effectiveness of the product with respect to the emergency use of such product.

(iv) For persons other than manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(2) UNAPPROVED USE.—With respect to the emergency use of a product that is an unapproved use of an approved product:

(A) For a manufacturer of the product who carries out any activity for which the authorization is issued, the Secretary shall, to the extent practicable given the circumstances of the emergency, establish conditions described in clauses (i) and (ii) of paragraph (1)(A), and may establish conditions described in clauses (iii) and (iv) of such paragraph.

(B)(i) If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change, such authorization may not authorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer.

(ii) In the circumstances described in clause (i), for a person who does not manufacture the product and who chooses to act under this clause, an authorization under this section regarding the emergency use shall, to the extent practicable given the circumstances of the emergency, authorize such person to provide appropriate information with respect to such product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). While the authorization under this section is effective, such additional information shall not be considered labeling for purposes of section 502.

(C) The Secretary may establish with respect to the distribution and administration of the product for the unapproved use conditions no more restrictive than those established by the Secretary with respect to the distribution and administration of the product for the approved use.

(3) GOOD MANUFACTURING PRACTICE.—With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including such requirements established under section 501.

(4) ADVERTISING.—The Secretary may establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), including, as appropriate—

(A) with respect to drugs and biological products, requirements applicable to prescription drugs pursuant to section 502(n); or

(B) with respect to devices, requirements applicable to restricted devices pursuant to section 502(r).

(f) DURATION OF AUTHORIZATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), an authorization under this section shall be effective until the earlier of the termination of the declaration under subsection (b) or a revocation under subsection (g).

(2) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—Notwithstanding the termination of the declaration under subsection (b) or a revocation under subsection (g), an authorization shall continue to be effective to provide for continued use of an unapproved product with respect to a patient to whom it was administered during the period described by paragraph

(1), to the extent found necessary by such patient's attending physician.

(g) REVOCATION OF AUTHORIZATION.—

(1) REVIEW.—The Secretary shall periodically review the circumstances and the appropriateness of an authorization under this section.

(2) REVOCATION.—The Secretary may revoke an authorization under this section if the criteria under subsection (c) for issuance of such authorization are no longer met or other circumstances make such revocation appropriate to protect the public health or safety.

(h) PUBLICATION; CONFIDENTIAL INFORMATION.—

(1) PUBLICATION.—The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, and an explanation of the reasons therefor (which may include a summary of data or information that has been submitted to the Secretary in an application under section 505(i) or section 520(g), even if such summary may indirectly reveal the existence of such application).

(2) CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5 of such Code.

(i) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

(j) RULES OF CONSTRUCTION.—The following applies with respect to this section:

(1) Nothing in this section impairs the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution.

(2) Nothing in this section impairs the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law.

(3) Nothing in this section (including any exercise of authority by a manufacturer under subsection (e)(2)) impairs the authority of the United States to use or manage quantities of a product that are owned or controlled by the United States (including quantities in the stockpile maintained under section 319F–2 of the Public Health Service Act).

(k) RELATION TO OTHER PROVISIONS.—If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of section 505(i), section 520(g), or any other provision of this Act or section 351 of the Public Health Service Act.

(l) OPTION TO CARRY OUT AUTHORIZED ACTIVITIES.—Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such

activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall report to the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out any activity under the authorization. This section only has legal effect on a person who carries out an activity for which an authorization under this section is issued. This section does not modify or affect activities carried out pursuant to other provisions of this Act or section 351 of the Public Health Service Act. Nothing in this subsection may be construed as restricting the Secretary from imposing conditions on persons who carry out any activity pursuant to an authorization under this section.

Subchapter F—New Animal Drugs for Minor Use and Minor Species

SEC. 571. [21 U.S.C. 360ccc] CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES.

(a)(1) Except as provided in paragraph (3) of this section, any person may file with the Secretary an application for conditional approval of a new animal drug intended for a minor use or a minor species. Such an application may not be a supplement to an application approved under section 512. Such application must comply in all respects with the provisions of section 512 of this Act except sections 512(a)(4), 512(b)(2), 512(c)(1), 512(c)(2), 512(c)(3), 512(d)(1), 512(e), 512(h), and 512(n) unless otherwise stated in this section, and any additional provisions of this section. New animal drugs are subject to application of the same safety standards that would be applied to such drugs under section 512(d) (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).

(2) The applicant shall submit to the Secretary as part of an application for the conditional approval of a new animal drug—

(A) all information necessary to meet the requirements of section 512(b)(1) except section 512(b)(1)(A);

(B) full reports of investigations which have been made to show whether or not such drug is safe under section 512(d) (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance) and there is a reasonable expectation of effectiveness for use;

(C) data for establishing a conditional dose;

(D) projections of expected need and the justification for that expectation based on the best information available;

(E) information regarding the quantity of drug expected to be distributed on an annual basis to meet the expected need; and

(F) a commitment that the applicant will conduct additional investigations to meet the requirements for the full demonstration of effectiveness under section 512(d)(1)(E) within 5 years.

(3) A person may not file an application under paragraph (1) if—

(A) the application seeks conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal.

(B) the person has previously filed an application for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not

subsequently conditionally approved by the Secretary under subsection (b), or

(C) the person obtained the application, or data or other information contained therein, directly or indirectly from the person who filed for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b).

(b) Within 180 days after the filing of an application pursuant to subsection (a), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(1) issue an order, effective for one year, conditionally approving the application if the Secretary finds that none of the grounds for denying conditional approval, specified in subsection (c) of this section applies and publish a Federal Register notice of the conditional approval, or

(2) give the applicant notice of an opportunity for an informal hearing on the question whether such application can be conditionally approved.

(c) If the Secretary finds, after giving the applicant notice and an opportunity for an informal hearing, that—

(1) any of the provisions of section 512(d)(1) (A) through (D) or (F) through (I) are applicable;

(2) the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such drug, is insufficient to show that there is a reasonable expectation that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or

(3) another person has received approval under section 512 for the same drug in the same dosage form for the same intended use, and that person is able to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended;

the Secretary shall issue an order refusing to conditionally approve the application. If, after such notice and opportunity for an informal hearing, the Secretary finds that paragraphs (1) through (3) do not apply, the Secretary shall issue an order conditionally approving the application effective for one year and publish a Federal Register notice of the conditional approval. Any order issued under this subsection refusing to conditionally approve an application shall state the findings upon which it is based.

(d) A conditional approval under this section is effective for a 1-year period and is thereafter renewable by the Secretary annually for up to 4 additional 1-year terms. A conditional approval shall be in effect for no more than 5 years from the date of approval under subsection (b)(1) or (c) of this section unless extended as provided for in subsection (h) of this section. The following shall also apply:

(1) No later than 90 days from the end of the 1-year period for which the original or renewed conditional approval is effective, the applicant may submit a request to renew a conditional approval for an additional 1-year term.

(2) A conditional approval shall be deemed renewed at the end of the 1-year period, or at the end of a 90-day extension that the Secretary may, at the Secretary's discretion, grant by letter in order to complete review of the renewal request, unless the Secretary determines before the expiration of the 1-year period or the 90-day extension that—

(A) the applicant failed to submit a timely renewal request;

(B) the request fails to contain sufficient information to show that—

(i) the applicant is making sufficient progress toward meeting approval requirements under section 512(d)(1)(E), and is likely to be able to fulfill those requirements and obtain an approval under section 512 before the expiration of the 5-year maximum term of the conditional approval;

(ii) the quantity of the drug that has been distributed is consistent with the conditionally approved intended use and conditions of use, unless there is adequate explanation that ensures that the drug is only used for its intended purpose; or

(iii) the same drug in the same dosage form for the same intended use has not received approval under section 512, or if such a drug has been approved, that the holder of the approved application is unable to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended; or

(C) any of the provisions of section 512(e)(1) (A) through (B) or (D) through (F) are applicable.

(3) If the Secretary determines before the end of the 1-year period or the 90-day extension, if granted, that a conditional approval should not be renewed, the Secretary shall issue an order refusing to renew the conditional approval, and such conditional approval shall be deemed withdrawn and no longer in effect. The Secretary shall thereafter provide an opportunity for an informal hearing to the applicant on the issue whether the conditional approval shall be reinstated.

(e)(1) The Secretary shall issue an order withdrawing conditional approval of an application filed pursuant to subsection (a) if the Secretary finds that another person has received approval under section 512 for the same drug in the same dosage form for the same intended use and that person is able to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended.

(2) The Secretary shall, after due notice and opportunity for an informal hearing to the applicant, issue an order withdrawing conditional approval of an application filed pursuant to subsection (a) if the Secretary finds that—

(A) any of the provisions of section 512(e)(1) (A) through (B) or (D) through (F) are applicable; or

(B) on the basis of new information before the Secretary with respect to such drug, evaluated together with the evidence available to the Secretary when the application was conditionally approved, that there is not a reasonable expectation

that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

(3) The Secretary may also, after due notice and opportunity for an informal hearing to the applicant, issue an order withdrawing conditional approval of an application filed pursuant to subsection (a) if the Secretary finds that any of the provisions of section 512(e)(2) are applicable.

(f)(1) The label and labeling of a new animal drug with a conditional approval under this section shall—

(A) bear the statement, "conditionally approved by FDA pending a full demonstration of effectiveness under application number"; and

(B) contain such other information as prescribed by the Secretary.

(2) An intended use that is the subject of a conditional approval under this section shall not be included in the same product label with any intended use approved under section 512.

(g) A conditionally approved new animal drug application may not be amended or supplemented to add indications for use.

(h) 180 days prior to the termination date established under subsection (d) of this section, an applicant shall have submitted all the information necessary to support a complete new animal drug application in accordance with section 512(b)(1) or the conditional approval issued under this section is no longer in effect. Following review of this information, the Secretary shall either—

(1) issue an order approving the application under section 512(c) if the Secretary finds that none of the grounds for denying approval specified in section 512(d)(1) applies, or

(2) give the applicant an opportunity for a hearing before the Secretary under section 512(d) on the question whether such application can be approved.

Upon issuance of an order approving the application, product labeling and administrative records of approval shall be modified accordingly. If the Secretary has not issued an order under section 512(c) approving such application prior to the termination date established under subsection (d) of this section, the conditional approval issued under this section is no longer in effect unless the Secretary grants an extension of an additional 180-day period so that the Secretary can complete review of the application. The decision to grant an extension is committed to the discretion of the Secretary and not subject to judicial review.

(i) The decision of the Secretary under subsection (c), (d), or (e) of this section refusing or withdrawing conditional approval of an application shall constitute final agency action subject to judicial review.

(j) In this section and section 572, the term "transgenic animal" means an animal whose genome contains a nucleotide sequence that has been intentionally modified in vitro, and the progeny of such an animal; Provided that the term "transgenic animal" does not include an animal of which the nucleotide sequence of the genome has been modified solely by selective breeding.

SEC. 572. [21 U.S.C. 360ccc–1] INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES.

(a)(1) The Secretary shall establish an index limited to—

(A) new animal drugs intended for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; and

(B) new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance).

(2) The index shall not include a new animal drug that is contained in or a product of a transgenic animal.

(b) Any person intending to file a request under this section shall be entitled to one or more conferences to discuss the requirements for indexing a new animal drug.

(c)(1) Any person may submit a request to the Secretary for a determination whether a new animal drug may be eligible for inclusion in the index. Such a request shall include—

(A) information regarding the need for the new animal drug, the species for which the new animal drug is intended, the proposed intended use and conditions of use, and anticipated annual distribution;

(B) information to support the conclusion that the proposed use meets the conditions of subparagraph (A) or (B) of subsection (a)(1) of this section;

(C) information regarding the components and composition of the new animal drug;

(D) a description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug;

(E) an environmental assessment that meets the requirements of the National Environmental Policy Act of 1969, as amended, and as defined in 21 CFR Part 25, as it appears on the date of enactment of this provision and amended thereafter or information to support a categorical exclusion from the requirement to prepare an environmental assessment;

(F) information sufficient to support the conclusion that the proposed use of the new animal drug is safe under section 512(d) with respect to individuals exposed to the new animal drug through its manufacture or use; and

(G) such other information as the Secretary may deem necessary to make this eligibility determination.

(2) Within 90 days after the submission of a request for a determination of eligibility for indexing based on subsection (a)(1)(A) of this section, or 180 days for a request submitted based on subsection (a)(1)(B) of this section, the Secretary shall grant or deny the request, and notify the person who requested such determination of the Secretary's decision. The Secretary shall grant the request if the Secretary finds that—

(A) the same drug in the same dosage form for the same intended use is not approved or conditionally approved;

(B) the proposed use of the drug meets the conditions of subparagraph (A) or (B) of subsection (a)(1), as appropriate;

(C) the person requesting the determination has established appropriate specifications for the manufacture and control of the new animal drug and has demonstrated an understanding of the requirements of current good manufacturing practices;

(D) the new animal drug will not significantly affect the human environment; and

(E) the new animal drug is safe with respect to individuals exposed to the new animal drug through its manufacture or use.

If the Secretary denies the request, the Secretary shall thereafter provide due notice and an opportunity for an informal conference. A decision of the Secretary to deny an eligibility request following an informal conference shall constitute final agency action subject to judicial review.

(d)(1) With respect to a new animal drug for which the Secretary has made a determination of eligibility under subsection (c), the person who made such a request may ask that the Secretary add the new animal drug to the index established under subsection (a). The request for addition to the index shall include—

(A) a copy of the Secretary's determination of eligibility issued under subsection (c);

(B) a written report that meets the requirements in subsection (d)(2) of this section;

(C) a proposed index entry;

(D) facsimile labeling;

(E) anticipated annual distribution of the new animal drug;

(F) a written commitment to manufacture the new animal drug and animal feeds bearing or containing such new animal drug according to current good manufacturing practices;

(G) a written commitment to label, distribute, and promote the new animal drug only in accordance with the index entry;

(H) upon specific request of the Secretary, information submitted to the expert panel described in paragraph (3); and

(I) any additional requirements that the Secretary may prescribe by general regulation or specific order.

(2) The report required in paragraph (1) shall—

(A) be authored by a qualified expert panel;

(B) include an evaluation of all available target animal safety and effectiveness information, including anecdotal information;

(C) state the expert panel's opinion regarding whether the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm being caused by the absence of an approved or conditionally approved new animal drug for the minor species in question;

(D) include information from which labeling can be written; and

(E) include a recommendation regarding whether the new animal drug should be limited to use under the professional supervision of a licensed veterinarian.

(3) A qualified expert panel, as used in this section, is a panel that—

(A) is composed of experts qualified by scientific training and experience to evaluate the target animal safety and effectiveness of the new animal drug under consideration;

(B) operates external to FDA; and

(C) is not subject to the Federal Advisory Committee Act, 5 U.S.C. App. 2.

The Secretary shall define the criteria for selection of a qualified expert panel and the procedures for the operation of the panel by regulation.

(4) Within 180 days after the receipt of a request for listing a new animal drug in the index, the Secretary shall grant or deny the request. The Secretary shall grant the request if the request for indexing continues to meet the eligibility criteria in subsection (a) and the Secretary finds, on the basis of the report of the qualified expert panel and other information available to the Secretary, that the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question. If the Secretary denies the request, the Secretary shall thereafter provide due notice and the opportunity for an informal conference. The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

(e)(1) The index established under subsection (a) shall include the following information for each listed drug—

(A) the name and address of the person who holds the index listing;

(B) the name of the drug and the intended use and conditions of use for which it is being indexed;

(C) product labeling; and

(D) conditions and any limitations that the Secretary deems necessary regarding use of the drug.

(2) The Secretary shall publish the index, and revise it periodically.

(3) The Secretary may establish by regulation a process for reporting changes in the conditions of manufacturing or labeling of indexed products.

(f)(1) If the Secretary finds, after due notice to the person who requested the index listing and an opportunity for an informal conference, that—

(A) the expert panel failed to meet the requirements as set forth by the Secretary by regulation;

(B) on the basis of new information before the Secretary, evaluated together with the evidence available to the Secretary when the new animal drug was listed in the index, the benefits of using the new animal drug for the indexed use do not outweigh its risks to the target animal;

(C) the conditions of subsection (c)(2) of this section are no longer satisfied;

(D) the manufacture of the new animal drug is not in accordance with current good manufacturing practices;

(E) the labeling, distribution, or promotion of the new animal drug is not in accordance with the index entry;

(F) the conditions and limitations of use associated with the index listing have not been followed; or

(G) the request for indexing contains any untrue statement of material fact,

the Secretary shall remove the new animal drug from the index. The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

(2) If the Secretary finds that there is a reasonable probability that the use of the drug would present a risk to the health of humans or other animals, the Secretary may—

(A) suspend the listing of such drug immediately;

(B) give the person listed in the index prompt notice of the Secretary's action; and

(C) afford that person the opportunity for an informal conference.

The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

(g) For purposes of indexing new animal drugs under this section, to the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of section 512 minor species new animal drugs and animal feeds bearing or containing new animal drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of minor species animal drugs. Such regulations may, at the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such article, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of such article, as the Secretary finds will enable the Secretary to evaluate the safety and effectiveness of such article in the event of the filing of a request for an index listing pursuant to this section.

(h) The labeling of a new animal drug that is the subject of an index listing shall state, prominently and conspicuously—

(1) "NOT APPROVED BY FDA.—Legally marketed as an FDA indexed product. Extra-label use is prohibited.";

(2) except in the case of new animal drugs indexed for use in an early life stage of a food-producing animal, "This product is not to be used in animals intended for use as food for humans or other animals."; and

(3) such other information as may be prescribed by the Secretary in the index listing.

(i)(1) In the case of any new animal drug for which an index listing pursuant to subsection (a) is in effect, the person who has an index listing shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, and other data or information, received or otherwise obtained by such person with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general

regulation, or by order with respect to such listing, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (f). Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(j)(1) Safety and effectiveness data and information which has been submitted in support of a request for a new animal drug to be indexed under this section and which has not been previously disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the drug indexed in accordance with the request,

(B) if the Secretary has determined that such drug cannot be indexed and all legal appeals have been exhausted,

(C) if the indexing of such drug is terminated and all legal appeals have been exhausted, or

(D) if the Secretary has determined that such drug is not a new animal drug.

(2) Any request for data and information pursuant to paragraph (1) shall include a verified statement by the person making the request that any data or information received under such paragraph shall not be disclosed by such person to any other person—

(A) for the purpose of, or as part of a plan, scheme, or device for, obtaining the right to make, use, or market, or making, using, or marketing, outside the United States, the drug identified in the request for indexing; and

(B) without obtaining from any person to whom the data and information are disclosed an identical verified statement, a copy of which is to be provided by such person to the Secretary, which meets the requirements of this paragraph.

SEC. 573. [21 U.S.C. 360ccc–2] DESIGNATED NEW ANIMAL DRUGS FOR MINOR USE OR MINOR SPECIES.

(a) DESIGNATION.—

(1) The manufacturer or the sponsor of a new animal drug for a minor use or use in a minor species may request that the Secretary declare that drug a "designated new animal drug". A request for designation of a new animal drug shall be made before the submission of an application under section 512(b) or section 571 for the new animal drug.

(2) The Secretary may declare a new animal drug a "designated new animal drug" if—

(A) it is intended for a minor use or use in a minor species; and

(B) the same drug in the same dosage form for the same intended use is not approved under section 512 or 571 or

designated under this section at the time the request is made.

(3) Regarding the termination of a designation—

(A) the sponsor of a new animal drug shall notify the Secretary of any decision to discontinue active pursuit of approval under section 512 or 571 of an application for a designated new animal drug. The Secretary shall terminate the designation upon such notification;

(B) the Secretary may also terminate designation if the Secretary independently determines that the sponsor is not actively pursuing approval under section 512 or 571 with due diligence;

(C) the sponsor of an approved designated new animal drug shall notify the Secretary of any discontinuance of the manufacture of such new animal drug at least one year before discontinuance. The Secretary shall terminate the designation upon such notification; and

(D) the designation shall terminate upon the expiration of any applicable exclusivity period under subsection (c).

(4) Notice respecting the designation or termination of designation of a new animal drug shall be made available to the public.

(b) GRANTS AND CONTRACTS FOR DEVELOPMENT OF DESIGNATED NEW ANIMAL DRUGS.—

(1) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in connection with the development of designated new animal drugs.

(2) For purposes of paragraph (1) of this section—

(A) The term ''qualified safety and effectiveness testing'' means testing—

(i) which occurs after the date such new animal drug is designated under this section and before the date on which an application with respect to such drug is submitted under section 512; and

(ii) which is carried out under an investigational exemption under section 512(j).

(B) The term ''manufacturing expenses'' means expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug which occur after the new animal drug is designated under this section and before the date on which an application with respect to such new animal drug is submitted under section 512 or 571.

(c) EXCLUSIVITY FOR DESIGNATED NEW ANIMAL DRUGS.—

(1) Except as provided in subsection (c)(2), if the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary may not approve or conditionally approve another application submitted for such new animal drug with the same intended use as the designated new animal drug for another applicant before the expiration of seven years from the date of approval or conditional approval of the application.

(2) If an application filed pursuant to section 512 or section 571 is approved for a designated new animal drug, the Secretary may, during the 7-year exclusivity period beginning on the date of the application approval or conditional approval, approve or conditionally approve another application under section 512 or section 571 for such drug for such minor use or minor species for another applicant if—

(A) the Secretary finds, after providing the holder of such an approved application notice and opportunity for the submission of views, that in the granted exclusivity period the holder of the approved application cannot assure the availability of sufficient quantities of the drug to meet the needs for which the drug was designated; or

(B) such holder provides written consent to the Secretary for the approval or conditional approval of other applications before the expiration of such exclusivity period.

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

SEC. 601. [21 U.S.C. 361] A cosmetic shall be deemed to be adulterated—[103]

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a).

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[103] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

MISBRANDED COSMETICS

SEC. 602. [21 U.S.C. 362] A cosmetic shall be deemed to be misbranded—[104]

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

REGULATIONS MAKING EXEMPTIONS

SEC. 603. [21 U.S.C. 363] The Secretary shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. [21 U.S.C. 371] (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

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[104] See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

(b) The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 403(j), 404(a), 406, 501(b), or 502 (d) or (h) of this Act, and any action for the amendment or repeal of any definition and standard of identity under section 401 of this Act for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations)[105] shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested persons, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the

[105] Section 3(b) of Public Law 103–396 attempted to amend section 701(e)(1) by striking "or maple syrup (regulated under section 168.140 of title 21, Code of Federal Regulations).". The probable intent of the Congress was to strike "or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations)".

issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence, so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal libel for condemnation, exclusion of imports, or other proceeding arising under or in respect of this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

(h)(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

(C) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.

(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

(3) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

(4) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.

(5) Not later than July 1, 2000, the Secretary after evaluating the effectiveness of the Good Guidance Practices document, published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.

EXAMINATIONS AND INVESTIGATIONS

SEC. 702. [21 U.S.C. 372] (a)(1) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

(2)(A) In addition to the authority established in paragraph (1), the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal department or agency, is authorized to conduct examinations and investigations for the purposes of this Act through the officers and employees of such other department or agency, subject to subparagraph (B). Such a memorandum shall include provisions to ensure adequate training of such officers and employees to conduct the examinations and investigations. The memorandum of understanding shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other department or agency.

(B) A memorandum of understanding under subparagraph (A) between the Secretary and another Federal department or agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and such department or agency.

(C) For any fiscal year in which the Secretary and the head of another Federal department or agency carries out one or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of such department or agency shall with respect to their respective departments or agencies submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for such year—

(i) the number of officers or employees that carried out one or more programs, projects, or activities under such memorandum;

(ii) the number of additional articles that were inspected or examined as a result of such memorandum; and

(iii) the number of additional examinations or investigations that were carried out pursuant to such memorandum.

(3) In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States, when in his opinion and with due regard to the enforcement of all

the provisions of this Act, the facilities at his disposal will permit of such inspection.

(4) For the purposes of this subsection, the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

(c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department duly authorized by the Secretary to make such inspection.

(d) The Secretary is authorized and directed, upon request from the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

(e) Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this Act relating to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 304;

(4) make arrests without warrant for offenses under this Act with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 304(a)(2), seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 304(a)(2). In the event of seizure pursuant to this paragraph (5)[106], libel proceedings under section 304(a)(2) shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

[106] So in law. Probably should be "this paragraph".

RECORDS OF INTERSTATE SHIPMENT

SEC. 703. [21 U.S.C. 373] For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates, except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

FACTORY INSPECTION

SEC. 704. [21 U.S.C. 374] (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have

been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k)[107] section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(2) The provisions of the third sentence of paragraph (1) shall not apply to—

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice;

(C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale;

(D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or

(B) required to be maintained under section 412.

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[107] So in law. A comma probably should appear after "section 505(i) or (k)". See the amendment made by section 125(b)(2)(L) of Public Law 105–115 (111 Stat. 2326).

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

(f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

(2) Within 15 days after the receipt of a written request from the Secretary to an accredited person described in paragraph (3) for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.

(3) For purposes of paragraphs (1) and (2), an accredited person described in this paragraph is a person who—

(A) is accredited under subsection (g); or

(B) is accredited under section 523.

(g)(1) Not later than one year after the date of the enactment of this subsection [108], the Secretary shall, subject to the provisions of

[108] Subsection (g) was added by section 201 of Public Law 107–250 (116 Stat. 1602), which was enacted Oct. 26, 2002.

this subsection, accredit persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 510(h) or are inspections of such establishments required to register under section 510(i). The owner or operator of such an establishment that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct such inspections.

(2) Not later than 180 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall inform those requesting accreditation, within 60 days after the receipt of such request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at device establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited. In the first year following the publication in the Federal Register of criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1), the Secretary shall accredit no more than 15 persons who request to perform duties specified in paragraph (1).

(3) An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this Act and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this Act.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices, and such person shall agree in writing that at a minimum the person will—

(i) certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with this Act, and recommendations made during an inspection or at an inspection's closing meeting;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the Secretary;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under this Act, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(4) The Secretary shall publish on the Internet site of the Food and Drug Administration a list of persons who are accredited under paragraph (2). Such list shall be updated to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection or the suspension or withdrawal of accreditation, or the modification of the particular activities for which the person is accredited.

(5)(A) To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall (i) audit the performance of such persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of a device establishment and the performance of accredited persons, and (ii) take such additional measures as the Secretary determines to be appropriate.

(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation, poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection. The Secretary may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspections by persons accredited under paragraph (2) if the following conditions are met:

(i) The Secretary classified the results of the most recent inspection described in paragraph (1) as ''no action indicated'' or ''voluntary action indicated''.

(ii) With respect to inspections to be conducted by an accredited person during a 2-year period—

(I) the owner or operator of the establishment submits to the Secretary a notice requesting clearance to use an accredited person to conduct the inspection, and the Secretary provides such clearance; and

(II) such notice identifies the accredited person whom the establishment has selected to conduct the inspection, and the Secretary agrees to the selected accredited person.

(iii) With respect to the devices that are manufactured, prepared, propagated, compounded, or processed by the establishment, at least one of such devices is marketed in the United States, and 1 or both of the following additional conditions are met:

(I) At least one of such devices is marketed, or is intended to be marketed, in one or more foreign countries, one of which countries certifies, accredits, or otherwise recognizes the person (accredited under paragraph (2) and identified under clause (ii)(II)) as a person authorized to conduct such inspections of device establishments.

(II) The owner or operator of the establishment submits to the Secretary a statement that the law of a country in which such a device is marketed, or is intended to be marketed, recognizes an inspection of the establishment by the Secretary or by a person accredited under paragraph (2), and not later than 30 days after receiving such statement, the Secretary informs the owner or operator of the establishment that the owner or operator may submit a notice requesting clearance under clause (ii).

(iv)(I) In the case of an inspection to be conducted pursuant to section 510(h), persons accredited under paragraph (2) did not conduct inspections of the establishment during the previous 4 years, except that the establishment may petition the Secretary for a waiver of such condition. Such a waiver may be granted only if the petition states a commercial reason for the waiver; the Secretary determines that the public health would be served by granting the waiver; and the Secretary has conducted an inspection of the establishment during the four-year period preceding the date on which the notice under clause (ii) is submitted to the Secretary. Such a waiver is deemed to be granted only if the Secretary has not determined that the public health would not be served by granting the waiver; and the owner or operator of the device establishment has requested in writing, not later than 18 months following the most recent inspection of such establishment by a person accredited under paragraph (2), that the Secretary inspect the establishment and the Secretary has not conducted an inspection within 30 months after the most recent inspection. With respect to such a waiver that is granted or deemed to be granted, no additional such waiver may be granted or deemed to be granted until after the Secretary has conducted an inspection of the establishment.

(II) In the case of an inspection to be conducted of a device establishment required to register pursuant to section 510(i), the Secretary periodically conducts inspections of the establishment.

(B)(i) The Secretary shall respond to a notice under subparagraph (A) from a device establishment not later than 30 days after the Secretary receives the notice. Through such response, the Secretary shall (I) provide clearance under such subparagraph, and agree to the selection of an accredited person, or (II) make a request under clause (ii). If the Secretary fails to respond to the notice within such 30-day period, the establishment is deemed to

have such clearance, and to have the agreement of the Secretary for such selection.

(ii) The request referred to in clause (i)(II) is—

(I) a request to the device establishment involved to submit to the Secretary compliance data in accordance with clause (iii); or

(II) a request to the establishment, or to the accredited person identified in the notice under subparagraph (A), for information concerning the relationship between the establishment and such accredited person, including information about the number of inspections of the establishment, or other establishments owned or operated by the owner or operator of the establishment, that have been conducted by the accredited person.

The Secretary may make both such requests.

(iii) The compliance data to be submitted by a device establishment under clause (ii) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding two-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other relevant compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

(iv)(I) Not later than 60 days after receiving compliance data under clause (iii) from a device establishment, the Secretary shall provide or deny clearance under subparagraph (A). The Secretary may deny clearance if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of clause (iii). The Secretary shall provide to the establishment a statement of such reasons for such determination. If the Secretary fails to provide such statement to the establishment within such 60-day period, the establishment is deemed to have such clearance.

(II) If, during the two-year period following clearance under subparagraph (A), the Secretary determines that the device establishment is substantially not in compliance with this Act, the Secretary may, after notice and a written response, notify the establishment that the eligibility of the establishment for the inspections by accredited persons has been suspended.

(v)(I) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1). Not later than 60 days after receiving the information sought by the request, the Secretary shall agree to, or reject, the selection of such person by the device establishment involved. The Secretary may reject the selection if the Secretary provides to the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case

may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person. If within such 60-day period the Secretary fails to agree to or reject the selection in accordance with this subclause, the Secretary is deemed to have agreed to the selection.

(II) If the Secretary rejects the selection of an accredited person by a device establishment, the establishment may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A).

(vi) In the case of a device establishment that under clause (iv) is denied clearance under subparagraph (A), or whose selection of an accredited person is rejected under clause (v), the Secretary shall designate a person to review the findings of the Secretary under such clause if, during the 30-day period beginning on the date on which the establishment receives the findings, the establishment requests the review. The review shall commence not later than 30 days after the establishment requests the review, unless the Secretary and the establishment otherwise agree.

(C)(i) In the case of a device establishment for which the Secretary classified the results of the most recent inspection of the establishment by a person accredited under paragraph (2) as ''official action indicated'', the establishment, if otherwise eligible under subparagraph (A), is eligible for further inspections by persons accredited under such paragraph if (I) the Secretary issues a written statement to the owner or operator of the establishment that the violations leading to such classification have been resolved, and (II) the Secretary, either upon the Secretary's own initiative or a petition of the owner or operator of the establishment, notifies the establishment that it has clearance to use an accredited person for the inspections. The Secretary shall respond to such petition within 30 days after the receipt of the petition.

(ii) If the Secretary denies a petition under clause (i), the device establishment involved may, after the expiration of one year after such denial, again petition the Secretary for a determination of eligibility for inspection by persons accredited by the Secretary under paragraph (2). If the Secretary denies such petition, the Secretary shall provide the establishment with such reasons for such denial within 60 days after the denial. If, as of the expiration of 48 months after the receipt of the first petition, the establishment has not been inspected by the Secretary, the establishment is eligible for further inspections by accredited persons.

(7)(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report (including for inspections classified as ''no action indicated'') in a form and manner

consistent with such reports prepared by employees and officials designated by the Secretary to conduct inspections.

(B) At a minimum, an inspection report under subparagraph (A) shall identify the persons responsible for good manufacturing practice compliance at the inspected device establishment, the dates of the inspection, the scope of the inspection, and shall describe in detail each observation identified by the accredited person, identify other matters that relate to or may influence compliance with this Act, and describe any recommendations during the inspection or at the inspection's closing meeting.

(C) An inspection report under subparagraph (A) shall be sent to the Secretary and to the designated representative of the inspected device establishment at the same time, but under no circumstances later than three weeks after the last day of the inspection. The report to the Secretary shall be accompanied by all written inspection observations previously provided to the designated representative of the establishment.

(D) Any statement or representation made by an employee or agent of a device establishment to a person accredited under paragraph (2) to conduct inspections shall be subject to section 1001 of title 18, United States Code.

(E) If at any time during an inspection by an accredited person the accredited person discovers a condition that could cause or contribute to an unreasonable risk to the public health, the accredited person shall immediately notify the Secretary of the identification of the device establishment subject to inspection and such condition.

(8) Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(9) Nothing in this subsection affects the authority of the Secretary to inspect any device establishment pursuant to this Act.

(10)(A) For fiscal year 2005 and each subsequent fiscal year, no device establishment may be inspected during the fiscal year involved by a person accredited under paragraph (2) if—

(i) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the preceding fiscal year (referred to in this subparagraph as the ''first prior fiscal year''), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such first prior fiscal year; and

(ii) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the fiscal year preceding the first prior fiscal year (referred to in this subparagraph as the ''second prior fiscal year''), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such second prior fiscal year.

(B)(i) Subject to clause (ii), the Comptroller General of the United States shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the Food and Drug Administration with respect to devices (referred to in this

subparagraph as the "compliance budget"), and of such amount, the amount that was obligated for inspections by the Secretary of device establishments (referred to in this subparagraph as the "inspection budget").

(ii) For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 515.

(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress a report describing the findings made through such determinations.

(C) For purposes of this paragraph:

(i) The term "base amount" means the inspection budget determined under subparagraph (B) for fiscal year 2002.

(ii) The term "adjusted base amount", in the case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

(iii) The term "adjusted base amount", with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted based amount applicable to the preceding year increased by 5 percent.

(11) The authority provided by this subsection terminates on October 1, 2012.

(12) No later than four years after the enactment of this subsection the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);

(B) the number of persons who sought accreditation under this subsection, as well as the number of persons who were accredited under this subsection;

(C) the reasons why persons who sought accreditation, but were denied accreditation, were denied;

(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this Act, and whether the number of audits conducted is sufficient to permit these assessments;

(E) whether this subsection is achieving the goal of ensuring more information about device establishment compliance is being presented to the Secretary, and whether that information is of a quality consistent with information obtained by the Secretary pursuant to inspections conducted by Federal employees;

(F) whether this subsection is advancing efforts to allow device establishments to rely upon third-party inspections for

purposes of compliance with the laws of foreign governments; and

(G) whether the Congress should continue, modify, or terminate the program under this subsection.

(13) The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(14) Notwithstanding any provision of this subsection, this subsection does not have any legal effect on any agreement described in section 803(b) between the Secretary and a foreign country.

PUBLICITY

SEC. 705. [21 U.S.C. 375] (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

SEAFOOD INSPECTION

SEC. 706. [21 U.S.C. 376] The Secretary, upon application of any packer of any seafood for shipment or sale within the jurisdiction of this Act, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this Act and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Secretary is hereby authorized to promulgate regulations governing the sanitary and other conditions under which the service herein provided shall be granted and maintained and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000 or both such imprisonment and fine.

ADVERTISING OF CERTAIN FOODS

SEC. 707. [21 U.S.C. 378] (a)(1) Except as provided in subsection (c), before the Secretary may initiate any action under chapter III—

(A) with respect to any food which the Secretary determines is misbranded under section 403(a)(2) because of its advertising, or

(B) with respect to a food's advertising which the Secretary determines causes the food to be so misbranded,

the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

(2) The notice required by paragraph (1) shall—

(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary's determination that such advertising has caused such food to be misbranded, and

(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

(b)(1) If the Secretary notifies the Federal Trade Commission under subsection (a) of action proposed to be taken under chapter III with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

(A) it has initiated under the Federal Trade Commission Act an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 with respect to such advertising,

(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act respecting such advertising, or

(D) pursuant to section 16(b) of such Act it has made a certification to the Attorney General respecting such advertising,

the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice to the Federal Trade Commission.

(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a)—

(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary's notice,

(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a). The Commission shall promptly notify the Secretary of the commencement by the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

(c) The requirements of subsections (a) and (b) do not apply with respect to action under chapter III with respect to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health.

(d) For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under chapter III because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act with respect to such advertising.

CONFIDENTIAL INFORMATION

SEC. 708. [21 U.S.C. 379] The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this Act, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

PRESUMPTION

SEC. 709. [21 U.S.C. 379a] In any action to enforce the requirements of this Act respecting a device, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

SEC. 710. [21 U.S.C. 379b] CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY.

(a) AUTHORITY.—The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

(b) AWARDING OF CONTRACT.—The Secretary shall solicit contract proposals under subsection (a) from interested parties. In awarding contracts under such subsection, the Secretary shall review such proposals and give priority to those alternatives that are the most cost effective for the Federal Government and that allow for the use of donated land, federally owned property, or lease-purchase arrangements. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal Government over the duration of the contract, as compared to the Government purchase price including borrowing by the Secretary of the Treasury.

(c) DONATIONS.—In carrying out this section, the Secretary shall have the power, in connection with real property, buildings, and facilities, to accept on behalf of the Food and Drug Administration gifts or donations of services or property, real or personal, as the Secretary determines to be necessary.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $100,000,000 for fiscal year 1991, and such sums as may be necessary for each of the subsequent fiscal years, to remain available until expended.

SEC. 711. [21 U.S.C. 379d] AUTOMATION OF FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this Act.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated each fiscal year such sums as are necessary to carry out this section.

SUBCHAPTER B—COLORS

LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

When Color Additives Deemed Unsafe

SEC. 721. [21 U.S.C. 379e] (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)). A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject to this section.

Listing of Colors

(b)(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs or devices, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2)(A) Such regulations may list any color additive for use generally in or on food, or in or on drugs or devices, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt

from the term "food additive" because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

(5)(A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive;

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug or devices, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal: *Provided,* That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

(C)(i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order

issued in accordance with paragraph (1) of section 701(e) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C)[109], as well as representatives of the Department, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendation, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order therefore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

(iii) Where—

(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred

[109] So in law. Probably should be "this subparagraph".

to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of any advisory committee established under this Act, while attending conferences or meetings of their committees or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS–18 of the General Schedule[110], including traveltime; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) of all uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would

[110] The General Schedule under section 5332 of title 5, United States Code, no longer includes the grade GS–18. The grades are GS–1 through GS–15.

be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

Certification of Colors

(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

Procedure for Issuance, Amendment, or Repeal of Regulations

(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b)(5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day) by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c))[111]. The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of

[111] Section 7(c) of the Administrative Procedure Act has been superseded by section 556(d) of title 5, United States Code. See Public Law 89–554.

the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearings) shall be subject to the requirements of section 409(f)(2); and

(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

Fees

(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

Exemptions

(f) The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug or device, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

NOTE.—Section 201 of the Labor-Federal Security Appropriation Act, 1944 (21 U.S.C. 377), provides that the Secretary in carrying into effect this Act "is authorized to cooperate with associations and scientific societies in the revision of the United States Pharmacopeia and in the development of methods of analysis and mechanical and physical tests necessary to carry out the work of the Food and Drug Administration."

SUBCHAPTER C—FEES

PART 1—FREEDOM OF INFORMATION FEES

SEC. 731. [21 U.S.C. 379f] RECOVERY AND RETENTION OF FEES FOR FREEDOM OF INFORMATION REQUESTS.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may—

(1) set and charge fees, in accordance with section 552(a)(4)(A) of title 5, United States Code, to recover all reasonable costs incurred in processing requests made under section 552 of title 5, United States Code, for records obtained or created under this Act or any other Federal law for which responsibility for administration has been delegated to the Commissioner by the Secretary;

(2) retain all fees charged for such requests; and

(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section.

(b) USE OF FEES.—The Secretary and the Commissioner of Food and Drugs shall not use fees received under this section for any

purpose other than funding the processing of requests described in subsection (a)(1). Such fees shall not be used to reduce the amount of funds made to carry out other provisions of this Act.

(c) WAIVER OF FEES.—Nothing in this section shall supersede the right of a requester to obtain a waiver of fees pursuant to section 552(a)(4)(A) of title 5, United States Code.

PART 2—FEES RELATING TO DRUGS

SEC. 735. [21 U.S.C. 379g] DEFINITIONS.[112]

For purposes of this subchapter:

(1) The term "human drug application" means an application for—

(A) approval of a new drug submitted under section 505(b)(1),

(B) approval of a new drug submitted under section 505(b)(2) after September 30, 1992, which requests approval of—

(i) a molecular entity which is an active ingredient (including any salt or ester of an active ingredient), or

(ii) an indication for a use,

that had not been approved under an application submitted under section 505(b), or

(C) licensure of a biological product under section 351 of the Public Health Service Act.

Such term does not include a supplement to such an application, does not include an application with respect to whole blood or a blood component for transfusion, does not include an application with respect to a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act, does not include an application with respect to a large volume parenteral drug product approved before September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (C), of a large volume biological product intended for single dose injection for intravenous use or infusion.

(2) The term "supplement" means a request to the Secretary to approve a change in a human drug application which has been approved.

(3) The term "prescription drug product" means a specific strength or potency of a drug in final dosage form—

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[112] Sections 503 and 504 of Public Law 107–188 (116 Stat. 688, 689) amended sections 735 and 736, respectively. Section 509 of such Public Law provides as follows:

"SEC. 509. SUNSET CLAUSE.

"The amendments made by sections 503 and 504 cease to be effective October 1, 2007, and section 505 ceases to be effective 120 days after such date.".

(A) for which a human drug application has been approved,

(B) which may be dispensed only under prescription pursuant to section 503(b), and

(C) which is on the list of products described in section 505(j)(7)(A) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act.

Such term does not include whole blood or a blood component for transfusion, does not include a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act. Such term does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.

(4) The term ''final dosage form'' means, with respect to a prescription drug product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing.

(5) The term ''prescription drug establishment'' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form. For purposes of this paragraph, the term ''manufactured'' does not include packaging.

(6) The term ''process for the review of human drug applications'' means the following activities of the Secretary with respect to the review of human drug applications and supplements:

(A) The activities necessary for the review of human drug applications and supplements.

(B) The issuance of action letters which approve human drug applications or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of prescription drug establishments and other facilities undertaken as part of the Secretary's review of pending human drug applications and supplements.

(D) Activities necessary for the review of applications for licensure of establishments subject to section 351 of the Public Health Service Act and for the release of lots of biologics under such section.

(E) Monitoring of research conducted in connection with the review of human drug applications.

(F) In the case of drugs approved after October 1, 2002, under human drug applications or supplements: collecting,

developing, and reviewing safety information on the drugs, including adverse event reports, during a period of time after approval of such applications or supplements, not to exceed three years.

(7) The term "costs of resources allocated for the process for the review of human drug applications" means the expenses incurred in connection with the process for the review of human drug applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors,

(B) management of information, and the acquisition, maintenance, and repair of computer resources,

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

(D) collecting fees under section 736 and accounting for resources allocated for the review of human drug applications and supplements.

(8) The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April 1997.

(9) The term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

SEC. 736. [21 U.S.C. 379h] AUTHORITY TO ASSESS AND USE DRUG FEES.[113]

(a) TYPES OF FEES.—Beginning in fiscal year 2003, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) HUMAN DRUG APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 1992, a human drug application or a supplement shall be subject to a fee as follows:

(i) A fee established under subsection (c)(4) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection (c)(4) for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect to

[113] See footnote for the beginning of section 735.

safety or effectiveness are required. Such fee shall be half of the amount of the fee established under clause (i).

(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.

(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a human drug application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application or supplement which is refused for filing.

(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

(F) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each person that—

(i) is named as the applicant in a human drug application; and

(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall be assessed an annual fee established under subsection (c)(4) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee

shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before October 1 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

(i) that did not manufacture the product in the previous fiscal year; and

(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.

(3) PRESCRIPTION DRUG PRODUCT FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under subsection (c)(4). Such fee shall be payable on or before October 1 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

(B) EXCEPTION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 505(j)(7)(A) with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 505(b) or 505(j), under an abbreviated application filed under section 507[114] (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

[114] So in law. Section 507 was repealed by section 125(b)(1) of Public Law 105–115 (111 Stat. 2325).

(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts:

Type of Fee Revenue	Fiscal Year 2003	Fiscal Year 2004	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007
Application/Supplement	$74,300,000	$77,000,000	$84,000,000	$86,434,000	$86,434,000
Establishment	$74,300,000	$77,000,000	$84,000,000	$86,433,000	$86,433,000
Product	$74,300,000	$77,000,000	$84,000,000	$86,433,000	$86,433,000
Total Fee Revenue	$222,900,000	$231,000,000	$252,000,000	$259,300,000	$259,300,000

If, after the date of the enactment of the Prescription Drug User Fee Amendments of 2002 [115], legislation is enacted requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of human drug applications.

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—The revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or

(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2003 under this subsection.

(2) WORKLOAD ADJUSTMENT.—Beginning with fiscal year 2004, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications, commercial investigational new drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary. The Secretary shall publish in the Federal Register the fee

[115] Subtitle A of title V of Public Law 107–188, which was enacted June 12, 2002.

revenues and fees resulting from the adjustment and the supporting methodologies.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for the fiscal year established in subsection (b), as adjusted for inflation under paragraph (1).

(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of human drug applications for the first three months of fiscal year 2008. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2007. If the Secretary has carryover balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.

(4) ANNUAL FEE SETTING.—The Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2002, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

(d) FEE WAIVER OR REDUCTION.—

(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—

(A) such waiver or reduction is necessary to protect the public health,

(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

(C) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or

(D) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

(3) RULES RELATING TO SMALL BUSINESSES.—

(A) DEFINITION.—In paragraph (1)(D), the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates.

(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(D) the application fee for the first human drug application that a small business or its

affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

(e) EFFECT OF FAILURE TO PAY FEES.—A human drug application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

(f) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for human drug applications and supplements, prescription drug establishments, and prescription drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation.[116] Such sums as

[116] The amendment described in section 504(f)(1) of Public Law 107–188 (116 Stat. 691) cannot be executed. The amendment includes language to strike "Fees collected for a fiscal year" and all that follows through "fiscal year limitation.". The latter term appears at the end of the first sentence and at the end of the second sentence, but the amendatory instructions do not identify to which instance of the use of such term the amendment applies.

The probable intent of the Congress is that the second sentence remain in effect, since section 738(h)(1) of this act, which relates to the crediting and availability of device fees, has language substantially similar to the second sentence and was added after the enactment of Public Law 107–188. (Section 738 was added by section 102 of Public Law 107–250, enacted Oct. 26, 2002. Public Law 107–188 was enacted June 12, 2002.)

Section 504(f)(1) of Public Law 107–188 provides as follows:

Continued

may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(II) such costs are not more than 5 percent below the level specified in such subparagraph.

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

(A) $222,900,000 for fiscal year 2003;

(B) $231,000,000 for fiscal year 2004;

(C) $252,000,000 for fiscal year 2005;

(D) $259,300,000 for fiscal year 2006; and

(E) $259,300,000 for fiscal year 2007;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

"(1) IN GENERAL.—Section 736(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(1)) is amended by striking 'Fees collected for a fiscal year' and all that follows through 'fiscal year limitation.' and inserting the following: 'Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.'".

(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

PART 3—FEES RELATING TO DEVICES

SEC. 737. [21 U.S.C. 379i] DEFINITIONS.[117]

For purposes of this subchapter:

(1) The term ''premarket application'' means—

(A) an application for approval of a device submitted under section 515(c) or section 351 of the Public Health Service Act; or

(B) a product development protocol described in section 515(f).

Such term does not include a supplement, a premarket report, or a premarket notification submission.

(2) The term ''premarket report'' means a report submitted under section 515(c)(2).

(3) The term ''premarket notification submission'' means a report submitted under section 510(k).

(4)(A) The term ''supplement'', with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which—

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[117] Part 3 was added by title I of Public Law 107–250 (116 Stat. 1589). See section 102 of that title. Section 107 of that title provides as follows:

''SEC. 107. SUNSET CLAUSE.

''The amendments made by this title cease to be effective October 1, 2007, except that section 103 with respect to annual reports ceases to be effective January 31, 2008.''.

(i) an application or report has been approved under section 515(d), or an application has been approved under section 351 of the Public Health Service Act; or

(ii) a notice of completion has become effective under section 515(f).

(B) The term "panel-track supplement" means a supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

(C) The term "180-day supplement" means a supplement to an approved premarket application or premarket report under section 515 that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

(D) The term "real-time supplement" means a supplement to an approved premarket application or premarket report under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

(E) The term "efficacy supplement" means a supplement to an approved premarket application under section 351 of the Public Health Service Act that requires substantive clinical data.

(5) The term "process for the review of device applications" means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions.

(E) Review of device applications subject to section 351 of the Public Health Service Act for an investigational new drug application under section 505(i) or for an investigational device exemption under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) or 520(g).

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of such applications, reports, supplements, or submissions and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

(I) Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515(b) in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act.

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

(6) The term ''costs of resources allocated for the process for the review of device applications'' means the expenses incurred in connection with the process for the review of device applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

(7) The term ''adjustment factor'' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April 2002.

(8) The term ''affiliate'' means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

SEC. 738. [21 U.S.C. 379j] AUTHORITY TO ASSESS AND USE DEVICE FEES.[118]

(a) TYPES OF FEES.—

(1) IN GENERAL.—Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 [119], the Secretary shall assess and collect fees in accordance with this section.

(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (d) and (e), each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under subsection (c)(5) for the fiscal year involved in accordance with the following:

(i) A premarket application.

(ii) For a premarket report, a fee equal to the fee that applies under clause (i).

(iii) For a panel track supplement, a fee equal to the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 21.5 percent of the fee that applies under clause (i).

(v) For a real-time supplement, a fee equal to 7.2 percent of the fee that applies under clause (i).

(vi) For an efficacy supplement, a fee equal to the fee that applies under clause (i).

(vii) For a premarket notification submission, a fee equal to 1.42 percent of the fee that applies under clause (i), subject to any adjustment under subsection (e)(2)(C)(ii).

(B) EXCEPTIONS.—

(i) HUMANITARIAN DEVICE EXEMPTION.—An application under section 520(m) is not subject to any fee under subparagraph (A).

(ii) FURTHER MANUFACTURING USE.—No fee shall be required under subparagraph (A) for the submission of a premarket application under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only.

(iii) STATE OR FEDERAL GOVERNMENT SPONSORS.—No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, or premarket notification submission submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

(iv) PREMARKET NOTIFICATIONS BY THIRD PARTIES.—No fee shall be required under subparagraph (A) for a premarket notification submission reviewed by an accredited person pursuant to section 523.

(v) PEDIATRIC CONDITIONS OF USE.—

(I) IN GENERAL.—No fee shall be required under subparagraph (A) for a premarket application,

[118] See footnote for the beginning of section 737.
[119] Public Law 107–250, enacted Oct. 26, 2002.

premarket report, or premarket notification submission if the proposed conditions of use for the device involved are solely for a pediatric population. No fee shall be required under such subparagraph for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

(II) SUBSEQUENT PROPOSAL OF ADULT CONDITIONS OF USE.—In the case of a person who submits a premarket application or premarket report for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to such application that proposes conditions of use for any adult population is subject to the fee that applies under such subparagraph for a premarket application.

(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, or premarket notification submission except that invoices for applications submitted between October 1, 2002, and the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 [120] shall be payable on October 30, 2002. Applicants submitting portions of applications pursuant to section 515(c)(3) shall pay such fees upon submission of the first portion of such applications. The fees credited to fiscal year 2003 under this section shall include all fees payable from October 1, 2002, through September 30, 2003.

(D) REFUNDS.—

(i) APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is refused for filing.

(ii) APPLICATION WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is withdrawn prior to the filing decision of the Secretary.

(iii) APPLICATION WITHDRAWN BEFORE FIRST ACTION.—After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement. The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

[120] See footnote for paragraph (1).

(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (e), (g), and (h), the fees under subsection (a) shall be established to generate the following revenue amounts: $25,125,000 in fiscal year 2003; $27,255,000 in fiscal year 2004; $29,785,000 in fiscal year 2005; $32,615,000 in fiscal year 2006, and $35,000,000 in fiscal year 2007. If legislation is enacted after the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts under this subsection shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of device applications.

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—The revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or

(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2003 under this subsection.

(2) WORKLOAD ADJUSTMENT.—After the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall, beginning with fiscal year 2004, be adjusted further each fiscal year to reflect changes in the workload of the Secretary for the process for the review of device applications. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of premarket applications, investigational new device applications, premarket reports, supplements, and premarket notification submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for the fiscal year established in subsection (b), as adjusted for inflation under paragraph (1).

(3) COMPENSATING ADJUSTMENT.—After the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), and for workload in

accordance with paragraph (2), the fee revenues shall, beginning with fiscal year 2004, be adjusted further each fiscal year, if necessary, to reflect the cumulative amount by which collections for previous fiscal years, beginning with fiscal year 2003, fell below the cumulative revenue amounts for such fiscal years specified in subsection (b), adjusted for such fiscal years for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2).

(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fees and fee revenues established in subsection (b) if such adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of device applications for the first three months of fiscal year 2008. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2007. If the Secretary has carryover user fee balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.

(5) ANNUAL FEE SETTING.—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, establish, for the next fiscal year, and publish in the Federal Register, fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustment provided under this subsection and subsection (e)(2)(C)(ii), except that the fees established for fiscal year 2003 shall be based on a premarket application fee of $154,000.

(6) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of device applications.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.—

(1) IN GENERAL.—The Secretary shall grant a waiver of the fee required under subsection (a) for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (vi) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—

(i) IN GENERAL.—For purposes of this subsection, the term "small business" means an entity that reported $30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.

(ii) ADJUSTMENT.—The Secretary may adjust the $30,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 16 percent or more than would occur without small business exemptions and lower fee rates. To adjust this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.

(B) EVIDENCE OF QUALIFICATION.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate. The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, partners, and parent firms, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, partners, and parent firms, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.

(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(5) may be paid at a reduced rate of 38 percent of the fee established under such subsection for a premarket application, a premarket report, or a supplement.

(D) REQUEST FOR FEE WAIVER OR REDUCTION.—An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—For fiscal year 2004 and each subsequent fiscal year, where the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(vii) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—For purposes of this subsection, the term ''small business'' means an entity that reported

$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.

(B) EVIDENCE OF QUALIFICATION.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate. The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, partners, and parent firms, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, partners, and parent firms, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.

(C) REDUCED FEES.—

(i) IN GENERAL.—For fiscal year 2004 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 80 percent of the fee that applies under subsection (a)(2)(A)(vii), as adjusted under clause (ii) and as established under subsection (c)(5).

(ii) ADJUSTMENT PER FEE REVENUE AMOUNT.—For fiscal year 2004 and each subsequent fiscal year, the Secretary, in setting the revenue amount under subsection (c)(5) for premarket notification submissions, shall determine the revenue amount that would apply if all such submissions for the fiscal year involved paid a fee equal to 1.42 percent of the amount that applies under subsection (a)(2)(A)(i) for premarket applications, and shall adjust the fee under subsection (a)(2)(A)(vii) for premarket notification submissions such that the reduced fees collected under clause (i) of this subparagraph, when added to fees for such submissions that are not paid at the reduced rate, will equal such revenue amount for the fiscal year.

(D) REQUEST FOR REDUCTION.—An applicant seeking a fee reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

(f) EFFECT OF FAILURE TO PAY FEES.—A premarket application, premarket report, supplement, or premarket notification submission submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

(g) CONDITIONS.—

(1) PERFORMANCE GOALS THROUGH FISCAL YEAR 2005; TERMINATION OF PROGRAM AFTER FISCAL YEAR 2005.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products:

(A)(i) For each of the fiscal years 2003 and 2004, the Secretary is expected to meet all of the goals identified for the fiscal year involved in any letter referred to in section 101(3) of the Medical Device User Fee and Modernization Act of 2002 (referred to in this paragraph as ''performance goals'') if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is equal to or greater than $205,720,000 multiplied by the adjustment factor applicable to the fiscal year.

(ii) For each of the fiscal years 2003 and 2004, if the amount so appropriated for the fiscal year involved, excluding the amount of fees appropriated for such fiscal year, is less than the amount that applies under clause (i) for such fiscal year, the following applies:

(I) The Secretary is expected to meet such goals to the extent practicable, taking into account the amounts that are available to the Secretary for such purpose, whether from fees under subsection (a) or otherwise.

(II) The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Secretary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for fiscal year 2005. A report under the preceding sentence shall be submitted to the Congress not later than July 1 of the fiscal year with which the report is concerned.

(B)(i) For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

(I) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;

(II) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and

(III) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.

(ii) For fiscal year 2005, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:

(I) The Secretary is expected to meet such goals to the extent practicable, taking into account the amounts that are available to the Secretary for such

purpose, whether from fees under subsection (a) or otherwise.

(II) The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Secretary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for fiscal year 2006. The report under the preceding sentence shall be submitted to the Congress not later than July 1, 2005.

(C) For fiscal year 2006, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if the total of the amounts so appropriated for fiscal years 2003 through 2006, excluding the amount of fees appropriated for such fiscal years, is less than the sum of—

(i) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2006; and

(ii) an amount equal to the sum that applies for purposes of subparagraph (B)(i).

(D) For fiscal year 2007, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(i) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is less than $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2007; or

(ii) pursuant to subparagraph (C), fees were not assessed under subsection (a) for fiscal year 2006.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of subparagraph (C) or (D) of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, and premarket notification submissions, and at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of device applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2002 multiplied by the adjustment factor.

(B) COMPLIANCE.—

(i) IN GENERAL.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of device applications—

(I) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(II)(aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(bb) such costs are not more than 5 percent below the level specified in such subparagraph.

(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

(A) $25,125,000 for fiscal year 2003;
(B) $27,255,000 for fiscal year 2004;
(C) $29,785,000 for fiscal year 2005;
(D) $32,615,000 for fiscal year 2006; and
(E) $35,000,000 for fiscal year 2007,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application fees.

(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

(i) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a

claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(j) WRITTEN REQUESTS FOR REFUNDS.—To qualify for consideration for a refund under subsection (a)(2)(D), a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

PART 4—FEES RELATING TO ANIMAL DRUGS

SEC. 739. [21 U.S.C. 379j–11] DEFINITIONS.[121]

For purposes of this subchapter:

(1) The term ''animal drug application'' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

(2) The term ''supplemental animal drug application'' means—

(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

(3) The term ''animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

(4) The term ''animal drug establishment'' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

(5) The term ''investigational animal drug submission'' means—

(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

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[121] Part 4 was added by section 3 of Public Law 108–130 (117 Stat. 1361). Section 5 of such Public Law provides as follows:

''SEC. 5. SUNSET.

''The amendments made by section 3 shall not be in effect after October 1, 2008, and section 4 shall not be in effect after 120 days after such date.''.

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

(6) The term "animal drug sponsor" means either an applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

(7) The term "final dosage form" means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

(8) The term "process for the review of animal drug applications" means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not such activities after an animal drug has been approved.

(9) The term "costs of resources allocated for the process for the review of animal drug applications" means the expenses incurred in connection with the process for the review of animal drug applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities,

(B) management of information, and the acquisition, maintenance, and repair of computer resources,

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

(D) collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(10) The term "adjustment factor" applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator year being 2003.

(11) The term "affiliate" refers to the definition set forth in section 735(9).

SEC. 740. [21 U.S.C. 379j–12] AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.[122]

(a) TYPES OF FEES.—Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection (b) for an animal drug application; and

(ii) A fee established in subsection (b) for a supplemental animal drug application for which safety or effectiveness data are required, in an amount that is equal to 50 percent of the amount of the fee under clause (i).

(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was

[122] See footnote for the beginning of section 739.

accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) ANIMAL DRUG PRODUCT FEE.—Each person—

(A) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510, and

(B) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application;

shall pay for each such animal drug product the annual fee established in subsection (b). Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

(3) ANIMAL DRUG ESTABLISHMENT FEE.—Each person—

(A) who owns or operates, directly or through an affiliate, an animal drug establishment, and

(B) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510, and

(C) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual fee established in subsection (b) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which

the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee shall be paid on or before January 31 of each year. The establishment shall be assessed only one fee per fiscal year under this section: *Provided, however,* That where a single establishment manufactures both animal drug products and prescription drug products, as defined in section 735(3), such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 736(a)(2), within a single fiscal year.

(4) ANIMAL DRUG SPONSOR FEE.—Each person—

(A) who meets the definition of an animal drug sponsor within a fiscal year; and

(B) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

shall be assessed an annual fee established under subsection (b). The fee shall be paid on or before January 31 of each year. Each animal drug sponsor shall pay only one such fee each fiscal year.

(b) FEE AMOUNTS.—Except as provided in subsection (a)(1) and subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

(1) TOTAL FEE REVENUES FOR APPLICATION AND SUPPLEMENT FEES.—The total fee revenues to be collected in animal drug application fees under subsection (a)(1)(A)(i) and supplemental animal drug application fees under subsection (a)(1)(A)(ii) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(2) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

(3) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(3) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

(4) TOTAL FEE REVENUES FOR SPONSOR FEES.—The total fee revenues to be collected in sponsor fees under subsection (a)(4) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—The revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending

June 30 preceding the fiscal year for which fees are being established; or

(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2004 under this subsection.

(2) WORKLOAD ADJUSTMENT.—After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004 to reflect changes in review workload. With respect to such adjustment:

(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b), as adjusted for inflation under paragraph (1).

(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2008, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2009. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2008.

(4) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total

costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

(d) FEE WAIVER OR REDUCTION.—

(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that—

(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person,

(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds, or

(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation)),

(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication, or

(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

(3) RULES FOR SMALL BUSINESSES.—

(A) DEFINITION.—In paragraph (1)(E), the term ''small business'' means an entity that has fewer than 500 employees, including employees of affiliates.

(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

(e) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all

fees owed by such person have been paid. An investigational animal drug submission under section 739(5)(B) that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

(f) ASSESSMENT OF FEES.—

(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department

of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

(A) $5,000,000 for fiscal year 2004;
(B) $8,000,000 for fiscal year 2005;
(C) $10,000,000 for fiscal year 2006;
(D) $10,000,000 for fiscal year 2007; and
(E) $10,000,000 for fiscal year 2008;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees.

(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriations Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of

animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications, and

(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.

SUBCHAPTER D—INFORMATION AND EDUCATION

SEC. 741. [21 U.S.C. 379k] INFORMATION SYSTEM.

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

SEC. 742. [21 U.S.C. 379l] EDUCATION.

(a) IN GENERAL.—The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 704;

(3) training to achieve product specialization in such inspections; and

(4) training in administrative process and procedure and integrity issues.

(b) INTRAMURAL FELLOWSHIPS AND OTHER TRAINING PROGRAMS.—The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians.

SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

SEC. 746. [21 U.S.C. 379o] ENVIRONMENTAL IMPACT.

Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

SUBCHAPTER F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

SEC. 751. [21 U.S.C. 379r] NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS.

(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—

(1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and

(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) EXEMPTION.—

(1) IN GENERAL.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

(C) would not unduly burden interstate commerce.

(2) TIMELY ACTION.—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

(c) SCOPE.—

(1) IN GENERAL.—This section shall not apply to—

(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

(d) EXCEPTIONS.—

(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997) or a final regulation promulgated by the Secretary establishing conditions under which the drug

is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after the date of enactment of the Food and Drug Administration Modernization Act of 1997.

(2) STATE INITIATIVES.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this Act.

SEC. 752. [21 U.S.C. 379s] PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling or packaging that—

(1) protects an important public interest that would otherwise be unprotected;

(2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and

(3) would not unduly burden interstate commerce.

(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

SUBCHAPTER G—SAFETY REPORTS

SEC. 756. [21 U.S.C. 379v] SAFETY REPORT DISCLAIMERS.

With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product that is a food, drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report or information), such report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or caused or contributed to a death, serious injury, or serious illness.

CHAPTER VIII—IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

SEC. 801. [21 U.S.C. 381] (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs or devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs or devices be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in

violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph [123] shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d)(1) Except as provided in paragraph (2) and section 804, no drug subject to section 503(b) or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

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[123] So in law. Probably should be "subsection".

(2) The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.

(3)(A) Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

(i) The importer of such article of a drug or device or importer of such article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

(I) Such statement provides that such article is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

(III) The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an article described in paragraph (4).

(ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

(iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

(iv) The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary.

(v) Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph.

(B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial

owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

(C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation.

(4) The importation into the United States of blood, blood components, source plasma, or source leukocytes or of a component, accessory, or part thereof is not permitted pursuant to paragraph (3) unless the importation complies with section 351(a) of the Public Health Service Act or the Secretary permits the importation under appropriate circumstances and conditions, as determined by the Secretary. The importation of tissue or a component or part of tissue is not permitted pursuant to paragraph (3) unless the importation complies with section 361 of the Public Health Service Act.

(e)(1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

(2) Paragraph (1) does not apply to any device—

(A) which does not comply with an applicable requirement of section 514 or 515,

(B) which under section 520(g) is exempt from either such section, or

(C) which is a banned device under section 516,

unless, in addition to the requirements of paragraph (1), either (i) the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export or (ii) the device is eligible for export under section 802.

(3) A new animal drug that requires approval under section 512 shall not be exported pursuant to paragraph (1) if such drug has been banned in the United States.

(4)(A) Any person who exports a drug, animal drug, or device may request that the Secretary—

(i) certify in writing that the exported drug, animal drug, or device meets the requirements of paragraph (1) or section 802; or

(ii) certify in writing that the drug, animal drug, or device being exported meets the applicable requirements of this Act upon a showing that the drug or device meets the applicable requirements of this Act.

The Secretary shall issue such a certification within 20 days of the receipt of a request for such certification.

(B) If the Secretary issues a written export certification within the 20 days prescribed by subparagraph (A), a fee for such certification may be charged but shall not exceed $175 for each certification. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration.

(f)(1) If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 802) being exported in accordance with subsection (e) is being exported to a country that has different or additional labeling requirements or conditions for use and such country requires the drug to be labeled in accordance with those requirements or uses, such drug may be labeled in accordance with such requirements and conditions for use in the country to which such drug is being exported if it also is labeled in accordance with the requirements of this Act.

(2) If, pursuant to paragraph (1), the labeling of an exported drug includes conditions for use that have not been approved under this Act, the labeling must state that such conditions for use have not been approved under this Act. A drug exported under section 802 is exempt from this section.

(g)(1) With respect to a prescription drug being imported or offered for import into the United States, the Secretary, in the case of an individual who is not in the business of such importations, may not send a warning notice to the individual unless the following conditions are met:

(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

(i) importation is in violation of section 801(a) because the drug is or appears to be adulterated, misbranded, or in violation of section 505;

(ii) importation is in violation of section 801(a) because the drug is or appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii) importation is or appears to be in violation of section 801(d)(1); or

(iv) importation otherwise is or appears to be in violation of Federal law.

(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

(C) The notice states the reasons underlying such determination by the Secretary, including a brief application to the principal facts involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

(2) For purposes of this section, the term "warning notice", with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly

suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this Act.

(h)(1)[124] The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this Act.

(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))).

(i)(1)[125] For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

(4) The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).

(j)(1) If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and such officer or qualified employee is unable to inspect, examine, or investigate such article upon the article being offered for import at a port of entry into

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[124] Subsections (h) and (i) were added by section 302 of Public Law 107–188 (116 Stat. 662). In such section 302, subsection (f) provides as follows:

"(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section and the amendments made by this section, there are authorized to be appropriated $100,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006, in addition to other authorizations of appropriations that are available for such purpose.".

[125] See footnote for subsection (h)(1).

the United States, the officer or qualified employee shall request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

(2) The Secretary shall request the Secretary of Treasury to remove an article held pursuant to paragraph (1) to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held.

(3) An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

(4) With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that such article is being held under this subsection.

(k)(1) If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person who has been debarred under section 306(b)(3), such article shall be held at the port of entry for the article, and may not be delivered to such person. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(2) An article of food held under paragraph (1) may be delivered to a person who is not a debarred person under section 306(b)(3) if such person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this Act, as determined by the Secretary.

(l)(1)[126] If an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415, such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be

[126] So in law. There is no paragraph (2). See section 305(c) of Public Law 107–188 (116 Stat. 668).

transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(m)(1) In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

(2)(A) Regulations under paragraph (1) shall require that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration. Nothing in the preceding sentence may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

(B)(i) If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary, and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1). Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(ii) In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(3)(A) This subsection may not be construed as limiting the authority of the Secretary to obtain information under any other provision of this Act.

(B) This subsection may not be construed as authorizing the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(n)(1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, the Secretary may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: "UNITED STATES: REFUSED ENTRY".

(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.

(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this Act.

(o) If an article that is a drug or device is being imported or offered for import into the United States, and the importer, owner, or consignee of such article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 510(i) of each establishment that with respect to such article is required under such section to register with the Secretary, the article may be refused admission. If the article is refused admission for failure to submit such a statement, the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such a statement is submitted to the Secretary. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

EXPORTS OF CERTAIN UNAPPROVED PRODUCTS

SEC. 802. [21 U.S.C. 382] (a) A drug or device—

(1) which, in the case of a drug—

(A)(i) requires approval by the Secretary under section 505 before such drug may be introduced or delivered for introduction into interstate commerce; or

(ii) requires licensing by the Secretary under section 351 of the Public Health Service Act or by the Secretary of Agriculture under the Act of March 4, 1913 (known as the Virus-Serum Toxin Act) before it may be introduced or delivered for introduction into interstate commerce;

(B) does not have such approval or license; and

(C) is not exempt from such sections or Act; and

(2) which, in the case of a device—

(A) does not comply with an applicable requirement under section 514 or 515;

(B) under section 520(g) is exempt from either such section; or

(C) is a banned device under section 516, is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug or device is, except as provided in subsection (f), authorized under subsection (b), (c), (d), or (e) or section 801(e)(2). If[127] a drug or device described in paragraphs (1) and (2) may be exported under subsection (b) and if an application for such drug or device under section 505 or 515 or section 351 of the Public Health Service Act was disapproved, the Secretary shall notify the appropriate public health official of the country to which such drug will be exported of such disapproval.

(b)(1)(A) A drug or device described in subsection (a) may be exported to any country, if the drug or device complies with the laws of that country and has valid marketing authorization by the appropriate authority—

(i) in Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa; or

(ii) in the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association) if the drug or device is marketed in that country or the drug or device is authorized for general marketing in the European Economic Area.

(B) The Secretary may designate an additional country to be included in the list of countries described in clauses (i) and (ii) of subparagraph (A) if all of the following requirements are met in such country:

(i) Statutory or regulatory requirements which require the review of drugs and devices for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs and devices which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices.

(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for—

(I) the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength; and

(II) the manufacture, preproduction design validation, packing, storage, and installation of a device are adequate to assure that the device will be safe and effective.

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[127] Placement of sentence is so in law. See section 2102(d)(1) of Public Law 104–134 (chapter 1A of title II; 110 Stat. 1321–313, 1321–315). Sentence probably should appear after and below subparagraph (C), with the same indentation as the section designation.

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and devices and procedures to withdraw approval and remove drugs and devices found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs and devices must be in accordance with the approval of the drug or device.

(v) The valid marketing authorization system in such country or countries is equivalent to the systems in the countries described in clauses (i) and (ii) of subparagraph (A).

The Secretary shall not delegate the authority granted under this subparagraph.

(C) An appropriate country official, manufacturer, or exporter may request the Secretary to take action under subparagraph (B) to designate an additional country or countries to be added to the list of countries described in clauses (i) and (ii) of subparagraph (A) by submitting documentation to the Secretary in support of such designation. Any person other than a country requesting such designation shall include, along with the request, a letter from the country indicating the desire of such country to be designated.

(2) A drug described in subsection (a) may be directly exported to a country which is not listed in clause (i) or (ii) of paragraph (1)(A) if—

(A) the drug complies with the laws of that country and has valid marketing authorization by the responsible authority in that country; and

(B) the Secretary determines that all of the following requirements are met in that country:

(i) Statutory or regulatory requirements which require the review of drugs for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.

(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength.

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs must be in accordance with the approval of the drug.

(3) The exporter of a drug described in subsection (a) which would not meet the conditions for approval under this Act or conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A) may petition the Secretary for authorization to export such drug to a country which is not described in clause (i) or (ii) of paragraph (1)(A) or which is not described in paragraph (2). The Secretary shall permit such export if—

(A) the person exporting the drug—

(i) certifies that the drug would not meet the conditions for approval under this Act or the conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A); and

(ii) provides the Secretary with credible scientific evidence, acceptable to the Secretary, that the drug would be safe and effective under the conditions of use in the country to which it is being exported; and

(B) the appropriate health authority in the country to which the drug is being exported—

(i) requests approval of the export of the drug to such country;

(ii) certifies that the health authority understands that the drug is not approved under this Act or in a country described in clause (i) or (ii) of paragraph (1)(A); and

(iii) concurs that the scientific evidence provided pursuant to subparagraph (A) is credible scientific evidence that the drug would be reasonably safe and effective in such country.

The Secretary shall take action on a request for export of a drug under this paragraph within 60 days of receiving such request.

(c) A drug or device intended for investigational use in any country described in clause (i) or (ii) of subsection (b)(1)(A) may be exported in accordance with the laws of that country and shall be exempt from regulation under section 505(i) or 520(g).

(d) A drug or device intended for formulation, filling, packaging, labeling, or further processing in anticipation of market authorization in any country described in clause (i) or (ii) of subsection (b)(1)(A) may be exported for use in accordance with the laws of that country.

(e)(1) A drug or device which is used in the diagnosis, prevention, or treatment of a tropical disease or another disease not of significant prevalence in the United States and which does not otherwise qualify for export under this section shall, upon approval of an application, be permitted to be exported if the Secretary finds that the drug or device will not expose patients in such country to an unreasonable risk of illness or injury and the probable benefit to health from the use of the drug or device (under conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling of the drug or device) outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available drug or device treatment.

(2) The holder of an approved application for the export of a drug or device under this subsection shall report to the Secretary—

(A) the receipt of any credible information indicating that the drug or device is being or may have been exported from a country for which the Secretary made a finding under paragraph (1)(A) to a country for which the Secretary cannot make such a finding; and

(B) the receipt of any information indicating adverse reactions to such drug.

(3)(A) If the Secretary determines that—

(i) a drug or device for which an application is approved under paragraph (1) does not continue to meet the requirements of such paragraph; or

(ii) the holder of an approved application under paragraph (1) has not made the report required by paragraph (2),

the Secretary may, after providing the holder of the application an opportunity for an informal hearing, withdraw the approved application.

(B) If the Secretary determines that the holder of an approved application under paragraph (1) or an importer is exporting a drug or device from the United States to an importer and such importer is exporting the drug or device to a country for which the Secretary cannot make a finding under paragraph (1) and such export presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug or device to such importer, provide the person exporting the drug or device from the United States prompt notice of the prohibition, and afford such person an opportunity for an expedited hearing.

(f) A drug or device may not be exported under this section—

(1) if the drug or device is not manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements or does not meet international standards as certified by an international standards organization recognized by the Secretary;

(2) if the drug or device is adulterated under clause (1), (2)(A), or (3) of section 501(a) or subsection (c) or (d) of section 501;

(3) if the requirements of subparagraphs (A) through (D) of section 801(e)(1) have not been met;

(4)(A) if the drug or device is the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the probability of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States and the only means of limiting the hazard is to prohibit the export of the drug or device; or

(B) if the drug or device presents an imminent hazard to the public health of the country to which the drug or device would be exported;

(5) if the labeling of the drug or device is not—

(A) in accordance with the requirements and conditions for use in—

(i) the country in which the drug or device received valid marketing authorization under subsection (b); and

(ii) the country to which the drug or device would be exported; and

(B) in the language and units of measurement of the country to which the drug or device would be exported or in the language designated by such country; or

(6) if the drug or device is not promoted in accordance with the labeling requirements set forth in paragraph (5).

In making a finding under paragraph (4)(B), (5), or (6) the Secretary shall consult with the appropriate public health official in the affected country.

(g) The exporter of a drug or device exported under subsection (b)(1) shall provide a simple notification to the Secretary identifying the drug or device when the exporter first begins to export such drug or device to any country listed in clause (i) or (ii) of subsection (b)(1)(A). When an exporter of a drug or device first begins to export a drug or device to a country which is not listed in clause (i) or (ii) of subsection (b)(1)A)[128], the exporter shall provide a simple notification to the Secretary identifying the drug or device and the country to which such drug or device is being exported. Any exporter of a drug or device shall maintain records of all drugs or devices exported and the countries to which they were exported.

(h) For purposes of this section—

(1) a reference to the Secretary shall in the case of a biological product which is required to be licensed under the Act of March 4, 1913 (37 Stat. 832–833) (commonly known as the Virus-Serum Toxin Act) be considered to be a reference to the Secretary of Agriculture, and

(2) the term "drug" includes drugs for human use as well as biologicals under section 351 of the Public Health Service Act or the Act of March 4, 1913 (37 Stat. 832–833) (commonly known as the Virus-Serum Toxin Act).

(i) Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 801(e)(1).

OFFICE OF INTERNATIONAL RELATIONS

SEC. 803. [21 U.S.C. 383] (a) There is established in the Department of Health and Human Services an Office of International Relations.

(b) In carrying out the functions of the office under subsection (a), the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this Act. In such agreements, the Secretary shall encourage the mutual recognition of—

(1) good manufacturing practice regulations promulgated under section 520(f), and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

(c)(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation

[128] So in law. See section 2102(d)(1) of Public Law 104–134 (chapter 1A of title II; 110 Stat. 1321–315, 1321–319). Probably should have a beginning parenthesis before "A)".

and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act.

(2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

(3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.

(4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

(5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 201(ff).

SEC. 804. [21 U.S.C. 384] IMPORTATION OF PRESCRIPTION DRUGS.

(a) DEFINITIONS.—In this section:

(1) IMPORTER.—The term "importer" means a pharmacist or wholesaler.

(2) PHARMACIST.—The term "pharmacist" means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

(3) PRESCRIPTION DRUG.—The term "prescription drug" means a drug subject to section 503(b), other than—

(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

(C) an infused drug (including a peritoneal dialysis solution);

(D) an intravenously injected drug;

(E) a drug that is inhaled during surgery; or

(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

(4) QUALIFYING LABORATORY.—The term "qualifying laboratory" means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

(5) WHOLESALER.—

(A) IN GENERAL.—The term "wholesaler" means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

(B) EXCLUSION.—The term "wholesaler" does not include a person authorized to import drugs under section 801(d)(1).

(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

(c) LIMITATION.—The regulations under subsection (b) shall—

(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

(d) INFORMATION AND RECORDS.—

(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

(A) The name and quantity of the active ingredient of the prescription drug.

(B) A description of the dosage form of the prescription drug.

(C) The date on which the prescription drug is shipped.

(D) The quantity of the prescription drug that is shipped.

(E) The point of origin and destination of the prescription drug.

(F) The price paid by the importer for the prescription drug.

(G) Documentation from the foreign seller specifying—

(i) the original source of the prescription drug; and

(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

(I) The name, address, telephone number, and professional license number (if any) of the importer.

(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

(i) is approved for marketing in the United States and is not adulterated or misbranded; and

(ii) meets all labeling requirements under this Act.

(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

(e) TESTING.—The regulations under subsection (b) shall require—

(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

(2) if the tests are conducted by the importer—

(A) that information needed to—

(i) authenticate the prescription drug being tested; and

(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug

that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

(i) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

(B) exercise discretion to permit individuals to make such importations in circumstances in which—

(i) the importation is clearly for personal use; and

(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

(2) WAIVER AUTHORITY.—

(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

(B) is accompanied by a copy of a valid prescription;

(C) is imported from Canada, from a seller registered with the Secretary;

(D) is a prescription drug approved by the Secretary under chapter V;

(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

(k) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

(l) EFFECTIVENESS OF SECTION.—

(1) COMMENCEMENT OF PROGRAM.—This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will—

(A) pose no additional risk to the public's health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

(2) TERMINATION OF PROGRAM.—

(A) IN GENERAL.—If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

(B) PROCEDURE.—The Secretary shall not submit a certification under subparagraph (A) unless, after a hearing on the record under sections 556 and 557 of title 5, United States Code, the Secretary—

(i)(I) determines that it is more likely than not that implementation of this section would result in an increase in the risk to the public health and safety;

(II) identifies specifically, in qualitative and quantitative terms, the nature of the increased risk;

(III) identifies specifically the causes of the increased risk; and

(IV)(aa) considers whether any measures can be taken to avoid, reduce, or mitigate the increased risk; and

(bb) if the Secretary determines that any measures described in item (aa) would require additional statutory authority, submits to Congress a report describing the legislation that would be required;

(ii) identifies specifically, in qualitative and quantitative terms, the benefits that would result from implementation of this section (including the benefit of reductions in the cost of covered products to consumers in the United States, allowing consumers to procure needed medication that consumers might not otherwise be able to procure without foregoing other necessities of life); and

(iii)(I) compares in specific terms the detriment identified under clause (i) with the benefits identified under clause (ii); and

(II) determines that the benefits do not outweigh the detriment.

(m) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

CHAPTER IX—MISCELLANEOUS

SEPARABILITY CLAUSE

SEC. 901. [21 U.S.C. 391] If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

SEC. 902. [21 U.S.C. 392] (a) This Act shall take effect twelve months after the date of its enactment. The Federal Food and Drug Act of June 30, 1906, as amended (U.S.C., 1934 ed., title 21, secs. 1–15), shall remain in force until such effective date, and except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided,* That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary [of Agriculture] is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary [of Agriculture] shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403(i) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401: *Provided further,* That sections 502(j), 505, and 601(a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601(a) relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further,* That the Act of March 4, 1923 (U.S.C., 1945 ed., title 21, sec. 321a; 32 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U.S.C., 1946 ed., title

21, sec. 321b; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drug Act, section 10A, approved August 27, 1935 (U.S.C., 1946 ed., title 21, sec. 372a [49 Stat. 871, ch. 739]), shall remain in force and effect and be applicable to the provisions of this Act.

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U.S.C., 1946 ed., title 21, secs. 71–96; 34 Stat. 1260 *et seq.*).

(c) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 351 of Public Health Service Act (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 (37 Stat. 832–833); the Filled Cheese Act of June 6, 1896 (U.S.C., 1946 ed., title 26, ch. 17, secs. 2350–2362); the Filled Milk Act of March 4, 1923 (U.S.C. 1946 ed., title 21, ch. 3, secs. 61–64); or the Import Milk Act of February 15, 1927 (U.S.C., 1946 ed., title 21, ch. 4, secs. 141–149).

SEC. 903. [21 U.S.C. 393] FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

(b) MISSION.—The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

(c) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other

science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.

(d) COMMISSIONER.—

(1) APPOINTMENT.—There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the "Commissioner") who shall be appointed by the President by and with the advice and consent of the Senate.

(2) GENERAL POWERS.—The Secretary, through the Commissioner, shall be responsible for executing this Act and for—

(A) providing overall direction to the Food and Drug Administration and establishing and implementing general policies respecting the management and operation of programs and activities of the Food and Drug Administration;

(B) coordinating and overseeing the operation of all administrative entities within the Administration;

(C) research relating to foods, drugs, cosmetics, and devices in carrying out this Act;

(D) conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration; and

(E) performing such other functions as the Secretary may prescribe.

(e) TECHNICAL AND SCIENTIFIC REVIEW GROUPS.—The Secretary through the Commissioner of Food and Drugs may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under the Federal Food, Drug, and Cosmetic Act, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(f) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with such persons.

(2) OBJECTIVES OF AGENCY PLAN.—The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to—

(A) maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act;

(B) maximizing the availability and clarity of information for consumers and patients concerning new products;

(C) implementing inspection and postmarket monitoring provisions of this Act;

(D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);

(E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this Act for the review of all applications and submissions described in subparagraph (A) and submitted after the date of enactment of the Food and Drug Administration Modernization Act of 1997; and

(F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

(g) ANNUAL REPORT.—The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that—

(1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f);

(2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and

(3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.

SEC. 904. [21 U.S.C. 394] SCIENTIFIC REVIEW GROUPS.

Without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

(1) establish such technical and scientific review groups as are needed to carry out the functions of the Food and Drug Administration (including functions prescribed under this Act); and

(2) appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

SEC. 905. [21 U.S.C. 395] LOAN REPAYMENT PROGRAM.

(a) IN GENERAL.—

(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the Food and Drug Administration, in consideration of

the Federal Government agreeing to repay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of such health professionals.

(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the Food and Drug Administration for purposes of paragraph (1) for a period of not less than 3 years.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III of the Public Health Service Act, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

SEC. 906. [21 U.S.C. 396] PRACTICE OF MEDICINE.

Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

SEC. 907. [21 U.S.C. 397] CONTRACTS FOR EXPERT REVIEW.

(a) IN GENERAL.—

(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary may use the authority granted in paragraph (1) whenever the Secretary determines that use of

a contract described in paragraph (1) will improve the timeliness of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

(b) REVIEW OF EXPERT REVIEW.—

(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

(2) LIMITATION.—A final decision by the Secretary on any such application or submission shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).

SEC. 908. [21 U.S.C. 398] NOTICES TO STATES REGARDING IMPORTED FOOD.

(a) IN GENERAL.—If the Secretary has credible evidence or information indicating that a shipment of imported food or portion thereof presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall provide notice regarding such threat to the States in which the food is held or will be held, and to the States in which the manufacturer, packer, or distributor of the food is located, to the extent that the Secretary has knowledge of which States are so involved. In providing notice to a State, the Secretary shall request the State to take such action as the State considers appropriate, if any, to protect the public health regarding the food involved.

(b) RULE OF CONSTRUCTION.—Subsection (a) may not be construed as limiting the authority of the Secretary with respect to food under any other provision of this Act.

SEC. 909. [21 U.S.C. 399] GRANTS TO STATES FOR INSPECTIONS.

(a) IN GENERAL.—The Secretary is authorized to make grants to States, territories, and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) that undertake examinations, inspections, and investigations, and related activities under section 702. The funds provided under such grants shall only be available for the costs of conducting such examinations, inspections, investigations, and related activities.

(b) NOTICES REGARDING ADULTERATED IMPORTED FOOD.—The Secretary may make grants to the States for the purpose of assisting the States with the costs of taking appropriate action to protect

the public health in response to notification under section 908, including planning and otherwise preparing to take such action.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.

5 U.S.C. § 3113
Federal reemployment prohibition following certain controlled substance convictions

Title 5. Government Organization and Employees

Chapter 31. Authority for Employment

§ 3113. Restriction on reemployment after conviction of certain crimes [1]

An employee shall be separated from service and barred from reemployment in the Federal service, if—

(1) the employee is convicted of a violation of section 201(b) of title 18; and

(2) such violation related to conduct prohibited under section 1010(a) of the Controlled Substances Import and Export Act (21 U.S.C. 960(a)).

[1] Added by Public Law 105–61, Title VI, § 638(a), Oct. 10, 1997, 111 Stat. 1316.

5 U.S.C. § 8902a
Debarment of health care providers for certain controlled substance convictions

Chapter 89. Health Insurance

§ 8902a. Debarment and other sanctions [1]

(a)(1) For the purpose of this section—

(A) the term "provider of health care services or supplies" or "provider" means a physician, hospital, or other individual or entity which furnishes health care services or supplies;

(B) the term "individual covered under this chapter" or "covered individual" means an employee, annuitant, family member, or former spouse covered by a health benefits plan described by section 8903 or 8903a;

(C) an individual or entity shall be considered to have been "convicted" of a criminal offense if—

(i) a judgment of conviction for such offense has been entered against the individual or entity by a Federal, State, or local court;

(ii) there has been a finding of guilt against the individual or entity by a Federal, State, or local court with respect to such offense;

(iii) a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court with respect to such offense; or

(iv) in the case of an individual, the individual has entered a first offender or other program pursuant to which a judgment of conviction for such offense has been withheld;

without regard to the pendency or outcome of any appeal (other than a judgment of acquittal based on innocence) or request for relief on behalf of the individual or entity; and

(D) the term "should know" means that a person, with respect to information, acts in deliberate ignorance of, or in reckless disregard of, the truth or falsity of the information, and no proof of specific intent to defraud is required; [2]

(2)(A) Notwithstanding section 8902(j) or any other provision of this chapter, if, under subsection (b), (c), or (d), a provider is barred from participating in the program under this chapter, no payment may be made by a carrier pursuant to any contract under this chapter (either to such provider or by reimbursement) for any service or supply furnished by such provider during the period of the debarment.

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[1] Added by Public Law 100–654, Title I, § 101(a), Nov. 14, 1988, 102 Stat. 3837, and amended by Public Law 105–266, § 2, Oct. 19, 1998, 112 Stat. 2363.

[2] So in original. The semicolon probably should be a period.

(B) Each contract under this chapter shall contain such provisions as may be necessary to carry out subparagraph (A) and the other provisions of this section.

(b) The Office of Personnel Management shall bar the following providers of health care services or supplies from participating in the program under this chapter:

(1) Any provider that has been convicted, under Federal or State law, of a criminal offense relating to fraud, corruption, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care service or supply.

(2) Any provider that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care service or supply.

(3) Any provider that has been convicted, under Federal or State law, in connection with the interference with or obstruction of an investigation or prosecution of a criminal offense described in paragraph (1) or (2).

(4) Any provider that has been convicted, under Federal or State law, of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

(5) Any provider that is currently debarred, suspended, or otherwise excluded from any procurement or nonprocurement activity (within the meaning of section 2455 of the Federal Acquisition Streamlining Act of 1994).

(c) The Office may bar the following providers of health care services from participating in the program under this chapter:

(1) Any provider—

(A) whose license to provide health care services or supplies has been revoked, suspended, restricted, or not renewed, by a State licensing authority for reasons relating to the provider's professional competence, professional performance, or financial integrity; or

(B) that surrendered such a license while a formal disciplinary proceeding was pending before such an authority, if the proceeding concerned the provider's professional competence, professional performance, or financial integrity.

(2) Any provider that is an entity directly or indirectly owned, or with a control interest of 5 percent or more held, by an individual who has been convicted of any offense described in subsection (b), against whom a civil monetary penalty has been assessed under subsection (d), or who has been debarred from participation under this chapter.

(3) Any individual who directly or indirectly owns or has a control interest in a sanctioned entity and who knows or should know of the action constituting the basis for the entity's conviction of any offense described in subsection (b), assessment with a civil monetary penalty under subsection (d), or debarment from participation under this chapter.

(4) Any provider that the Office determines, in connection with claims presented under this chapter, has charged for

health care services or supplies in an amount substantially in excess of such provider's customary charge for such services or supplies (unless the Office finds there is good cause for such charge), or charged for health care services or supplies which are substantially in excess of the needs of the covered individual or which are of a quality that fails to meet professionally recognized standards for such services or supplies.

(5) Any provider that the Office determines has committed acts described in subsection (d).

Any determination under paragraph (4) relating to whether a charge for health care services or supplies is substantially in excess of the needs of the covered individual shall be made by trained reviewers based on written medical protocols developed by physicians. In the event such a determination cannot be made based on such protocols, a physician in an appropriate specialty shall be consulted.

(d) Whenever the Office determines—

(1) in connection with claims presented under this chapter, that a provider has charged for a health care service or supply which the provider knows or should have known involves—

(A) an item or service not provided as claimed;

(B) charges in violation of applicable charge limitations under section 8904(b); or

(C) an item or service furnished during a period in which the provider was debarred from participation under this chapter pursuant to a determination by the Office under this section, other than as permitted under subsection (g)(2)(B);

(2) that a provider of health care services or supplies has knowingly made, or caused to be made, any false statement or misrepresentation of a material fact which is reflected in a claim presented under this chapter; or

(3) that a provider of health care services or supplies has knowingly failed to provide any information required by a carrier or by the Office to determine whether a payment or reimbursement is payable under this chapter or the amount of any such payment or reimbursement;

the Office may, in addition to any other penalties that may be prescribed by law, and after consultation with the Attorney General, impose a civil monetary penalty of not more than $10,000 for any item or service involved. In addition, such a provider shall be subject to an assessment of not more than twice the amount claimed for each such item or service. In addition, the Office may make a determination in the same proceeding to bar such provider from participating in the program under this chapter.

(e) The Office—

(1) may not initiate any debarment proceeding against a provider, based on such provider's having been convicted of a criminal offense, later than 6 years after the date on which such provider is so convicted; and

(2) may not initiate any action relating to a civil penalty, assessment, or debarment under this section, in connection with

any claim, later than 6 years after the date the claim is presented, as determined under regulations prescribed by the Office.

(f) In making a determination relating to the appropriateness of imposing or the period of any debarment under this section (where such debarment is not mandatory), or the appropriateness of imposing or the amount of any civil penalty or assessment under this section, the Office shall take into account—

(1) the nature of any claims involved and the circumstances under which they were presented;

(2) the degree of culpability, history of prior offenses or improper conduct of the provider involved; and

(3) such other matters as justice may require.

(g)(1)(A) Except as provided in subparagraph (B), debarment of a provider under subsection (b) or (c) shall be effective at such time and upon such reasonable notice to such provider, and to carriers and covered individuals, as shall be specified in regulations prescribed by the Office. Any such provider that is debarred from participation may request a hearing in accordance with subsection (h)(1).

(B) Unless the Office determines that the health or safety of individuals receiving health care services warrants an earlier effective date, the Office shall not make a determination adverse to a provider under subsection (c)(5) or (d) until such provider has been given reasonable notice and an opportunity for the determination to be made after a hearing as provided in accordance with subsection (h)(1).

(2)(A) Except as provided in subparagraph (B), a debarment shall be effective with respect to any health care services or supplies furnished by a provider on or after the effective date of such provider's debarment.

(B) A debarment shall not apply with respect to inpatient institutional services furnished to an individual who was admitted to the institution before the date the debarment would otherwise become effective until the passage of 30 days after such date, unless the Office determines that the health or safety of the individual receiving those services warrants that a shorter period, or that no such period, be afforded.

(3) Any notice of debarment referred to in paragraph (1) shall specify the date as of which debarment becomes effective and the minimum period of time for which such debarment is to remain effective. In the case of a debarment under paragraph (1), (2), (3), or (4) of subsection (b), the minimum period of debarment shall not be less than 3 years, except as provided in paragraph (4)(B)(ii).

(4)(A) A provider barred from participating in the program under this chapter may, after the expiration of the minimum period of debarment referred to in paragraph (3), apply to the Office, in such manner as the Office may by regulation prescribe, for termination of the debarment.

(B) The Office may—

(i) terminate the debarment of a provider, pursuant to an application filed by such provider after the end of the minimum debarment period, if the Office determines, based on the conduct of the applicant, that—

(I) there is no basis under subsection (b), (c), or (d) for continuing the debarment; and

(II) there are reasonable assurances that the types of actions which formed the basis for the original debarment have not recurred and will not recur; or

(ii) notwithstanding any provision of subparagraph (A), terminate the debarment of a provider, pursuant to an application filed by such provider before the end of the minimum debarment period, if the Office determines that—

(I) based on the conduct of the applicant, the requirements of subclauses (I) and (II) of clause (i) have been met; and

(II) early termination under this clause is warranted based on the fact that the provider is the sole community provider or the sole source of essential specialized services in a community, or other similar circumstances.

(5) The Office shall—

(A) promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification of a provider barred from participation in the program under this chapter of the fact of the debarment, as well as the reasons for such debarment;

(B) request that appropriate investigations be made and sanctions invoked in accordance with applicable law and policy; and

(C) request that the State or local agency or authority keep the Office fully and currently informed with respect to any actions taken in response to the request.

(h)(1) Any provider of health care services or supplies that is the subject of an adverse determination by the Office under this section shall be entitled to reasonable notice and an opportunity to request a hearing of record, and to judicial review as provided in this subsection after the Office renders a final decision. The Office shall grant a request for a hearing upon a showing that due process rights have not previously been afforded with respect to any finding of fact which is relied upon as a cause for an adverse determination under this section. Such hearing shall be conducted without regard to subchapter II of chapter 5 and chapter 7 of this title by a hearing officer who shall be designated by the Director of the Office and who shall not otherwise have been involved in the adverse determination being appealed. A request for a hearing under this subsection shall be filed within such period and in accordance with such procedures as the Office shall prescribe by regulation.

(2) Any provider adversely affected by a final decision under paragraph (1) made after a hearing to which such provider was a party may seek review of such decision in the United States District Court for the District of Columbia or for the district in which the plaintiff resides or has his or her principal place of business by filing a notice of appeal in such court within 60 days after the date the decision is issued, and by simultaneously sending copies of such notice by certified mail to the Director of the Office and to the Attorney General. In answer to the appeal, the Director of the Office shall promptly file in such court a certified copy of the transcript of the record, if the Office conducted a hearing, and other evidence

upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and evidence of record, a judgment affirming, modifying, or setting aside, in whole or in part, the decision of the Office, with or without remanding the case for a rehearing. The district court shall not set aside or remand the decision of the Office unless there is not substantial evidence on the record, taken as whole, to support the findings by the Office of a cause for action under this section or unless action taken by the Office constitutes an abuse of discretion.

(3) Matters that were raised or that could have been raised in a hearing under paragraph (1) or an appeal under paragraph (2) may not be raised as a defense to a civil action by the United States to collect a penalty or assessment imposed under this section.

(i) A civil action to recover civil monetary penalties or assessments under subsection (d) shall be brought by the Attorney General in the name of the United States, and may be brought in the United States district court for the district where the claim involved was presented or where the person subject to the penalty resides. Amounts recovered under this section shall be paid to the Office for deposit into the Employees Health Benefits Fund. The amount of a penalty or assessment as finally determined by the Office, or other amount the Office may agree to in compromise, may be deducted from any sum then or later owing by the United States to the party against whom the penalty or assessment has been levied.

(j) The Office shall prescribe regulations under which, with respect to services or supplies furnished by a debarred provider to a covered individual during the period of such provider's debarment, payment or reimbursement under this chapter may be made, notwithstanding the fact of such debarment, if such individual did not know or could not reasonably be expected to have known of the debarment. In any such instance, the carrier involved shall take appropriate measures to ensure that the individual is informed of the debarment and the minimum period of time remaining under the terms of the debarment.

7 U.S.C. § 2015(b)
Food Stamp Act, Public Law 88–525, sec. 6(b)
Eligibility disqualifications for trafficking in controlled substances

Title 7. Agriculture

Chapter 51. Food Stamp Program

§ 2015. Eligibility disqualifications [1]

* * * * * * *

(b) Fraud and misrepresentation; disqualification penalties; ineligibility period; applicable procedures

(1) Any person who has been found by any State or Federal court or administrative agency to have intentionally (A) made a false or misleading statement, or misrepresented, concealed or withheld facts, or (B) committed any act that constitutes a violation of this chapter, the regulations issued thereunder, or any State statute, for the purpose of using, presenting, transferring, acquiring, receiving, or possessing coupons or authorization cards shall, immediately upon the rendering of such determination, become ineligible for further participation in the program—

(i) for a period of 1 year upon the first occasion of any such determination;

(ii) for a period of 2 years upon—

(I) the second occasion of any such determination; or

(II) the first occasion of a finding by a Federal, State, or local court of the trading of a controlled substance (as defined in section 802 of Title 21) for coupons; and

(iii) permanently upon—

(I) the third occasion of any such determination;

(II) the second occasion of a finding by a Federal, State, or local court of the trading of a controlled substance (as defined in section 802 of Title 21) for coupons;

(III) the first occasion of a finding by a Federal, State, or local court of the trading of firearms, ammunition, or explosives for coupons; or

(IV) a conviction of an offense under subsection (b) or (c) of section 2024 of this title involving an item covered by subsection (b) or (c) of section 2024 of this title having a value of $500 or more.

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[1] Public Law 88–525, § 6, Aug. 31, 1964, 78 Stat. 704; Public Law 94–339, § 3, July 5, 1976, 90 Stat. 800; Public Law 95–113, Title XIII, § 1301, Sept. 29, 1977, 91 Stat. 964; Public Law 96–58, §§ 5, 9, Aug. 14, 1979, 93 Stat. 391, 392; Public Law 97–35, Title I, § 112, Aug. 13, 1981, 95 Stat. 362; Public Law 103–66, Title XIII, § 13942, Aug. 10, 1993, 107 Stat. 677; Public Law 104–193, Title VIII, §§ 813, 814, Aug. 22, 1996, 110 Stat. 2314, 2315.

During the period of such ineligibility, no household shall receive increased benefits under this chapter as the result of a member of such household having been disqualified under this subsection.

(2) Each State agency shall proceed against an individual alleged to have engaged in such activity either by way of administrative hearings, after notice and an opportunity for a hearing at the State level, or by referring such matters to appropriate authorities for civil or criminal action in a court of law.

(3) Such periods of ineligibility as are provided for in paragraph (1) of this subsection shall remain in effect, without possibility of administrative stay, unless and until the finding upon which the ineligibility is based is subsequently reversed by a court of appropriate jurisdiction, but in no event shall the period of ineligibility be subject to review.

(4) The Secretary shall prescribe such regulations as the Secretary may deem appropriate to ensure that information concerning any such determination with respect to a specific individual is forwarded to the Office of the Secretary by any appropriate State or Federal entity for the use of the Secretary in administering the provisions of this section. No State shall withhold such information from the Secretary or the Secretary's designee for any reason whatsoever.

* * * * * * *

7 U.S.C. § 2021(b)
Food Stamp Act, Public Law 88–525, sec. 12(b)
Disqualification of food stores for selling controlled substances for food stamps

§ 2021. Civil money penalties and disqualification of retail food stores and wholesale food concerns [1]

* * * * * * *

(b) Period of disqualification

Disqualification under subsection (a) of this section shall be—

(1) for a reasonable period of time, of no less than six months nor more than five years, upon the first occasion of disqualification;

(2) for a reasonable period of time, of no less than twelve months nor more than ten years, upon the second occasion of disqualification;

(3) permanent upon—

(A) the third occasion of disqualification;

(B) the first occasion or any subsequent occasion of a disqualification based on the purchase of coupons or trafficking in coupons or authorization cards by a retail food store or wholesale food concern, except that the Secretary shall have the discretion to impose a civil money penalty of up to $20,000 for each violation (except that the amount of civil money penalties imposed for violations occurring during a single investigation may not exceed $40,000) in lieu of disqualification under this subparagraph, for such purchase of coupons or trafficking in coupons or cards that constitutes a violation of the provisions of this chapter or the regulations issued pursuant to this chapter, if the Secretary determines that there is substantial evidence that such store or food concern had an effective policy and program in effect to prevent violations of the chapter and the regulations, including evidence that—

(i) the ownership of the store or food concern was not aware of, did not approve of, did not benefit from, and was not involved in the conduct of the violation; and

(ii)(I) the management of the store or food concern was not aware of, did not approve of, did not benefit from, and was not involved in the conduct of the violation; or

[1] Public Law 88–525, § 12, Aug. 31, 1964, 78 Stat. 707; Public Law 97–253, Title I, § 175, Sept. 8, 1982, 96 Stat. 781; Public Law 100–435, Title III, § 344, Sept. 19, 1988, 102 Stat. 1664; Public Law 101–624, Title XVII, § 1743, Nov. 28, 1990, 104 Stat. 3795; Public Law 103–66, Title XIII, §§ 13943, 13944, Aug. 10, 1993, 107 Stat. 677; Public Law 104–127, Title IV, § 401(a), Apr. 4, 1996, 110 Stat. 1026.

(II) the management was aware of, approved of, benefited from, or was involved in the conduct of no more than 1 previous violation by the store or food concern; or

(C) a finding of the sale of firearms, ammunition, explosives, or controlled substance (as defined in section 802 of Title 21) for coupons, except that the Secretary shall have the discretion to impose a civil money penalty of up to $20,000 for each violation (except that the amount of civil money penalties imposed for violations occurring during a single investigation may not exceed $40,000) in lieu of disqualification under this subparagraph if the Secretary determines that there is substantial evidence (including evidence that neither the ownership nor management of the store or food concern was aware of, approved, benefited from, or was involved in the conduct or approval of the violation) that the store or food concern had an effective policy and program in effect to prevent violations of this chapter; and

(4) for a reasonable period of time to be determined by the Secretary, including permanent disqualification, on the knowing submission of an application for the approval or reauthorization to accept and redeem coupons that contains false information about a substantive matter that was a part of the application.

* * * * * * *

8 U.S.C. § 1101(a)(43)

Immigration and Nationality Act, Public Law 82–414 (Act of June 27, 1952), sec. 101(a)(43)

Inclusion of certain controlled substance offenses within the definition of aggravated felony

Title 8. Aliens and Nationality

Chapter 12. Immigration and Nationality

§ 1101. Definitions [1]

(a) As used in this chapter—

* * * * * * *

(43) The term "aggravated felony" means—

(A) murder, rape, or sexual abuse of a minor;

(B) illicit trafficking in a controlled substance (as defined in section 802 of Title 21), including a drug trafficking crime (as defined in section 924(c) of Title 18);

(C) illicit trafficking in firearms or destructive devices (as defined in section 921 of Title 18) or in explosive materials (as defined in section 841(c) of that title);

(D) an offense described in section 1956 of Title 18 (relating to laundering of monetary instruments) or section 1957 of that title (relating to engaging in monetary transactions in property derived from specific unlawful activity) if the amount of the funds exceeded $10,000;

(E) an offense described in—

(i) section 842(h) or (i) of Title 18, or section 844(d), (e), (f), (g), (h), or (i) of that title (relating to explosive materials offenses);

(ii) section 922(g)(1), (2), (3), (4), or (5), (j), (n), (o), (p), or (r) or 924(b) or (h) of Title 18 (relating to firearms offenses); or

(iii) section 5861 of Title 26 (relating to firearms offenses);

(F) a crime of violence (as defined in section 16 of Title 18, but not including a purely political offense) for which the term of imprisonment at [2] least one year;

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[1] June 27, 1952, c. 477, Title I, § 101, 66 Stat. 166; Nov. 18, 1988, Public Law 100–690, Title VII, § 7342, 102 Stat. 4469; Nov. 29, 1990, Public Law 101–649, Title V, § 501(a), 104 Stat. 5048; Dec. 12, 1991, Public Law 102–232, Title III, § 306(a)(1), 105 Stat. 1751; Oct. 25, 1994, Public Law 103–416, Title II, § 222(a), 108 Stat. 4320; Apr. 24, 1996, Public Law 104–132, Title IV, § 440(e), 110 Stat. 1277; Sept. 30, 1996, Public Law 104–208, Div. C, Title III, §§ 321(a), (b), 322(a)(1), (2)(A), 110 Stat. 3009–627, 3009–628, 3009–629; Dec. 19, 2003, Public Law 108–193, § 4(b)(5), 117 Stat. 2879.

[2] So in original. Probably should be preceded by "is".

(G) a theft offense (including receipt of stolen property) or burglary offense for which the term of imprisonment at [3] least one year;

(H) an offense described in section 875, 876, 877, or 1202 of Title 18 (relating to the demand for or receipt of ransom);

(I) an offense described in section 2251, 2251A, or 2252 of Title 18 (relating to child pornography);

(J) an offense described in section 1962 of Title 18 (relating to racketeer influenced corrupt organizations), or an offense described in section 1084 (if it is a second or subsequent offense) or 1955 of that title (relating to gambling offenses), for which a sentence of one year imprisonment or more may be imposed;

(K) an offense that—

(i) relates to the owning, controlling, managing, or supervising of a prostitution business;

(ii) is described in section 2421, 2422, or 2423 of Title 18 (relating to transportation for the purpose of prostitution) if committed for commercial advantage; or

(iii) is described in any of sections 1581–1585 or 1588–1591 of Title 18 (relating to peonage, slavery, involuntary servitude, and trafficking in persons);

(L) an offense described in—

(i) section 793 (relating to gathering or transmitting national defense information), 798 (relating to disclosure of classified information), 2153 (relating to sabotage) or 2381 or 2382 (relating to treason) of Title 18;

(ii) section 421 of Title 50 (relating to protecting the identity of undercover intelligence agents); or

(iii) section 421 of Title 50 (relating to protecting the identity of undercover agents);

(M) an offense that—

(i) involves fraud or deceit in which the loss to the victim or victims exceeds $10,000; or

(ii) is described in section 7201 of Title 26 (relating to tax evasion) in which the revenue loss to the Government exceeds $10,000;

(N) an offense described in paragraph (1)(A) or (2) of section 1324(a) of this title (relating to alien smuggling), except in the case of a first offense for which the alien has affirmatively shown that the alien committed the offense for the purpose of assisting, abetting, or aiding only the alien's spouse, child, or parent (and no other individual) to violate a provision of this chapter [4]

(O) an offense described in section 1325(a) or 1326 of this title committed by an alien who was previously deported on the basis of a conviction for an offense described in another subparagraph of this paragraph;

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[3] So in original. Probably should be preceded by "is".
[4] So in original. Probably should be followed by a semicolon.

(P) an offense (i) which either is falsely making, forging, counterfeiting, mutilating, or altering a passport or instrument in violation of section 1543 of Title 18 or is described in section 1546(a) of such title (relating to document fraud) and (ii) for which the term of imprisonment is at least 12 months, except in the case of a first offense for which the alien has affirmatively shown that the alien committed the offense for the purpose of assisting, abetting, or aiding only the alien's spouse, child, or parent (and no other individual) to violate a provision of this chapter;

(Q) an offense relating to a failure to appear by a defendant for service of sentence if the underlying offense is punishable by imprisonment for a term of 5 years or more;

(R) an offense relating to commercial bribery, counterfeiting, forgery, or trafficking in vehicles the identification numbers of which have been altered for which the term of imprisonment is at least one year;

(S) an offense relating to obstruction of justice, perjury or subornation of perjury, or bribery of a witness, for which the term of imprisonment is at least one year;

(T) an offense relating to a failure to appear before a court pursuant to a court order to answer to or dispose of a charge of a felony for which a sentence of 2 years' imprisonment or more may be imposed; and

(U) an attempt or conspiracy to commit an offense described in this paragraph.

The term applies to an offense described in this paragraph whether in violation of Federal or State law and applies to such an offense in violation of the law of a foreign country for which the term of imprisonment was completed within the previous 15 years. Notwithstanding any other provision of law (including any effective date), the term applies regardless of whether the conviction was entered before, on, or after September 30, 1996.

* * * * * * *

8 U.S.C. § 1182(a)(2)(C)

Immigration and Nationality Act, Public Law 82–414 (Act of June 27, 1952), sec. 212(a)(2)(C)

Traffickers in controlled substances and their families are inadmissible aliens

§ 1182. Inadmissible aliens [1]

(a) Classes of aliens ineligible for visas or admission

Except as otherwise provided in this chapter, aliens who are inadmissible under the following paragraphs are ineligible to receive visas and ineligible to be admitted to the United States:

* * * * * * *

(2) Criminal and related grounds

* * * * * * *

(C) Controlled substance traffickers

Any alien who the consular officer or the Attorney General knows or has reason to believe—

(i) is or has been an illicit trafficker in any controlled substance or in any listed chemical (as defined in section 802 of title 21), or is or has been a knowing aider, abettor, assister, conspirator, or colluder with others in the illicit trafficking in any such controlled or listed substance or chemical, or endeavored to do so; or

(ii) is the spouse, son, or daughter of an alien inadmissible under clause (i), has, within the previous 5 years, obtained any financial or other benefit from the illicit activity of that alien, and knew or reasonably should have known that the financial or other benefit was the product of such illicit activity,

is inadmissible.

* * * * * * *

[1] June 27, 1952, c. 477, Title II, ch. 2, § 212, 66 Stat. 184; July 18, 1956, c. 629, Title III, § 301(a), 70 Stat. 575; July 14, 1960, Public Law 86–648, § 8, 74 Stat. 505; Oct. 27, 1986, Public Law 99–570, Title I, § 1751(a), 100 Stat. 3207–47; Dec. 22, 1987, Public Law 100–204, Title VIII, § 806(c), 101 Stat. 1399; Nov. 29, 1990, Public Law 101–649, Title VI, § 601(a), 104 Stat. 5068; Dec. 3, 1999, Public Law 106–120, Title VIII, § 809, 113 Stat. 1632.

8 U.S.C. § 1202(f)(2)

Immigration and Nationality Act, Public Law 82–414 (Act of June 27, 1952), sec. 222(f)(2)

Secretary of State may share visa record information related to trafficking in controlled substances with foreign governments on a reciprocal basis

§ 1202. Application for visas [1]

* * * * * * *

(f) Confidential nature of records

The records of the Department of State and of diplomatic and consular offices of the United States pertaining to the issuance or refusal of visas or permits to enter the United States shall be considered confidential and shall be used only for the formulation, amendment, administration, or enforcement of the immigration, nationality, and other laws of the United States, except that—

* * * * * * *

(2) the Secretary of State, in the Secretary's discretion and on the basis of reciprocity, may provide to a foreign government information in the Department of State's computerized visa lookout database and, when necessary and appropriate, other records covered by this section related to information in the database—

(A) with regard to individual aliens, at any time on a case-by-case basis for the purpose of preventing, investigating, or punishing acts that would constitute a crime in the United States, including, but not limited to, terrorism or trafficking in controlled substances, persons, or illicit weapons; or

(B) with regard to any or all aliens in the database, pursuant to such conditions as the Secretary of State shall establish in an agreement with the foreign government in which that government agrees to use such information and records for the purposes described in subparagraph (A) or to deny visas to persons who would be inadmissible to the United States.

* * * * * * *

[1] June 27, 1952, c. 477, Title II, ch. 3, § 222, 66 Stat. 194; Oct. 26, 2001, Public Law 107–56, Title IV, § 413, 115 Stat. 353.

8 U.S.C. § 1227(a)(2)(B)

Immigration and Nationality Act, Public Law 82–414 (Act of June 27, 1952), sec. 237(a)(2)(B)

Deportable conduct related to controlled substances

§ 1227. Deportable aliens [1]

(a) Classes of deportable aliens

Any alien (including an alien crewman) in and admitted to the United States shall, upon the order of the Attorney General, be removed if the alien is within one or more of the following classes of deportable aliens:

* * * * * * *

(2) Criminal offenses

* * * * * * *

(B) Controlled substances

(i) Conviction

Any alien who at any time after admission has been convicted of a violation of (or a conspiracy or attempt to violate) any law or regulation of a State, the United States, or a foreign country relating to a controlled substance (as defined in section 802 of Title 21), other than a single offense involving possession for one's own use of 30 grams or less of marijuana, is deportable.

(ii) Drug abusers and addicts

Any alien who is, or at any time after admission has been, a drug abuser or addict is deportable.

* * * * * * *

[1] June 27, 1952, c. 477, Title II, ch. 4, § 237, formerly ch. 5, § 241, 66 Stat. 204; July 18, 1956, c. 629, Title III, § 301(b), 70 Stat. 575; July 14, 1960, Public Law 86–648, § 9, 74 Stat. 505; Oct. 27, 1986, Public Law 99–570, Title I, § 1751(b), 100 Stat. 3207–47; Nov. 29, 1990, Public Law 101–649, Title V, § 508(a), Title VI, § 602(a), 104 Stat. 5051, 5077; Dec. 12, 1991, Public Law 102–232, Title III, § 307(h)(1), 105 Stat. 1755; renumbered ch. 4, § 237 and amended Sept. 30, 1996, Public Law 104–208, Div. C, Title III, §§ 301(d), 308(e)(2)(C), (f)(1)(N), 110 Stat. 3009–579, 3009–619, 3009–621.

8 U.S.C. § 1357(d)
Immigration and Nationality Act, Public Law 82–414 (Act of June 27, 1952), sec. 287(d)
Detainer of aliens for controlled substance violations

§ 1357. Powers of immigration officers and employees [1]

* * * * * * *

(d) Detainer of aliens for violation of controlled substances laws
In the case of an alien who is arrested by a Federal, State, or local law enforcement official for a violation of any law relating to controlled substances, if the official (or another official)—

(1) has reason to believe that the alien may not have been lawfully admitted to the United States or otherwise is not lawfully present in the United States,

(2) expeditiously informs an appropriate officer or employee of the Service authorized and designated by the Attorney General of the arrest and of facts concerning the status of the alien, and

(3) requests the Service to determine promptly whether or not to issue a detainer to detain the alien,

the officer or employee of the Service shall promptly determine whether or not to issue such a detainer. If such a detainer is issued and the alien is not otherwise detained by Federal, State, or local officials, the Attorney General shall effectively and expeditiously take custody of the alien.

* * * * * * *

[1] June 27, 1952, c. 477, Title II, ch. 9, § 287, 66 Stat. 233; Oct. 27, 1986, Public Law 99–570, Title I, § 1751(d), 100 Stat. 3207–47; Oct. 24, 1988, Public Law 100–525, § 5, 102 Stat. 2615.

Title 10. Armed Forces

Chapter 18. Military Support for Civilian Law Enforcement Agencies

§ 371. Use of information collected during military operations [1]

(a) The Secretary of Defense may, in accordance with other applicable law, provide to Federal, State, or local civilian law enforcement officials any information collected during the normal course of military training or operations that may be relevant to a violation of any Federal or State law within the jurisdiction of such officials.

(b) The needs of civilian law enforcement officials for information shall, to the maximum extent practicable, be taken into account in the planning and execution of military training or operations.

(c) The Secretary of Defense shall ensure, to the extent consistent with national security, that intelligence information held by the Department of Defense and relevant to drug interdiction or other civilian law enforcement matters is provided promptly to appropriate civilian law enforcement officials.

§ 372. Use of military equipment and facilities [2]

(a) IN GENERAL.—The Secretary of Defense may, in accordance with other applicable law, make available any equipment (including associated supplies or spare parts), base facility, or research facility of the Department of Defense to any Federal, State, or local civilian law enforcement official for law enforcement purposes.

(b) EMERGENCIES INVOLVING CHEMICAL AND BIOLOGICAL AGENTS.—(1) In addition to equipment and facilities described in subsection (a), the Secretary may provide an item referred to in paragraph (2) to a Federal, State, or local law enforcement or emergency response agency to prepare for or respond to an emergency involving chemical or biological agents if the Secretary determines that the item is not reasonably available from another source. The requirement for a determination that an item is not reasonably available from another source does not apply to assistance provided under section 382 of this title pursuant to a request of the Attorney General for the assistance.

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[1] Added by Public Law 97–86, Title IX, § 905(a)(1), Dec. 1, 1981, 95 Stat. 1115, and amended by Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2043.

[2] Added by Public Law 97–86, Title IX, § 905(a)(1), Dec. 1, 1981, 95 Stat. 1115, and amended by Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2043; Public Law 104–106, Div. A, Title III, § 378, Feb. 10, 1996, 110 Stat. 284; Public Law 104–201, Div. A, Title XIV, § 1416(b), Sept. 23, 1996, 110 Stat. 2723.

(2) An item referred to in paragraph (1) is any material or expertise of the Department of Defense appropriate for use in preparing for or responding to an emergency involving chemical or biological agents, including the following:

(A) Training facilities.

(B) Sensors.

(C) Protective clothing.

(D) Antidotes.

§ 373. Training and advising civilian law enforcement officials [3]

The Secretary of Defense may, in accordance with other applicable law, make Department of Defense personnel available—

(1) to train Federal, State, and local civilian law enforcement officials in the operation and maintenance of equipment, including equipment made available under section 372 of this title; and

(2) to provide such law enforcement officials with expert advice relevant to the purposes of this chapter.

§ 374. Maintenance and operation of equipment [4]

(a) The Secretary of Defense may, in accordance with other applicable law, make Department of Defense personnel available for the maintenance of equipment for Federal, State, and local civilian law enforcement officials, including equipment made available under section 372 of this title.

(b)(1) Subject to paragraph (2) and in accordance with other applicable law, the Secretary of Defense may, upon request from the head of a Federal law enforcement agency, make Department of Defense personnel available to operate equipment (including equipment made available under section 372 of this title) with respect to—

(A) a criminal violation of a provision of law specified in paragraph (4)(A);

(B) assistance that such agency is authorized to furnish to a State, local, or foreign government which is involved in the enforcement of similar laws;

(C) a foreign or domestic counter-terrorism operation; or

(D) a rendition of a suspected terrorist from a foreign country to the United States to stand trial.

(2) Department of Defense personnel made available to a civilian law enforcement agency under this subsection may operate equipment for the following purposes:

(A) Detection, monitoring, and communication of the movement of air and sea traffic.

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[3] Added by Public Law 97–86, Title IX, § 905(a)(1), Dec. 1, 1981, 95 Stat. 1115, and amended by Public Law 99–145, Title XIV, § 1423(a), Nov. 8, 1985, 99 Stat. 752; Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2043.

[4] Added by Public Law 97–86, Title IX, § 905(a)(1), Dec. 1, 1981, 95 Stat. 1115, and amended by Public Law 98–525, Title XIV, § 1405(9), Oct. 19, 1984, 98 Stat. 2622; Public Law 99–570, Title III, § 3056, Oct. 27, 1986, 100 Stat. 3207–77; Public Law 99–661, Div. A, Title XIII, § 1373(c), Nov. 14, 1986, 100 Stat. 4007; Public Law 100–418, Title I, § 1214(a)(1), Aug. 23, 1988, 102 Stat. 1155; Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2043; Public Law 101–189, Div. A, Title XII, §§ 1210, 1216(b), (c), Nov. 29, 1989, 103 Stat. 1566, 1569; Public Law 102–484, Div. A, Title X, § 1042, Oct. 23, 1992, 106 Stat. 2492; Public Law 105–277, Div. B, Title II, § 201, Oct. 21, 1998, 112 Stat. 2681–567; Public Law 106–65, Div. A, Title X, § 1066(a)(4), Oct. 5, 1999, 113 Stat. 770.

(B) Detection, monitoring, and communication of the movement of surface traffic outside of the geographic boundary of the United States and within the United States not to exceed 25 miles of the boundary if the initial detection occurred outside of the boundary.

(C) Aerial reconnaissance.

(D) Interception of vessels or aircraft detected outside the land area of the United States for the purposes of communicating with such vessels and aircraft to direct such vessels and aircraft to go to a location designated by appropriate civilian officials.

(E) Operation of equipment to facilitate communications in connection with law enforcement programs specified in paragraph (4)(A).

(F) Subject to joint approval by the Secretary of Defense and the Attorney General (and the Secretary of State in the case of a law enforcement operation outside of the land area of the United States)—

(i) the transportation of civilian law enforcement personnel along with any other civilian or military personnel who are supporting, or conducting, a joint operation with civilian law enforcement personnel;

(ii) the operation of a base of operations for civilian law enforcement and supporting personnel; and

(iii) the transportation of suspected terrorists from foreign countries to the United States for trial (so long as the requesting Federal law enforcement agency provides all security for such transportation and maintains custody over the suspect through the duration of the transportation).

(3) Department of Defense personnel made available to operate equipment for the purpose stated in paragraph (2)(D) may continue to operate such equipment into the land area of the United States in cases involving the pursuit of vessels or aircraft where the detection began outside such land area.

(4) In this subsection:

(A) The term ''Federal law enforcement agency'' means a Federal agency with jurisdiction to enforce any of the following:

(i) The Controlled Substances Act (21 U.S.C. 801 et seq.) or the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.).

(ii) Any of sections 274 through 278 of the Immigration and Nationality Act (8 U.S.C. 1324–1328).

(iii) A law relating to the arrival or departure of merchandise (as defined in section 401 of the Tariff Act of 1930 (19 U.S.C. 1401) into or out of the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States) or any other territory or possession of the United States.

(iv) The Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.)

(v) Any law, foreign or domestic, prohibiting terrorist activities.

(B) The term "land area of the United States" includes the land area of any territory, commonwealth, or possession of the United States.

(c) The Secretary of Defense may, in accordance with other applicable law, make Department of Defense personnel available to any Federal, State, or local civilian law enforcement agency to operate equipment for purposes other than described in subsection (b)(2) only to the extent that such support does not involve direct participation by such personnel in a civilian law enforcement operation unless such direct participation is otherwise authorized by law.

§ 375. Restriction on direct participation by military personnel[5]

The Secretary of Defense shall prescribe such regulations as may be necessary to ensure that any activity (including the provision of any equipment or facility or the assignment or detail of any personnel) under this chapter does not include or permit direct participation by a member of the Army, Navy, Air Force, or Marine Corps in a search, seizure, arrest, or other similar activity unless participation in such activity by such member is otherwise authorized by law.

§ 376. Support not to affect adversely military preparedness[6]

Support (including the provision of any equipment or facility or the assignment or detail of any personnel) may not be provided to any civilian law enforcement official under this chapter if the provision of such support will adversely affect the military preparedness of the United States. The Secretary of Defense shall prescribe such regulations as may be necessary to ensure that the provision of any such support does not adversely affect the military preparedness of the United States.

§ 377. Reimbursement[7]

(a) To the extent otherwise required by section 1535 of title 31 (popularly known as the "Economy Act") or other applicable law, the Secretary of Defense shall require a civilian law enforcement agency to which support is provided under this chapter to reimburse the Department of Defense for that support.

(b) An agency to which support is provided under this chapter is not required to reimburse the Department of Defense for such support if such support—

(1) is provided in the normal course of military training or operations; or

(2) results in a benefit to the element of the Department of Defense providing the support that is substantially equivalent to that which would otherwise be obtained from military operations or training.

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[5] Added by Public Law 97–86, Title IX, § 905(a)(1), Dec. 1, 1981, 95 Stat. 1116, and amended by Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2045; Public Law 101–189, Div. A, Title XII, § 1211, Nov. 29, 1989, 103 Stat. 1567.

[6] Added by Public Law 97–86, Title IX, § 905(a)(1), Dec. 1, 1981, 95 Stat. 1116, and amended by Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2045.

[7] Added by Public Law 97–86, Title IX, § 905(a)(1), Dec. 1, 1981, 95 Stat. 1116, and amended by Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2045.

§ 378. Nonpreemption of other law [8]

Nothing in this chapter shall be construed to limit the authority of the executive branch in the use of military personnel or equipment for civilian law enforcement purposes beyond that provided by law before December 1, 1981.

§ 379. Assignment of Coast Guard personnel to naval vessels for law enforcement purposes [9]

(a) The Secretary of Defense and the Secretary of Homeland Security shall provide that there be assigned on board every appropriate surface naval vessel at sea in a drug-interdiction area members of the Coast Guard who are trained in law enforcement and have powers of the Coast Guard under title 14, including the power to make arrests and to carry out searches and seizures.

(b) Members of the Coast Guard assigned to duty on board naval vessels under this section shall perform such law enforcement functions (including drug-interdiction functions)—

(1) as may be agreed upon by the Secretary of Defense and the Secretary of Homeland Security; and

(2) as are otherwise within the jurisdiction of the Coast Guard.

(c) No fewer than 500 active duty personnel of the Coast Guard shall be assigned each fiscal year to duty under this section. However, if at any time the Secretary of Homeland Security, after consultation with the Secretary of Defense, determines that there are insufficient naval vessels available for purposes of this section, such personnel may be assigned other duty involving enforcement of laws listed in section 374(b)(4)(A) of this title.

(d) In this section, the term ''drug-interdiction area'' means an area outside the land area of the United States (as defined in section 374(b)(4)(B) of this title) in which the Secretary of Defense (in consultation with the Attorney General) determines that activities involving smuggling of drugs into the United States are ongoing.

§ 380. Enhancement of cooperation with civilian law enforcement officials [10]

(a) The Secretary of Defense, in cooperation with the Attorney General, shall conduct an annual briefing of law enforcement personnel of each State (including law enforcement personnel of the political subdivisions of each State) regarding information, training, technical support, and equipment and facilities available to civilian law enforcement personnel from the Department of Defense.

(b) Each briefing conducted under subsection (a) shall include the following:

(1) An explanation of the procedures for civilian law enforcement officials—

(A) to obtain information, equipment, training, expert advice, and other personnel support under this chapter; and

(B) to obtain surplus military equipment.

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[8] Added by Public Law 97–86, Title IX, § 905(a)(1), Dec. 1, 1981, 95 Stat. 1116, and amended by Public Law 98–525, Title XIV, § 1405(10), Oct. 19, 1984, 98 Stat. 2622; Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2045.

[9] Added by Public Law 99–570, Title III, § 3053(b)(1), Oct. 27, 1986, 100 Stat. 3207–75, and amended by Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2045; Public Law 107–296, Title XVII, § 1704(b)(1), Nov. 25, 2002, 116 Stat. 2314.

[10] Added by Public Law 100–180, Div. A, Title XII, § 1243(a), Dec. 4, 1987, 101 Stat. 1163, and amended by Public Law 100–456, Div. A, Title XI, § 1104(a), Sept. 29, 1988, 102 Stat. 2046.

(2) A description of the types of information, equipment and facilities, and training and advice available to civilian law enforcement officials from the Department of Defense.

(3) A current, comprehensive list of military equipment which is suitable for law enforcement officials from the Department of Defense or available as surplus property from the Administrator of General Services.

(c) The Attorney General and the Administrator of General Services shall—

(1) establish or designate an appropriate office or offices to maintain the list described in subsection (b)(3) and to furnish information to civilian law enforcement officials on the availability of surplus military equipment; and

(2) make available to civilian law enforcement personnel nationwide, tollfree telephone communication with such office or offices.

§ 381. Procurement by State and local governments of law enforcement equipment suitable for counter-drug activities through the Department of Defense [11]

(a) PROCEDURES.—(1) The Secretary of Defense shall establish procedures in accordance with this subsection under which States and units of local government may purchase law enforcement equipment suitable for counter-drug activities through the Department of Defense. The procedures shall require the following:

(A) Each State desiring to participate in a procurement of equipment suitable for counter-drug activities through the Department of Defense shall submit to the Department, in such form and manner and at such times as the Secretary prescribes, the following:

(i) A request for law enforcement equipment.

(ii) Advance payment for such equipment, in an amount determined by the Secretary based on estimated or actual costs of the equipment and administrative costs incurred by the Department.

(B) A State may include in a request submitted under subparagraph (A) only the type of equipment listed in the catalog produced under subsection (c).

(C) A request for law enforcement equipment shall consist of an enumeration of the law enforcement equipment that is desired by the State and units of local government within the State. The Governor of a State may establish such procedures as the Governor considers appropriate for administering and coordinating requests for law enforcement equipment from units of local government within the State.

(D) A State requesting law enforcement equipment shall be responsible for arranging and paying for shipment of the equipment to the State and localities within the State.

(2) In establishing the procedures, the Secretary of Defense shall coordinate with the General Services Administration and other Federal agencies for purposes of avoiding duplication of effort.

(b) REIMBURSEMENT OF ADMINISTRATIVE COSTS.—In the case of any purchase made by a State or unit of local government under

[11] Added by Public Law 103–160, Div. A, Title XI, § 1122(a)(1), Nov. 30, 1993, 107 Stat. 1754.

the procedures established under subsection (a), the Secretary of Defense shall require the State or unit of local government to reimburse the Department of Defense for the administrative costs to the Department of such purchase.

(c) GSA CATALOG.—The Administrator of General Services, in coordination with the Secretary of Defense, shall produce and maintain a catalog of law enforcement equipment suitable for counter-drug activities for purchase by States and units of local government under the procedures established by the Secretary under this section.

(d) DEFINITIONS.—In this section:

(1) The term "State" includes the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, and any territory or possession of the United States.

(2) The term "unit of local government" means any city, county, township, town, borough, parish, village, or other general purpose political subdivision of a State; an Indian tribe which performs law enforcement functions as determined by the Secretary of the Interior; or any agency of the District of Columbia government or the United States Government performing law enforcement functions in and for the District of Columbia or the Trust Territory of the Pacific Islands.

(3) The term "law enforcement equipment suitable for counter-drug activities" has the meaning given such term in regulations prescribed by the Secretary of Defense. In prescribing the meaning of the term, the Secretary may not include any equipment that the Department of Defense does not procure for its own purposes.

§ 382. Emergency situations involving chemical or biological weapons of mass destruction [12]

(a) IN GENERAL.—The Secretary of Defense, upon the request of the Attorney General, may provide assistance in support of Department of Justice activities relating to the enforcement of section 175 or 2332c of title 18 during an emergency situation involving a biological or chemical weapon of mass destruction. Department of Defense resources, including personnel of the Department of Defense, may be used to provide such assistance if—

(1) the Secretary of Defense and the Attorney General jointly determine that an emergency situation exists; and

(2) the Secretary of Defense determines that the provision of such assistance will not adversely affect the military preparedness of the United States.

(b) EMERGENCY SITUATIONS COVERED.—In this section, the term "emergency situation involving a biological or chemical weapon of mass destruction" means a circumstance involving a biological or chemical weapon of mass destruction—

(1) that poses a serious threat to the interests of the United States; and

(2) in which—

[12] Added by Public Law 104–201, Div. A, Title XIV, § 1416(a)(1), Sept. 23, 1996, 110 Stat. 2721, and amended by Public Law 105–85, Div. A, Title X, § 1073(a)(6), Nov. 18, 1997, 111 Stat. 1900.

(A) civilian expertise and capabilities are not readily available to provide the required assistance to counter the threat immediately posed by the weapon involved;

(B) special capabilities and expertise of the Department of Defense are necessary and critical to counter the threat posed by the weapon involved; and

(C) enforcement of section 175 or 2332c of title 18 would be seriously impaired if the Department of Defense assistance were not provided.

(c) FORMS OF ASSISTANCE.—The assistance referred to in subsection (a) includes the operation of equipment (including equipment made available under section 372 of this title) to monitor, contain, disable, or dispose of the weapon involved or elements of the weapon.

(d) REGULATIONS.—(1) The Secretary of Defense and the Attorney General shall jointly prescribe regulations concerning the types of assistance that may be provided under this section. Such regulations shall also describe the actions that Department of Defense personnel may take in circumstances incident to the provision of assistance under this section.

(2)(A) Except as provided in subparagraph (B), the regulations may not authorize the following actions:

(i) Arrest.

(ii) Any direct participation in conducting a search for or seizure of evidence related to a violation of section 175 or 2332c of title 18.

(iii) Any direct participation in the collection of intelligence for law enforcement purposes.

(B) The regulations may authorize an action described in subparagraph (A) to be taken under the following conditions:

(i) The action is considered necessary for the immediate protection of human life, and civilian law enforcement officials are not capable of taking the action.

(ii) The action is otherwise authorized under subsection (c) or under otherwise applicable law.

(e) REIMBURSEMENTS.—The Secretary of Defense shall require reimbursement as a condition for providing assistance under this section to the extent required under section 377 of this title.

(f) DELEGATIONS OF AUTHORITY.—(1) Except to the extent otherwise provided by the Secretary of Defense, the Deputy Secretary of Defense may exercise the authority of the Secretary of Defense under this section. The Secretary of Defense may delegate the Secretary's authority under this section only to an Under Secretary of Defense or an Assistant Secretary of Defense and only if the Under Secretary or Assistant Secretary to whom delegated has been designated by the Secretary to act for, and to exercise the general powers of, the Secretary.

(2) Except to the extent otherwise provided by the Attorney General, the Deputy Attorney General may exercise the authority of the Attorney General under this section. The Attorney General may delegate that authority only to the Associate Attorney General or an Assistant Attorney General and only if the Associate Attorney General or Assistant Attorney General to whom delegated has

been designated by the Attorney General to act for, and to exercise the general powers of, the Attorney General.

(g) RELATIONSHIP TO OTHER AUTHORITY.—Nothing in this section shall be construed to restrict any executive branch authority regarding use of members of the armed forces or equipment of the Department of Defense that was in effect before September 23, 1996.

10 U.S.C. § 912a (Art. 112a)
Controlled substance offenses under the Code of Military Justice

Chapter 47. Uniform Code of Military Justice

§ 912a. Art. 112a. Wrongful use, possession, etc., of controlled substances [1]

(a) Any person subject to this chapter who wrongfully uses, possesses, manufactures, distributes, imports into the customs territory of the United States, exports from the United States, or introduces into an installation, vessel, vehicle, or aircraft used by or under the control of the armed forces a substance described in subsection (b) shall be punished as a court-martial may direct.

(b) The substances referred to in subsection (a) are the following:

(1) Opium, heroin, cocaine, amphetamine, lysergic acid diethylamide, methamphetamine, phencyclidine, barbituric acid, and marijuana and any compound or derivative of any such substance.

(2) Any substance not specified in clause (1) that is listed on a schedule of controlled substances prescribed by the President for the purposes of this article.

(3) Any other substance not specified in clause (1) or contained on a list prescribed by the President under clause (2) that is listed in schedules I through V of section 202 of the Controlled Substances Act (21 U.S.C. 812.)

[1] Added by Public Law 98–209, § 8(a), Dec. 6, 1983, 97 Stat. 1403.

10 U.S.C. § 986
Defense Department may not grant a security clearance to anyone who unlawfully uses or is addicted to a controlled substance

Chapter 49. Miscellaneous Prohibitions and Penalties

§ 986. Security clearances: limitations [1]

(a) PROHIBITION.—After October 30, 2000, the Department of Defense may not grant or renew a security clearance for a person to whom this section applies who is described in subsection (c).

(b) COVERED PERSONS.—This section applies to the following persons:

(1) An officer or employee of the Department of Defense.

(2) A member of the Army, Navy, Air Force, or Marine Corps who is on active duty or is in an active status.

(3) An officer or employee of a contractor of the Department of Defense.

(c) PERSONS DISQUALIFIED FROM BEING GRANTED SECURITY CLEARANCES.—A person is described in this subsection if any of the following applies to that person:

(1) The person has been convicted in any court of the United States of a crime, was sentenced to imprisonment for a term exceeding one year, and was incarcerated as a result of that sentence for not less than one year.

(2) The person is an unlawful user of, or is addicted to, a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)).

(3) The person is mentally incompetent, as determined by a mental health professional approved by the Department of Defense.

(4) The person has been discharged or dismissed from the Armed Forces under dishonorable conditions.

(d) WAIVER AUTHORITY.—In a meritorious case, an exception to the prohibition in subsection (a) may be authorized for a person described in paragraph (1) or (4) of subsection (c) if there are mitigating factors. Any such waiver may be authorized only in accordance with standards and procedures prescribed by, or under the authority of, an Executive order or other guidance issued by the President.

(e) ANNUAL REPORT.—Not later than February 1 each year, the Secretary of Defense shall submit to the Committees on Armed Services of the Senate and House of Representatives a report identifying each waiver issued under subsection (d) during the preceding year with an explanation for each case of the disqualifying

[1] Added by Public Law 106–398, § 1 [Div. A, Title X, § 1071(a)], Oct. 30, 2000, 114 Stat. 1654, 1654A–275, and amended by Public Law 107–107, Div. A, Title X, § 1048(c)(3), Dec. 28, 2001, 115 Stat. 1226; Public Law 108–375, § 1062, Oct. 28, 2004, 118 Stat. 2056.

factor in subsection (c) that applied, and the reason for the waiver of the disqualification.

12 U.S.C. § 3420

Right to Financial Privacy Act, Public Law 95–630, sec. 1120

Financial institution served with a grand jury subpoena for customer records relating to a controlled substance investigation may not disclose the fact of a subpoena to the customer

Title 12. Banks and Banking

Chapter 35. Right to Financial Privacy

§ 3420. Grand jury information; notification of certain persons prohibited [1]

(a) Financial records about a customer obtained from a financial institution pursuant to a subpena issued under the authority of a Federal grand jury—

(1) shall be returned and actually presented to the grand jury unless the volume of such records makes such return and actual presentation impractical in which case the grand jury shall be provided with a description of the contents of the records.; [2]

(2) shall be used only for the purpose of considering whether to issue an indictment or presentment by that grand jury, or of prosecuting a crime for which that indictment or presentment is issued, or for a purpose authorized by rule 6(e) of the Federal Rules of Criminal Procedure, or for a purpose authorized by section 1112(a);

(3) shall be destroyed or returned to the financial institution if not used for one of the purposes specified in paragraph (2); and

(4) shall not be maintained, or a description of the contents of such records shall not be maintained by any Government authority other than in the sealed records of the grand jury, unless such record has been used in the prosecution of a crime for which the grand jury issued an indictment or presentment or for a purpose authorized by rule 6(e) of the Federal Rules of Criminal Procedure.

(b)(1) No officer, director, partner, employee, or shareholder of, or agent or attorney for, a financial institution shall, directly or indirectly, notify any person named in a grand jury subpoena served on such institution in connection with an investigation relating to a possible—

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[1] Public Law 95–630, Title XI, § 1120, Nov. 10, 1978, 92 Stat. 3709; Public Law 100–690, Title VI, § 6186(e), Nov. 18, 1988, 102 Stat. 4358; Public Law 101–73, Title IX, § 943, Aug. 9, 1989, 103 Stat. 497; Public Law 102–550, Title XV, § 1532, Oct. 28, 1992, 106 Stat. 4066; Public Law 107–56, Title III, § 358(f)(3), Oct. 26, 2001, 115 Stat. 327.

[2] So in original.

(A) crime against any financial institution or supervisory agency or crime involving a violation of the Controlled Substance Act,[3] the Controlled Substances Import and Export Act, section 1956 or 1957 of Title 18, sections 5313, 5316 and 5324 of Title 31, or section 6050I of Title 26; or

(B) conspiracy to commit such a crime,

about the existence or contents of such subpoena, or information that has been furnished to the grand jury in response to such subpoena.

(2) Section 1818 of this title and section 1786(k)(2) of this title shall apply to any violation of this subsection.

[3] So in original. Probably should be "Controlled Substances Act".

16 U.S.C. §§ 559b–559f
National Forest System Drug Control Act of 1996, Public Law 99–570, secs. 15002–15007
Drug control in the national forests

Title 16. Conservation

Chapter 3. Forests; Forest Service; Reforestation; Management

§ 559b. Prevention of manufacture, etc., of marijuana and other controlled substances [1]

(a) Purpose

The purpose of sections 559b to 559f of this title is to authorize the Secretary of Agriculture (hereinafter in sections 559b to 559f of this title referred to as the "Secretary") to take actions necessary, in connection with the administration and use of the National Forest System, to prevent the manufacture, distribution, or dispensing of marijuana and other controlled substances.

(b) Law enforcement authority

Nothing in sections 559b to 559f of this title shall diminish in any way the law enforcement authority of the Forest Service.

(c) Definitions

As used in sections 559b to 559f of this title, the terms "manufacture", "dispense", and "distribute" shall have the same meaning given such terms in section 802 of Title 21.

§ 559c. Powers of officers and employees of Forest Service [2]

For the purposes of sections 559b to 559f of this title, if specifically designated by the Secretary and specially trained, not to exceed 1,000 special agents and law enforcement officers of the Forest Service when in the performance of their duties shall have authority to—

(1) carry firearms;

(2) conduct, within the exterior boundaries of the National Forest System, investigations of violations of and enforce section 841 of Title 21 and other criminal violations relating to marijuana and other controlled substances that are manufactured, distributed, or dispensed on National Forest System lands and to conduct such investigations and enforcement of such laws outside the exterior boundaries of the National Forest System for offenses committed within the National Forest

[1] Public Law 99–570, Title XV, § 15002, Oct. 27, 1986, 100 Stat. 3207–191.
[2] Public Law 99–570, Title XV, § 15003, Oct. 27, 1986, 100 Stat. 3207–191; Public Law 100–690, Title VI, § 6254(b), Nov. 18, 1988, 102 Stat. 4364.

System or which affect the administration of the National Forest System (including the pursuit of persons suspected of such offenses who flee the National Forest System to avoid arrest);

(3) make arrests with a warrant or process for misdemeanor violations, or without a warrant or process for violations of such misdemeanors that any such officer or employee has probable cause to believe are being committed in his presence or view, or for a felony with a warrant or without a warrant if he has probable cause to believe that the person to be arrested has committed or is committing such felony, for offenses committed within the National Forest System or which affect the administration of the National Forest System;;[3]

(4) serve warrants and other process issued by a court or officer of competent jurisdiction;

(5) search with or without warrant or process any person, place, or conveyance according to Federal law or rule of law; and

(6) seize with or without warrant or process any evidentiary item according to Federal law or rule of law.

§ 559d. Cooperation with other Federal, State, and local law enforcement agencies[4]

For the purposes of sections 559b to 559f of this title, in exercising the authority provided by section 559c of this title—

(1) the Forest Service shall cooperate with any other Federal law enforcement agency having primary investigative jurisdiction over the offense committed;

(2) the Secretary may authorize the Forest Service to cooperate with the law enforcement officials of any Federal agency, State, or political subdivision in the investigation of violations of and enforcement of section 401 of the Controlled Substances Act (21 U.S.C. 841), other laws and regulations relating to marijuana and other controlled substances, and State drug control laws or ordinances for offenses committed within the National Forest System or which affect the administration of the National Forest System.[5]

(3) the Forest Service shall cooperate with the Attorney General in carrying out the seizure and forfeiture provisions of section 511 of the Controlled Substances Act (21 U.S.C. 881) for violations of the Controlled Substances Act relating to offenses committed within the National Forest System, or which affect the administration of the National Forest System;

(4) the Secretary is authorized to designate law enforcement officers of any other Federal agency, when the Secretary determines such designation to be economical and in the public interest, and with the concurrence of that agency, to exercise the powers and authorities of the Forest Service while assisting the Forest Service in the National Forest System, or for activities administered by the Forest Service; and

(5) the Forest Service is authorized to accept law enforcement designation from any other Federal agency or agency of

[3] So in original.
[4] Public Law 99–570, Title XV, § 15004, Oct. 27, 1986, 100 Stat. 3207–191; Public Law 100–690, Title VI, § 6254(c), Nov. 18, 1988, 102 Stat. 4364.
[5] So in original. Probably should be a semicolon.

a State or political subdivision thereof for the purpose of cooperating in a multi-agency law enforcement task force investigation of violations of the Controlled Substances Act and other offenses committed in the course of or in connection with such violations.

§ 559e. Forest Service authorization [6]

In order to improve Federal law enforcement activities relating to the use and production of narcotics and controlled substances on lands administered by the Forest Service, from amounts appropriated there shall be made available to the Secretary, in addition to sums made available under other authority of law, $10,000,000 for fiscal year 1989, and for each fiscal year thereafter, to be used for employment and training of additional and existing Forest Service law enforcement personnel, for expenses related to such employment, training, equipment, and facilities, and for cooperative programs with State and local law enforcement agencies.

§ 559f. Approval of Secretary of Agriculture and Attorney General [7]

The authorities conferred herein shall be exercised pursuant to an agreement approved by the Secretary of Agriculture and the Attorney General.

[6] Public Law 99–570, Title XV, § 15006, Oct. 27, 1986, 100 Stat. 3207–192; Public Law 100–690, Title VI, § 6254(d)(1), Nov. 18, 1988, 102 Stat. 4364.
[7] Public Law 99–570, Title XV, § 15007, Oct. 27, 1986, 100 Stat. 3207–192.

18 U.S.C. § 36
Drive-by shooting in furtherance of a major drug offense

Title 18. Crimes and Criminal Procedure

Chapter 2. Aircraft and Motor Vehicles

§ 36. Drive-by shooting [1]

(a) DEFINITION.—In this section, "major drug offense" means—

(1) a continuing criminal enterprise punishable under section 408(c) of the Controlled Substances Act (21 U.S.C. 848(c));

(2) a conspiracy to distribute controlled substances punishable under section 406 of the Controlled Substances Act (21 U.S.C. 846) section [2] 1013 of the Controlled Substances Import and Export Act (21 U.S.C. 963); or

(3) an offense involving major quantities of drugs and punishable under section 401(b)(1)(A) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(A)) or section 1010(b)(1) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)(1)).

(b) OFFENSE AND PENALTIES.—(1) A person who, in furtherance or to escape detection of a major drug offense and with the intent to intimidate, harass, injure, or maim, fires a weapon into a group of two or more persons and who, in the course of such conduct, causes grave risk to any human life shall be punished by a term of no more than 25 years, by fine under this title, or both.

(2) A person who, in furtherance or to escape detection of a major drug offense and with the intent to intimidate, harass, injure, or maim, fires a weapon into a group of 2 or more persons and who, in the course of such conduct, kills any person shall, if the killing—

(A) is a first degree murder (as defined in section 1111(a)), be punished by death or imprisonment for any term of years or for life, fined under this title, or both; or

(B) is a murder other than a first degree murder (as defined in section 1111(a)), be fined under this title, imprisoned for any term of years or for life, or both.

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[1] Added by Public Law 103–322, Title VI, § 60008(b), Sept. 13, 1994, 108 Stat. 1971, and amended by Public Law 104–294, Title VI, § 604(b)(30), Oct. 11, 1996, 110 Stat. 3508.

[2] So in original. Probably should be preceded by "or".

Chapter 7. Assault

§ 111. Assaulting, resisting, or impeding certain officers or employees [1]

(a) IN GENERAL.—Whoever—

(1) forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person designated in section 1114 of this title while engaged in or on account of the performance of official duties; or

(2) forcibly assaults or intimidates any person who formerly served as a person designated in section 1114 on account of the performance of official duties during such person's term of service,

shall, where the acts in violation of this section constitute only simple assault, be fined under this title or imprisoned not more than one year, or both, and in all other cases, be fined under this title or imprisoned not more than 8 years, or both.

(b) ENHANCED PENALTY.—Whoever, in the commission of any acts described in subsection (a), uses a deadly or dangerous weapon (including a weapon intended to cause death or danger but that fails to do so by reason of a defective component) or inflicts bodily injury, shall be fined under this title or imprisoned not more than 20 years, or both.

[1] June 25, 1948, c. 645, 62 Stat. 688; Nov. 18, 1988, Public Law 100–690, Title VI, § 6487(a), 102 Stat. 4386; Sept. 13, 1994, Public Law 103–322, Title XXXII, § 320101(a), 108 Stat. 2108; Apr. 24, 1996, Public Law 104–132, Title VII, § 727(c), 110 Stat. 1302; Nov. 2, 2002, Public Law 107–273, Div. C, Title I, § 11008(b), 116 Stat. 1818.

18 U.S.C. § 175b
Possession of various biological agents by an unlawful user of controlled substances

Chapter 10. Biological Weapons

§ 175b. Possession by restricted persons [1]

(a)(1) No restricted person shall ship or transport in or affecting interstate or foreign commerce, or possess in or affecting interstate or foreign commerce, any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a non-overlap or overlap select biological agent or toxin in sections 73.4 and 73.5 of title 42, Code of Federal Regulations, pursuant to section 351A of the Public Health Service Act, and is not excluded under sections 73.4 and 73.5 or exempted under section 73.6 of title 42, Code of Federal Regulations.

(2) Whoever knowingly violates this section shall be fined as provided in this title, imprisoned not more than 10 years, or both, but the prohibition contained in this section shall not apply with respect to any duly authorized United States governmental activity.

(b) TRANSFER TO UNREGISTERED PERSON.—

(1) SELECT AGENTS.—Whoever transfers a select agent to a person who the transferor knows or has reasonable cause to believe is not registered as required by regulations under subsection (b) or (c) of section 351A of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

(2) CERTAIN OTHER BIOLOGICAL AGENTS AND TOXINS.—Whoever transfers a biological agent or toxin listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 to a person who the transferor knows or has reasonable cause to believe is not registered as required by regulations under subsection (b) or (c) of section 212 of such Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

(c) UNREGISTERED FOR POSSESSION.—

(1) SELECT AGENTS.—Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a select agent for which such person has not obtained a registration required by regulations under section 351A(c) of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

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[1] Added by Public Law 107–56, Title VIII, § 817(2), Oct. 26, 2001, 115 Stat. 386, and amended by Public Law 107–188, Title II, § 231(a), (b)(1), (c)(2), June 12, 2002, 116 Stat. 660, 661; Public Law 107–273, Div. B, Title IV, § 4005(g), Nov. 2, 2002, 116 Stat. 1813; Public Law 108–458, § 6802(c), (d)(1), Dec. 17, 2004, 118 Stat. 3767.

(2) CERTAIN OTHER BIOLOGICAL AGENTS AND TOXINS.—Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a biological agent or toxin listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 for which such person has not obtained a registration required by regulations under section 212(c) of such Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

(d) In this section:

(1) The term ''select agent'' means a biological agent or toxin to which subsection (a) applies. Such term (including for purposes of subsection (a)) does not include any such biological agent or toxin that is in its naturally-occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source.

(2) The term ''restricted person'' means an individual who—

(A) is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

(B) has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(C) is a fugitive from justice;

(D) is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(E) is an alien illegally or unlawfully in the United States;

(F) has been adjudicated as a mental defective or has been committed to any mental institution;

(G)(i) is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism, or (ii) acts for or on behalf of, or operates subject to the direction or control of, a government or official of a country described in this subparagraph;

(H) has been discharged from the Armed Services of the United States under dishonorable conditions; or

(I) is a member of, acts for or on behalf of, or operates subject to the direction or control of, a terrorist organization as defined in section 212(a)(3)(B)(vi) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(3)(B)(vi)).

(3) The term ''alien'' has the same meaning as in section section 101(a)(3) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(3)).

(4) The term ''lawfully admitted for permanent residence'' has the same meaning as in section 101(a)(20) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(20)).

Chapter 11. Bribery, Graft, and Conflicts of Interest

§ 201. Bribery of public officials and witnesses [1]

(a) For the purpose of this section—

(1) the term "public official" means Member of Congress, Delegate, or Resident Commissioner, either before or after such official has qualified, or an officer or employee or person acting for or on behalf of the United States, or any department, agency or branch of Government thereof, including the District of Columbia, in any official function, under or by authority of any such department, agency, or branch of Government, or a juror;

(2) the term "person who has been selected to be a public official" means any person who has been nominated or appointed to be a public official, or has been officially informed that such person will be so nominated or appointed; and

(3) the term "official act" means any decision or action on any question, matter, cause, suit, proceeding or controversy, which may at any time be pending, or which may by law be brought before any public official, in such official's official capacity, or in such official's place of trust or profit.

(b) Whoever—

(1) directly or indirectly, corruptly gives, offers or promises anything of value to any public official or person who has been selected to be a public official, or offers or promises any public official or any person who has been selected to be a public official to give anything of value to any other person or entity, with intent—

(A) to influence any official act; or

(B) to influence such public official or person who has been selected to be a public official to commit or aid in committing, or collude in, or allow, any fraud, or make opportunity for the commission of any fraud, on the United States; or

(C) to induce such public official or such person who has been selected to be a public official to do or omit to do any act in violation of the lawful duty of such official or person;

(2) being a public official or person selected to be a public official, directly or indirectly, corruptly demands, seeks, receives, accepts, or agrees to receive or accept anything of value personally or for any other person or entity, in return for:

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[1] Added by Public Law 87–849, § 1(a), Oct. 23, 1962, 76 Stat. 1119, and amended by Public Law 91–405, Title II, § 204(d) (1), Sept. 22, 1970, 84 Stat. 853; Public Law 99–646, § 46(a)–(l), Nov. 10, 1986, 100 Stat. 3601–3604; Public Law 103–322, Title XXXIII, §§ 330011(b), 330016(2)(D), Sept. 13, 1994, 108 Stat. 2144, 2148.

(A) being influenced in the performance of any official act;

(B) being influenced to commit or aid in committing, or to collude in, or allow, any fraud, or make opportunity for the commission of any fraud, on the United States; or

(C) being induced to do or omit to do any act in violation of the official duty of such official or person;

(3) directly or indirectly, corruptly gives, offers, or promises anything of value to any person, or offers or promises such person to give anything of value to any other person or entity, with intent to influence the testimony under oath or affirmation of such first-mentioned person as a witness upon a trial, hearing, or other proceeding, before any court, any committee of either House or both Houses of Congress, or any agency, commission, or officer authorized by the laws of the United States to hear evidence or take testimony, or with intent to influence such person to absent himself therefrom;

(4) directly or indirectly, corruptly demands, seeks, receives, accepts, or agrees to receive or accept anything of value personally or for any other person or entity in return for being influenced in testimony under oath or affirmation as a witness upon any such trial, hearing, or other proceeding, or in return for absenting himself therefrom;

shall be fined under this title or not more than three times the monetary equivalent of the thing of value, whichever is greater, or imprisoned for not more than fifteen years, or both, and may be disqualified from holding any office of honor, trust, or profit under the United States.

(c) Whoever—

(1) otherwise than as provided by law for the proper discharge of official duty—

(A) directly or indirectly gives, offers, or promises anything of value to any public official, former public official, or person selected to be a public official, for or because of any official act performed or to be performed by such public official, former public official, or person selected to be a public official; or

(B) being a public official, former public official, or person selected to be a public official, otherwise than as provided by law for the proper discharge of official duty, directly or indirectly demands, seeks, receives, accepts, or agrees to receive or accept anything of value personally for or because of any official act performed or to be performed by such official or person;

(2) directly or indirectly, gives, offers, or promises anything of value to any person, for or because of the testimony under oath or affirmation given or to be given by such person as a witness upon a trial, hearing, or other proceeding, before any court, any committee of either House or both Houses of Congress, or any agency, commission, or officer authorized by the laws of the United States to hear evidence or take testimony, or for or because of such person's absence therefrom;

(3) directly or indirectly, demands, seeks, receives, accepts, or agrees to receive or accept anything of value personally for

or because of the testimony under oath or affirmation given or to be given by such person as a witness upon any such trial, hearing, or other proceeding, or for or because of such person's absence therefrom;

shall be fined under this title or imprisoned for not more than two years, or both.

(d) Paragraphs (3) and (4) of subsection (b) and paragraphs (2) and (3) of subsection (c) shall not be construed to prohibit the payment or receipt of witness fees provided by law, or the payment, by the party upon whose behalf a witness is called and receipt by a witness, of the reasonable cost of travel and subsistence incurred and the reasonable value of time lost in attendance at any such trial, hearing, or proceeding, or in the case of expert witnesses, a reasonable fee for time spent in the preparation of such opinion, and in appearing and testifying.

(e) The offenses and penalties prescribed in this section are separate from and in addition to those prescribed in sections 1503, 1504, and 1505 of this title.

18 U.S.C. § 342
Operation of a common carrier under the influence of alcohol or drugs

Chapter 17A. Common Carrier Operation Under The Influence of Alcohol or Drugs

§ 342. Operation of a common carrier under the influence of alcohol or drugs [1]

Whoever operates or directs the operation of a common carrier while under the influence of alcohol or any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)), shall be imprisoned not more than fifteen years or fined under this title, or both.

[1] Added by Public Law 99–570, Title I, § 1971(a), Oct. 27, 1986, 100 Stat. 3207–59, and amended by Public Law 100–690, Title VI, §§ 6473(a), (b), 6482(b), Nov. 18, 1988, 102 Stat. 4379, 4382.

18 U.S.C. § 371
Conspiracy to commit a Federal crime or defraud the United States

Chapter 19. Conspiracy

§ 371. Conspiracy to commit offense or to defraud United States [1]

If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

If, however, the offense, the commission of which is the object of the conspiracy, is a misdemeanor only, the punishment for such conspiracy shall not exceed the maximum punishment provided for such misdemeanor.

[1] June 25, 1948, c. 645, 62 Stat. 701; Sept. 13, 1994, Public Law 103–322, Title XXXIII, § 330016(1)(L), 108 Stat. 2147.

Chapter 26. Criminal Street Gangs

§ 521. Criminal street gangs [1]

(a) DEFINITIONS.—

"Conviction" includes a finding, under State or Federal law, that a person has committed an act of juvenile delinquency involving a violent or controlled substances felony.

"Criminal street gang" means an ongoing group, club, organization, or association of 5 or more persons—

(A) that has as 1 of its primary purposes the commission of 1 or more of the criminal offenses described in subsection (c);

(B) the members of which engage, or have engaged within the past 5 years, in a continuing series of offenses described in subsection (c); and

(C) the activities of which affect interstate or foreign commerce.

"State" means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(b) PENALTY.—The sentence of a person convicted of an offense described in subsection (c) shall be increased by up to 10 years if the offense is committed under the circumstances described in subsection (d).

(c) OFFENSES.—The offenses described in this section are—

(1) a Federal felony involving a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) for which the maximum penalty is not less than 5 years;

(2) a Federal felony crime of violence that has as an element the use or attempted use of physical force against the person of another; and

(3) a conspiracy to commit an offense described in paragraph (1) or (2).

(d) CIRCUMSTANCES.—The circumstances described in this section are that the offense described in subsection (c) was committed by a person who—

(1) participates in a criminal street gang with knowledge that its members engage in or have engaged in a continuing series of offenses described in subsection (c);

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[1] Added by Public Law 103–322, Title XV, § 150001(a), Sept. 13, 1994, 108 Stat. 2034, and amended by Public Law 104–294, Title VI, § 607(q), Oct. 11, 1996, 110 Stat. 3513; Public Law 107–273, Div. B, Title IV, § 4002(b)(3), Nov. 2, 2002, 116 Stat. 1807.

(2) intends to promote or further the felonious activities of the criminal street gang or maintain or increase his or her position in the gang; and

(3) has been convicted within the past 5 years for—

(A) an offense described in subsection (c);

(B) a State offense—

(i) involving a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) for which the maximum penalty is not less than 5 years' imprisonment; or

(ii) that is a felony crime of violence that has as an element the use or attempted use of physical force against the person of another;

(C) any Federal or State felony offense that by its nature involves a substantial risk that physical force against the person of another may be used in the course of committing the offense; or

(D) a conspiracy to commit an offense described in subparagraph (A), (B), or (C).

Chapter 40. Importation, Manufacture, Distribution and Storage of Explosive Materials

§ 842. Unlawful acts [1]

(a) It shall be unlawful for any person—

(1) to engage in the business of importing, manufacturing, or dealing in explosive materials without a license issued under this chapter;

(2) knowingly to withhold information or to make any false or fictitious oral or written statement or to furnish or exhibit any false, fictitious, or misrepresented identification, intended or likely to deceive for the purpose of obtaining explosive materials, or a license, permit, exemption, or relief from disability under the provisions of this chapter;

(3) other than a licensee or permittee knowingly—

(A) to transport, ship, cause to be transported, or receive any explosive materials; or

(B) to distribute explosive materials to any person other than a licensee or permittee; or

(4) who is a holder of a limited permit—

(A) to transport, ship, cause to be transported, or receive in interstate or foreign commerce any explosive materials; or

(B) to receive explosive materials from a licensee or permittee, whose premises are located outside the State of residence of the limited permit holder, or on more than 6 separate occasions, during the period of the permit, to receive explosive materials from 1 or more licensees or permittees whose premises are located within the State of residence of the limited permit holder.

(b) It shall be unlawful for any licensee or permittee to knowingly distribute any explosive materials to any person other than—

(1) a licensee;

(2) a holder of a user permit; or

(3) a holder of a limited permit who is a resident of the State where distribution is made and in which the premises of the transferor are located.

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[1] Added by Public Law 91–452, Title XI, § 1102(a), Oct. 15, 1970, 84 Stat. 953, and amended by Public Law 100–690, Title VI, § 6474(c),(d), Nov. 18, 1988, 102 Stat. 4380; Public Law 101–647, Title XXXV, § 3521, Nov. 29, 1990, 104 Stat. 4923; Public Law 103–322, Title XI, §§ 110508, 110516, Sept. 13, 1994, 108 Stat. 2018, 2020; Public Law 104–132, Title VI, § 603, Title VII, § 707, Apr. 24, 1996, 110 Stat. 1289, 1296; Public Law 106–54, § 2(a), Aug. 17, 1999, 113 Stat. 398; Public Law 107–296, Title XI, §§ 1112(e)(3), 1122(b), 1123, Nov. 25, 2002, 116 Stat. 2276, 2280, 2283; Public Law 108–177, Title III, § 372, Dec. 13, 2003, 117 Stat. 2627.

(c) It shall be unlawful for any licensee to distribute explosive materials to any person who the licensee has reason to believe intends to transport such explosive materials into a State where the purchase, possession, or use of explosive materials is prohibited or which does not permit its residents to transport or ship explosive materials into it or to receive explosive materials in it.

(d) It shall be unlawful for any person knowingly to distribute explosive materials to any individual who:

(1) is under twenty-one years of age;

(2) has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year;

(3) is under indictment for a crime punishable by imprisonment for a term exceeding one year;

(4) is a fugitive from justice;

(5) is an unlawful user of or addicted to any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(6) has been adjudicated a mental defective or who has been committed to a mental institution;

(7) is an alien, other than an alien who—

(A) is lawfully admitted for permanent residence (as defined in section 101 (a)(20) of the Immigration and Nationality Act);

(B) is in lawful nonimmigrant status, is a refugee admitted under section 207 of the Immigration and Nationality Act (8 U.S.C. 1157), or is in asylum status under section 208 of the Immigration and Nationality Act (8 U.S.C. 1158), and—

(i) is a foreign law enforcement officer of a friendly foreign government, as determined by the Secretary[2] in consultation with the Secretary of State, entering the United States on official law enforcement business, and the shipping, transporting, possession, or receipt of explosive materials is in furtherance of this official law enforcement business; or

(ii) is a person having the power to direct or cause the direction of the management and policies of a corporation, partnership, or association licensed pursuant to section 843(a), and the shipping, transporting, possession, or receipt of explosive materials is in furtherance of such power;

(C) is a member of a North Atlantic Treaty Organization (NATO) or other friendly foreign military force, as determined by the Attorney General in consultation with the Secretary of Defense, who is present in the United States under military orders for training or other military purpose authorized by the United States and the shipping, transporting, possession, or receipt of explosive materials is in furtherance of the authorized military purpose; or

(D) is lawfully present in the United States in cooperation with the Director of Central Intelligence, and the

[2] So in original. Probably should be "Attorney General".

shipment, transportation, receipt, or possession of the explosive materials is in furtherance of such cooperation;

(8) has been discharged from the armed forces under dishonorable conditions;

(9) having been a citizen of the United States, has renounced the citizenship of that person.

(e) It shall be unlawful for any licensee knowingly to distribute any explosive materials to any person in any State where the purchase, possession, or use by such person of such explosive materials would be in violation of any State law or any published ordinance applicable at the place of distribution.

(f) It shall be unlawful for any licensee or permittee willfully to manufacture, import, purchase, distribute, or receive explosive materials without making such records as the Attorney General may by regulation require, including, but not limited to, a statement of intended use, the name, date, place of birth, social security number or taxpayer identification number, and place of residence of any natural person to whom explosive materials are distributed. If explosive materials are distributed to a corporation or other business entity, such records shall include the identity and principal and local places of business and the name, date, place of birth, and place of residence of the natural person acting as agent of the corporation or other business entity in arranging the distribution.

(g) It shall be unlawful for any licensee or permittee knowingly to make any false entry in any record which he is required to keep pursuant to this section or regulations promulgated under section 847 of this title.

(h) It shall be unlawful for any person to receive, possess, transport, ship, conceal, store, barter, sell, dispose of, or pledge or accept as security for a loan, any stolen explosive materials which are moving as, which are part of, which constitute, or which have been shipped or transported in, interstate or foreign commerce, either before or after such materials were stolen, knowing or having reasonable cause to believe that the explosive materials were stolen.

(i) It shall be unlawful for any person—

(1) who is under indictment for, or who has been convicted in any court of, a crime punishable by imprisonment for a term exceeding one year;

(2) who is a fugitive from justice;

(3) who is an unlawful user of or addicted to any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(4) who has been adjudicated as a mental defective or who has been committed to a mental institution;

(5) who is an alien, other than an alien who—

(A) is lawfully admitted for permanent residence (as that term is defined in section 101(a)(20) of the Immigration and Nationality Act);

(B) is in lawful nonimmigrant status, is a refugee admitted under section 207 of the Immigration and Nationality Act (8 U.S.C. 1157), or is in asylum status under section 208 of the Immigration and Nationality Act (8 U.S.C. 1158), and—

(i) is a foreign law enforcement officer of a friendly foreign government, as determined by the Secretary[3] in consultation with the Secretary of State, entering the United States on official law enforcement business, and the shipping, transporting, possession, or receipt of explosive materials is in furtherance of this official law enforcement business; or

(ii) is a person having the power to direct or cause the direction of the management and policies of a corporation, partnership, or association licensed pursuant to section 843(a), and the shipping, transporting, possession, or receipt of explosive materials is in furtherance of such power;

(C) is a member of a North Atlantic Treaty Organization (NATO) or other friendly foreign military force, as determined by the Attorney General in consultation with the Secretary of Defense, who is present in the United States under military orders for training or other military purpose authorized by the United States and the shipping, transporting, possession, or receipt of explosive materials is in furtherance of the authorized military purpose; or

(D) is lawfully present in the United States in cooperation with the Director of Central Intelligence, and the shipment, transportation, receipt, or possession of the explosive materials is in furtherance of such cooperation;

(6) who has been discharged from the armed forces under dishonorable conditions;

(7) who, having been a citizen of the United States, has renounced the citizenship of that person;

to ship or transport any explosive in or affecting interstate or foreign commerce or to receive or possess any explosive which has been shipped or transported in or affecting interstate or foreign commerce.

(j) It shall be unlawful for any person to store any explosive material in a manner not in conformity with regulations promulgated by the Attorney General. In promulgating such regulations, the Attorney General shall take into consideration the class, type, and quantity of explosive materials to be stored, as well as the standards of safety and security recognized in the explosives industry.

(k) It shall be unlawful for any person who has knowledge of the theft or loss of any explosive materials from his stock, to fail to report such theft or loss within twenty-four hours of discovery thereof, to the Attorney General and to appropriate local authorities.

(l) It shall be unlawful for any person to manufacture any plastic explosive that does not contain a detection agent.

(m)(1) It shall be unlawful for any person to import or bring into the United States, or export from the United States, any plastic explosive that does not contain a detection agent.

(2) This subsection does not apply to the importation or bringing into the United States, or the exportation from the United States, of any plastic explosive that was imported or brought into, or manufactured in the United States prior to the date of enactment of

[3] So in original. Probably should be "Attorney General".

this subsection by or on behalf of any agency of the United States performing military or police functions (including any military reserve component) or by or on behalf of the National Guard of any State, not later than 15 years after the date of entry into force of the Convention on the Marking of Plastic Explosives, with respect to the United States.

(n)(1) It shall be unlawful for any person to ship, transport, transfer, receive, or possess any plastic explosive that does not contain a detection agent.

(2) This subsection does not apply to—

(A) the shipment, transportation, transfer, receipt, or possession of any plastic explosive that was imported or brought into, or manufactured in the United States prior to the date of enactment of this subsection by any person during the period beginning on that date and ending 3 years after that date of enactment; or

(B) the shipment, transportation, transfer, receipt, or possession of any plastic explosive that was imported or brought into, or manufactured in the United States prior to the date of enactment of this subsection by or on behalf of any agency of the United States performing a military or police function (including any military reserve component) or by or on behalf of the National Guard of any State, not later than 15 years after the date of entry into force of the Convention on the Marking of Plastic Explosives, with respect to the United States.

(o) It shall be unlawful for any person, other than an agency of the United States (including any military reserve component) or the National Guard of any State, possessing any plastic explosive on the date of enactment of this subsection, to fail to report to the Attorney General within 120 days after such date of enactment the quantity of such explosives possessed, the manufacturer or importer, any marks of identification on such explosives, and such other information as the Attorney General may prescribe by regulation.

(p) DISTRIBUTION OF INFORMATION RELATING TO EXPLOSIVES, DESTRUCTIVE DEVICES, AND WEAPONS OF MASS DESTRUCTION.—

(1) DEFINITIONS.—In this subsection—

(A) the term ''destructive device'' has the same meaning as in section 921(a)(4);

(B) the term ''explosive'' has the same meaning as in section 844(j); and

(C) the term ''weapon of mass destruction'' has the same meaning as in section 2332a(c)(2).

(2) PROHIBITION.—It shall be unlawful for any person—

(A) to teach or demonstrate the making or use of an explosive, a destructive device, or a weapon of mass destruction, or to distribute by any means information pertaining to, in whole or in part, the manufacture or use of an explosive, destructive device, or weapon of mass destruction, with the intent that the teaching, demonstration, or information be used for, or in furtherance of, an activity that constitutes a Federal crime of violence; or

(B) to teach or demonstrate to any person the making or use of an explosive, a destructive device, or a weapon of

mass destruction, or to distribute to any person, by any means, information pertaining to, in whole or in part, the manufacture or use of an explosive, destructive device, or weapon of mass destruction, knowing that such person intends to use the teaching, demonstration, or information for, or in furtherance of, an activity that constitutes a Federal crime of violence.

18 U.S.C. § 872
Extortion by public officials

Chapter 41. Extortion and Threats

§ 872. Extortion by officers or employees of the United States [1]

Whoever, being an officer, or employee of the United States or any department or agency thereof, or representing himself to be or assuming to act as such, under color or pretense of office or employment commits or attempts an act of extortion, shall be fined under this title or imprisoned not more than three years, or both; but if the amount so extorted or demanded does not exceed $1,000, he shall be fined under this title or imprisoned not more than one year, or both.

[1] June 25, 1948, c. 645, 62 Stat. 740; Oct. 31, 1951, c. 655, § 24(b), 65 Stat. 720; Sept. 13, 1994, Public Law 103–322, Title XXXIII, § 330016(1)(G), (K), 108 Stat. 2147; Oct. 11, 1996, Public Law 104–294, Title VI, § 606(a), 110 Stat. 3511.

18 U.S.C. § 912
Impersonating a Federal official

Chapter 43. False Personation

§ 912. Officer or employee of the United States[1]

Whoever falsely assumes or pretends to be an officer or employee acting under the authority of the United States or any department, agency or officer thereof, and acts as such, or in such pretended character demands or obtains any money, paper, document, or thing of value, shall be fined under this title or imprisoned not more than three years, or both.

[1] June 25, 1948, c. 645, 62 Stat. 742; Sept. 13, 1994, Public Law 103–322, Title XXXIII, § 330016(1)(H), 108 Stat. 2147.

Chapter 44. Firearms

§ 922. Unlawful acts [1]

(a) It shall be unlawful—

(1) for any person—

(A) except a licensed importer, licensed manufacturer, or licensed dealer, to engage in the business of importing, manufacturing, or dealing in firearms, or in the course of such business to ship, transport, or receive any firearm in interstate or foreign commerce; or

(B) except a licensed importer or licensed manufacturer, to engage in the business of importing or manufacturing ammunition, or in the course of such business, to ship, transport, or receive any ammunition in interstate or foreign commerce;

(2) for any importer, manufacturer, dealer, or collector licensed under the provisions of this chapter to ship or transport in interstate or foreign commerce any firearm to any person other than a licensed importer, licensed manufacturer, licensed dealer, or licensed collector, except that—

(A) this paragraph and subsection (b)(3) shall not be held to preclude a licensed importer, licensed manufacturer, licensed dealer, or licensed collector from returning a firearm or replacement firearm of the same kind and type to a person from whom it was received; and this paragraph shall not be held to preclude an individual from mailing a firearm owned in compliance with Federal, State, and local law to a licensed importer, licensed manufacturer, licensed dealer, or licensed collector;

(B) this paragraph shall not be held to preclude a licensed importer, licensed manufacturer, or licensed dealer from depositing a firearm for conveyance in the mails to

[1] Added by Public Law 90–351, Title IV, § 902, June 19, 1968, 82 Stat. 228, and amended by Public Law 90–618, Title I, § 102, Oct. 22, 1968, 82 Stat. 1216; Public Law 97–377, Title I, § 165(a), Dec. 21, 1982, 96 Stat. 1923; Public Law 99–308, § 102, May 19, 1986, 100 Stat. 451; Public Law 99–408, § 2, Aug. 28, 1986, 100 Stat. 920; Public Law 100–649, § 2(a), (f)(2)(A), Nov. 10, 1988, 102 Stat. 3816, 3818; Public Law 100–690, Title VII, § 7060(c), Nov. 18, 1988, 102 Stat. 4404; Public Law 101–647, Title XVII, § 1702(b)(1), Title XXII, §§ 2201, 2202, 2204(b), Title XXXV, § 3524, Nov. 29, 1990, 104 Stat. 4844, 4856, 4857, 4924; Public Law 103–159, Title I, § 102(a)(1), (b), Title III, § 302(a) to (c), Nov. 30, 1993, 107 Stat. 1536, 1539, 1545; Public Law 103–322, Title XI, §§ 110102(a), 110103(a), 110106, 110201(a), 110401(b), (c), 110511, 110514, Title XXXII, §§ 320904, 320927, Title XXXIII, § 330011(i), Sept. 13, 1994, 108 Stat. 1996, 1998, 2000, 2010, 2014, 2019, 2125, 2131, 2145; Public Law 104–208, Div. A, Title I, § 101(f) [Title VI, §§ 657, 658(b)], Sept. 30, 1996, 110 Stat. 3009–369, 3009–372; Public Law 104–294, Title VI, § 603(b), (c)(1), (d) to (f)(1), (g), Oct. 11, 1996, 110 Stat. 3503, 3504; Public Law 105–277, Div. A, § 101(b) [Title I, § 121], Oct. 21, 1998, 112 Stat. 2681–71; Public Law 107–273, Div. B, Title IV, § 4003(a)(1), Nov. 2, 2002, 116 Stat. 1811; Public Law 107–296, Title XI, § 1112(f)(4), (6), Nov. 25, 2002, 116 Stat. 2276.

any officer, employee, agent, or watchman who, pursuant to the provisions of section 1715 of this title, is eligible to receive through the mails pistols, revolvers, and other firearms capable of being concealed on the person, for use in connection with his official duty; and

(C) nothing in this paragraph shall be construed as applying in any manner in the District of Columbia, the Commonwealth of Puerto Rico, or any possession of the United States differently than it would apply if the District of Columbia, the Commonwealth of Puerto Rico, or the possession were in fact a State of the United States;

(3) for any person, other than a licensed importer, licensed manufacturer, licensed dealer, or licensed collector to transport into or receive in the State where he resides (or if the person is a corporation or other business entity, the State where it maintains a place of business) any firearm purchased or otherwise obtained by such person outside that State, except that this paragraph (A) shall not preclude any person who lawfully acquires a firearm by bequest or intestate succession in a State other than his State of residence from transporting the firearm into or receiving it in that State, if it is lawful for such person to purchase or possess such firearm in that State, (B) shall not apply to the transportation or receipt of a firearm obtained in conformity with subsection (b)(3) of this section, and (C) shall not apply to the transportation of any firearm acquired in any State prior to the effective date of this chapter;

(4) for any person, other than a licensed importer, licensed manufacturer, licensed dealer, or licensed collector, to transport in interstate or foreign commerce any destructive device, machinegun (as defined in section 5845 of the Internal Revenue Code of 1986), short-barreled shotgun, or short-barreled rifle, except as specifically authorized by the Attorney General consistent with public safety and necessity;

(5) for any person (other than a licensed importer, licensed manufacturer, licensed dealer, or licensed collector) to transfer, sell, trade, give, transport, or deliver any firearm to any person (other than a licensed importer, licensed manufacturer, licensed dealer, or licensed collector) who the transferor knows or has reasonable cause to believe does not reside in (or if the person is a corporation or other business entity, does not maintain a place of business in) the State in which the transferor resides; except that this paragraph shall not apply to (A) the transfer, transportation, or delivery of a firearm made to carry out a bequest of a firearm to, or an acquisition by intestate succession of a firearm by, a person who is permitted to acquire or possess a firearm under the laws of the State of his residence, and (B) the loan or rental of a firearm to any person for temporary use for lawful sporting purposes;

(6) for any person in connection with the acquisition or attempted acquisition of any firearm or ammunition from a licensed importer, licensed manufacturer, licensed dealer, or licensed collector, knowingly to make any false or fictitious oral

or written statement or to furnish or exhibit any false, fictitious, or misrepresented identification, intended or likely to deceive such importer, manufacturer, dealer, or collector with respect to any fact material to the lawfulness of the sale or other disposition of such firearm or ammunition under the provisions of this chapter;

(7) for any person to manufacture or import armor piercing ammunition, except that this paragraph shall not apply to—

(A) the manufacture or importation of such ammunition for the use of the United States or any department or agency thereof or any State or any department, agency, or political subdivision thereof;

(B) the manufacture of such ammunition for the purpose of exportation; and

(C) any manufacture or importation for the purposes of testing or experimentation authorized by the Attorney General;

(8) for any manufacturer or importer to sell or deliver armor piercing ammunition, except that this paragraph shall not apply to—

(A) the sale or delivery by a manufacturer or importer of such ammunition for use of the United States or any department or agency thereof or any State or any department, agency, or political subdivision thereof;

(B) the sale or delivery by a manufacturer or importer of such ammunition for the purpose of exportation;

(C) the sale or delivery by a manufacturer or importer of such ammunition for the purposes of testing or experimenting authorized by the Attorney General; and

(9) for any person, other than a licensed importer, licensed manufacturer, licensed dealer, or licensed collector, who does not reside in any State to receive any firearms unless such receipt is for lawful sporting purposes.

(b) It shall be unlawful for any licensed importer, licensed manufacturer, licensed dealer, or licensed collector to sell or deliver—

(1) any firearm or ammunition to any individual who the licensee knows or has reasonable cause to believe is less than eighteen years of age, and, if the firearm, or ammunition is other than a shotgun or rifle, or ammunition for a shotgun or rifle, to any individual who the licensee knows or has reasonable cause to believe is less than twenty-one years of age;

(2) any firearm to any person in any State where the purchase or possession by such person of such firearm would be in violation of any State law or any published ordinance applicable at the place of sale, delivery or other disposition, unless the licensee knows or has reasonable cause to believe that the purchase or possession would not be in violation of such State law or such published ordinance;

(3) any firearm to any person who the licensee knows or has reasonable cause to believe does not reside in (or if the person is a corporation or other business entity, does not maintain a place of business in) the State in which the licensee's place of business is located, except that this paragraph (A) shall not

apply to the sale or delivery of any rifle or shotgun to a resident of a State other than a State in which the licensee's place of business is located if the transferee meets in person with the transferor to accomplish the transfer, and the sale, delivery, and receipt fully comply with the legal conditions of sale in both such States (and any licensed manufacturer, importer or dealer shall be presumed, for purposes of this subparagraph, in the absence of evidence to the contrary, to have had actual knowledge of the State laws and published ordinances of both States), and (B) shall not apply to the loan or rental of a firearm to any person for temporary use for lawful sporting purposes;

(4) to any person any destructive device, machinegun (as defined in section 5845 of the Internal Revenue Code of 1986), short-barreled shotgun, or short-barreled rifle, except as specifically authorized by the Attorney General consistent with public safety and necessity; and

(5) any firearm or armor-piercing ammunition to any person unless the licensee notes in his records, required to be kept pursuant to section 923 of this chapter, the name, age, and place of residence of such person if the person is an individual, or the identity and principal and local places of business of such person if the person is a corporation or other business entity.

Paragraphs (1), (2), (3), and (4) of this subsection shall not apply to transactions between licensed importers, licensed manufacturers, licensed dealers, and licensed collectors. Paragraph (4) of this subsection shall not apply to a sale or delivery to any research organization designated by the Attorney General.

(c) In any case not otherwise prohibited by this chapter, a licensed importer, licensed manufacturer, or licensed dealer may sell a firearm to a person who does not appear in person at the licensee's business premises (other than another licensed importer, manufacturer, or dealer) only if—

(1) the transferee submits to the transferor a sworn statement in the following form:

"Subject to penalties provided by law, I swear that, in the case of any firearm other than a shotgun or a rifle, I am twenty-one years or more of age, or that, in the case of a shotgun or a rifle, I am eighteen years or more of age; that I am not prohibited by the provisions of chapter 44 of title 18, United States Code, from receiving a firearm in interstate or foreign commerce; and that my receipt of this firearm will not be in violation of any statute of the State and published ordinance applicable to the locality in which I reside. Further, the true title, name, and address of the principal law enforcement officer of the locality to which the firearm will be delivered are .....

Signature ..... Date ....."

and containing blank spaces for the attachment of a true copy of any permit or other information required pursuant to such statute or published ordinance;

(2) the transferor has, prior to the shipment or delivery of the firearm, forwarded by registered or certified mail (return

receipt requested) a copy of the sworn statement, together with a description of the firearm, in a form prescribed by the Attorney General, to the chief law enforcement officer of the transferee's place of residence, and has received a return receipt evidencing delivery of the statement or has had the statement returned due to the refusal of the named addressee to accept such letter in accordance with United States Post Office Department regulations; and

(3) the transferor has delayed shipment or delivery for a period of at least seven days following receipt of the notification of the acceptance or refusal of delivery of the statement.

A copy of the sworn statement and a copy of the notification to the local law enforcement officer, together with evidence of receipt or rejection of that notification shall be retained by the licensee as a part of the records required to be kept under section 923(g).

(d) It shall be unlawful for any person to sell or otherwise dispose of any firearm or ammunition to any person knowing or having reasonable cause to believe that such person—

(1) is under indictment for, or has been convicted in any court of, a crime punishable by imprisonment for a term exceeding one year;

(2) is a fugitive from justice;

(3) is an unlawful user of or addicted to any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(4) has been adjudicated as a mental defective or has been committed to any mental institution;

(5) who, being an alien—

(A) is illegally or unlawfully in the United States; or

(B) except as provided in subsection (y)(2), has been admitted to the United States under a nonimmigrant visa (as that term is defined in section 101(a)(26) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(26)));

(6) who[2] has been discharged from the Armed Forces under dishonorable conditions;

(7) who, having been a citizen of the United States, has renounced his citizenship;

(8) is subject to a court order that restrains such person from harassing, stalking, or threatening an intimate partner of such person or child of such intimate partner or person, or engaging in other conduct that would place an intimate partner in reasonable fear of bodily injury to the partner or child, except that this paragraph shall only apply to a court order that—

(A) was issued after a hearing of which such person received actual notice, and at which such person had the opportunity to participate; and

(B)(i) includes a finding that such person represents a credible threat to the physical safety of such intimate partner or child; or

[2] So in original. The word "who" probably should not appear.

(ii) by its terms explicitly prohibits the use, attempted use, or threatened use of physical force against such intimate partner or child that would reasonably be expected to cause bodily injury; or

(9) has been convicted in any court of a misdemeanor crime of domestic violence.

This subsection shall not apply with respect to the sale or disposition of a firearm or ammunition to a licensed importer, licensed manufacturer, licensed dealer, or licensed collector who pursuant to subsection (b) of section 925 of this chapter is not precluded from dealing in firearms or ammunition, or to a person who has been granted relief from disabilities pursuant to subsection (c) of section 925 of this chapter.

(e) It shall be unlawful for any person knowingly to deliver or cause to be delivered to any common or contract carrier for transportation or shipment in interstate or foreign commerce, to persons other than licensed importers, licensed manufacturers, licensed dealers, or licensed collectors, any package or other container in which there is any firearm or ammunition without written notice to the carrier that such firearm or ammunition is being transported or shipped; except that any passenger who owns or legally possesses a firearm or ammunition being transported aboard any common or contract carrier for movement with the passenger in interstate or foreign commerce may deliver said firearm or ammunition into the custody of the pilot, captain, conductor or operator of such common or contract carrier for the duration of the trip without violating any of the provisions of this chapter. No common or contract carrier shall require or cause any label, tag, or other written notice to be placed on the outside of any package, luggage, or other container that such package, luggage, or other container contains a firearm.

(f)(1) It shall be unlawful for any common or contract carrier to transport or deliver in interstate or foreign commerce any firearm or ammunition with knowledge or reasonable cause to believe that the shipment, transportation, or receipt thereof would be in violation of the provisions of this chapter.

(2) It shall be unlawful for any common or contract carrier to deliver in interstate or foreign commerce any firearm without obtaining written acknowledgement of receipt from the recipient of the package or other container in which there is a firearm.

(g) It shall be unlawful for any person—

(1) who has been convicted in any court of, a crime punishable by imprisonment for a term exceeding one year;

(2) who is a fugitive from justice;

(3) who is an unlawful user of or addicted to any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(4) who has been adjudicated as a mental defective or who has been committed to a mental institution;

(5) who, being an alien—

(A) is illegally or unlawfully in the United States; or

(B) except as provided in subsection (y)(2), has been admitted to the United States under a nonimmigrant visa (as

that term is defined in section 101(a)(26) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(26)));

(6) who has been discharged from the Armed Forces under dishonorable conditions;

(7) who, having been a citizen of the United States, has renounced his citizenship;

(8) who is subject to a court order that—

(A) was issued after a hearing of which such person received actual notice, and at which such person had an opportunity to participate;

(B) restrains such person from harassing, stalking, or threatening an intimate partner of such person or child of such intimate partner or person, or engaging in other conduct that would place an intimate partner in reasonable fear of bodily injury to the partner or child; and

(C)(i) includes a finding that such person represents a credible threat to the physical safety of such intimate partner or child; or

(ii) by its terms explicitly prohibits the use, attempted use, or threatened use of physical force against such intimate partner or child that would reasonably be expected to cause bodily injury; or

(9) who has been convicted in any court of a misdemeanor crime of domestic violence,

to ship or transport in interstate or foreign commerce, or possess in or affecting commerce, any firearm or ammunition; or to receive any firearm or ammunition which has been shipped or transported in interstate or foreign commerce.

(h) It shall be unlawful for any individual, who to that individual's knowledge and while being employed for any person described in any paragraph of subsection (g) of this section, in the course of such employment—

(1) to receive, possess, or transport any firearm or ammunition in or affecting interstate or foreign commerce; or

(2) to receive any firearm or ammunition which has been shipped or transported in interstate or foreign commerce.

(i) It shall be unlawful for any person to transport or ship in interstate or foreign commerce, any stolen firearm or stolen ammunition, knowing or having reasonable cause to believe that the firearm or ammunition was stolen.

(j) It shall be unlawful for any person to receive, possess, conceal, store, barter, sell, or dispose of any stolen firearm or stolen ammunition, or pledge or accept as security for a loan any stolen firearm or stolen ammunition, which is moving as, which is a part of, which constitutes, or which has been shipped or transported in, interstate or foreign commerce, either before or after it was stolen, knowing or having reasonable cause to believe that the firearm or ammunition was stolen.

(k) It shall be unlawful for any person knowingly to transport, ship, or receive, in interstate or foreign commerce, any firearm which has had the importer's or manufacturer's serial number removed, obliterated, or altered or to possess or receive any firearm

which has had the importer's or manufacturer's serial number removed, obliterated, or altered and has, at any time, been shipped or transported in interstate or foreign commerce.

(l) Except as provided in section 925(d) of this chapter, it shall be unlawful for any person knowingly to import or bring into the United States or any possession thereof any firearm or ammunition; and it shall be unlawful for any person knowingly to receive any firearm or ammunition which has been imported or brought into the United States or any possession thereof in violation of the provisions of this chapter.

(m) It shall be unlawful for any licensed importer, licensed manufacturer, licensed dealer, or licensed collector knowingly to make any false entry in, to fail to make appropriate entry in, or to fail to properly maintain, any record which he is required to keep pursuant to section 923 of this chapter or regulations promulgated thereunder.

(n) It shall be unlawful for any person who is under indictment for a crime punishable by imprisonment for a term exceeding one year to ship or transport in interstate or foreign commerce any firearm or ammunition or receive any firearm or ammunition which has been shipped or transported in interstate or foreign commerce.

(o)(1) Except as provided in paragraph (2), it shall be unlawful for any person to transfer or possess a machinegun.

(2) This subsection does not apply with respect to—

(A) a transfer to or by, or possession by or under the authority of, the United States or any department or agency thereof or a State, or a department, agency, or political subdivision thereof; or

(B) any lawful transfer or lawful possession of a machinegun that was lawfully possessed before the date this subsection takes effect.

(p)(1) It shall be unlawful for any person to manufacture, import, sell, ship, deliver, possess, transfer, or receive any firearm—

(A) that, after removal of grips, stocks, and magazines, is not as detectable as the Security Exemplar, by walk-through metal detectors calibrated and operated to detect the Security Exemplar; or

(B) any major component of which, when subjected to inspection by the types of x-ray machines commonly used at airports, does not generate an image that accurately depicts the shape of the component. Barium sulfate or other compounds may be used in the fabrication of the component.

(2) For purposes of this subsection—

(A) the term ''firearm'' does not include the frame or receiver of any such weapon;

(B) the term ''major component'' means, with respect to a firearm, the barrel, the slide or cylinder, or the frame or receiver of the firearm; and

(C) the term ''Security Exemplar'' means an object, to be fabricated at the direction of the Attorney General, that is—

(i) constructed of, during the 12-month period beginning on the date of the enactment of this subsection, 3.7 ounces of material type 17–4 PH stainless steel in a shape resembling a handgun; and

(ii) suitable for testing and calibrating metal detectors: *Provided, however,* That at the close of such 12-month period, and at appropriate times thereafter the Attorney General shall promulgate regulations to permit the manufacture, importation, sale, shipment, delivery, possession, transfer, or receipt of firearms previously prohibited under this subparagraph that are as detectable as a "Security Exemplar" which contains 3.7 ounces of material type 17–4 PH stainless steel, in a shape resembling a handgun, or such lesser amount as is detectable in view of advances in state-of-the-art developments in weapons detection technology.

(3) Under such rules and regulations as the Attorney General shall prescribe, this subsection shall not apply to the manufacture, possession, transfer, receipt, shipment, or delivery of a firearm by a licensed manufacturer or any person acting pursuant to a contract with a licensed manufacturer, for the purpose of examining and testing such firearm to determine whether paragraph (1) applies to such firearm. The Attorney General shall ensure that rules and regulations adopted pursuant to this paragraph do not impair the manufacture of prototype firearms or the development of new technology.

(4) The Attorney General shall permit the conditional importation of a firearm by a licensed importer or licensed manufacturer, for examination and testing to determine whether or not the unconditional importation of such firearm would violate this subsection.

(5) This subsection shall not apply to any firearm which—

(A) has been certified by the Secretary of Defense or the Director of Central Intelligence, after consultation with the Attorney General and the Administrator of the Federal Aviation Administration, as necessary for military or intelligence applications; and

(B) is manufactured for and sold exclusively to military or intelligence agencies of the United States.

(6) This subsection shall not apply with respect to any firearm manufactured in, imported into, or possessed in the United States before the date of the enactment of the Undetectable Firearms Act of 1988.

(q)(1) The Congress finds and declares that—

(A) crime, particularly crime involving drugs and guns, is a pervasive, nationwide problem;

(B) crime at the local level is exacerbated by the interstate movement of drugs, guns, and criminal gangs;

(C) firearms and ammunition move easily in interstate commerce and have been found in increasing numbers in and around schools, as documented in numerous hearings in both the Committee on the Judiciary the[3] House of Representatives and the Committee on the Judiciary of the Senate;

(D) in fact, even before the sale of a firearm, the gun, its component parts, ammunition, and the raw materials from which they are made have considerably moved in interstate commerce;

(E) while criminals freely move from State to State, ordinary citizens and foreign visitors may fear to travel to or through

[3] So in original. Probably should be "of the".

certain parts of the country due to concern about violent crime and gun violence, and parents may decline to send their children to school for the same reason;

(F) the occurrence of violent crime in school zones has resulted in a decline in the quality of education in our country;

(G) this decline in the quality of education has an adverse impact on interstate commerce and the foreign commerce of the United States;

(H) States, localities, and school systems find it almost impossible to handle gun-related crime by themselves—even States, localities, and school systems that have made strong efforts to prevent, detect, and punish gun-related crime find their efforts unavailing due in part to the failure or inability of other States or localities to take strong measures; and

(I) the Congress has the power, under the interstate commerce clause and other provisions of the Constitution, to enact measures to ensure the integrity and safety of the Nation's schools by enactment of this subsection.

(2)(A) It shall be unlawful for any individual knowingly to possess a firearm that has moved in or that otherwise affects interstate or foreign commerce at a place that the individual knows, or has reasonable cause to believe, is a school zone.

(B) Subparagraph (A) does not apply to the possession of a firearm—

(i) on private property not part of school grounds;

(ii) if the individual possessing the firearm is licensed to do so by the State in which the school zone is located or a political subdivision of the State, and the law of the State or political subdivision requires that, before an individual obtains such a license, the law enforcement authorities of the State or political subdivision verify that the individual is qualified under law to receive the license;

(iii) that is—

(I) not loaded; and

(II) in a locked container, or a locked firearms rack that is on a motor vehicle;

(iv) by an individual for use in a program approved by a school in the school zone;

(v) by an individual in accordance with a contract entered into between a school in the school zone and the individual or an employer of the individual;

(vi) by a law enforcement officer acting in his or her official capacity; or

(vii) that is unloaded and is possessed by an individual while traversing school premises for the purpose of gaining access to public or private lands open to hunting, if the entry on school premises is authorized by school authorities.

(3)(A) Except as provided in subparagraph (B), it shall be unlawful for any person, knowingly or with reckless disregard for the safety of another, to discharge or attempt to discharge a firearm that has moved in or that otherwise affects interstate or foreign commerce at a place that the person knows is a school zone.

(B) Subparagraph (A) does not apply to the discharge of a firearm—

(i) on private property not part of school grounds;

(ii) as part of a program approved by a school in the school zone, by an individual who is participating in the program;

(iii) by an individual in accordance with a contract entered into between a school in a school zone and the individual or an employer of the individual; or

(iv) by a law enforcement officer acting in his or her official capacity.

(4) Nothing in this subsection shall be construed as preempting or preventing a State or local government from enacting a statute establishing gun free school zones as provided in this subsection.

(r) It shall be unlawful for any person to assemble from imported parts any semiautomatic rifle or any shotgun which is identical to any rifle or shotgun prohibited from importation under section 925(d)(3) of this chapter as not being particularly suitable for or readily adaptable to sporting purposes except that this subsection shall not apply to—

(1) the assembly of any such rifle or shotgun for sale or distribution by a licensed manufacturer to the United States or any department or agency thereof or to any State or any department, agency, or political subdivision thereof; or

(2) the assembly of any such rifle or shotgun for the purposes of testing or experimentation authorized by the Attorney General.

(s)(1) Beginning on the date that is 90 days after the date of enactment of this subsection and ending on the day before the date that is 60 months after such date of enactment, it shall be unlawful for any licensed importer, licensed manufacturer, or licensed dealer to sell, deliver, or transfer a handgun (other than the return of a handgun to the person from whom it was received) to an individual who is not licensed under section 923, unless—

(A) after the most recent proposal of such transfer by the transferee—

(i) the transferor has—

(I) received from the transferee a statement of the transferee containing the information described in paragraph (3);

(II) verified the identity of the transferee by examining the identification document presented;

(III) within 1 day after the transferee furnishes the statement, provided notice of the contents of the statement to the chief law enforcement officer of the place of residence of the transferee; and

(IV) within 1 day after the transferee furnishes the statement, transmitted a copy of the statement to the chief law enforcement officer of the place of residence of the transferee; and

(ii)(I) 5 business days (meaning days on which State offices are open) have elapsed from the date the transferor furnished notice of the contents of the statement to the chief law enforcement officer, during which period the transferor has not received information from the chief law

enforcement officer that receipt or possession of the handgun by the transferee would be in violation of Federal, State, or local law; or

(II) the transferor has received notice from the chief law enforcement officer that the officer has no information indicating that receipt or possession of the handgun by the transferee would violate Federal, State, or local law;

(B) the transferee has presented to the transferor a written statement, issued by the chief law enforcement officer of the place of residence of the transferee during the 10-day period ending on the date of the most recent proposal of such transfer by the transferee, stating that the transferee requires access to a handgun because of a threat to the life of the transferee or of any member of the household of the transferee;

(C)(i) the transferee has presented to the transferor a permit that—

(I) allows the transferee to possess or acquire a handgun; and

(II) was issued not more than 5 years earlier by the State in which the transfer is to take place; and

(ii) the law of the State provides that such a permit is to be issued only after an authorized government official has verified that the information available to such official does not indicate that possession of a handgun by the transferee would be in violation of the law;

(D) the law of the State requires that, before any licensed importer, licensed manufacturer, or licensed dealer completes the transfer of a handgun to an individual who is not licensed under section 923, an authorized government official verify that the information available to such official does not indicate that possession of a handgun by the transferee would be in violation of law;

(E) the Attorney General has approved the transfer under section 5812 of the Internal Revenue Code of 1986; or

(F) on application of the transferor, the Attorney General has certified that compliance with subparagraph (A)(i)(III) is impracticable because—

(i) the ratio of the number of law enforcement officers of the State in which the transfer is to occur to the number of square miles of land area of the State does not exceed 0.0025;

(ii) the business premises of the transferor at which the transfer is to occur are extremely remote in relation to the chief law enforcement officer; and

(iii) there is an absence of telecommunications facilities in the geographical area in which the business premises are located.

(2) A chief law enforcement officer to whom a transferor has provided notice pursuant to paragraph (1)(A)(i)(III) shall make a reasonable effort to ascertain within 5 business days whether receipt or possession would be in violation of the law, including research in whatever State and local recordkeeping systems are available and in a national system designated by the Attorney General.

(3) The statement referred to in paragraph (1)(A)(i)(I) shall contain only—

(A) the name, address, and date of birth appearing on a valid identification document (as defined in section 1028(d)(1)) of the transferee containing a photograph of the transferee and a description of the identification used;

(B) a statement that the transferee—

(i) is not under indictment for, and has not been convicted in any court of, a crime punishable by imprisonment for a term exceeding 1 year, and has not been convicted in any court of a misdemeanor crime of domestic violence;

(ii) is not a fugitive from justice;

(iii) is not an unlawful user of or addicted to any controlled substance (as defined in section 102 of the Controlled Substances Act);

(iv) has not been adjudicated as a mental defective or been committed to a mental institution;

(v) is not an alien who—

(I) is illegally or unlawfully in the United States; or

(II) subject to subsection (y)(2), has been admitted to the United States under a nonimmigrant visa (as that term is defined in section 101(a)(26) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(26)));

(vi) has not been discharged from the Armed Forces under dishonorable conditions; and

(vii) is not a person who, having been a citizen of the United States, has renounced such citizenship;

(C) the date the statement is made; and

(D) notice that the transferee intends to obtain a handgun from the transferor.

(4) Any transferor of a handgun who, after such transfer, receives a report from a chief law enforcement officer containing information that receipt or possession of the handgun by the transferee violates Federal, State, or local law shall, within 1 business day after receipt of such request, communicate any information related to the transfer that the transferor has about the transfer and the transferee to—

(A) the chief law enforcement officer of the place of business of the transferor; and

(B) the chief law enforcement officer of the place of residence of the transferee.

(5) Any transferor who receives information, not otherwise available to the public, in a report under this subsection shall not disclose such information except to the transferee, to law enforcement authorities, or pursuant to the direction of a court of law.

(6)(A) Any transferor who sells, delivers, or otherwise transfers a handgun to a transferee shall retain the copy of the statement of the transferee with respect to the handgun transaction, and shall retain evidence that the transferor has complied with subclauses (III) and (IV) of paragraph (1)(A)(i) with respect to the statement.

(B) Unless the chief law enforcement officer to whom a statement is transmitted under paragraph (1)(A)(i)(IV) determines that a transaction would violate Federal, State, or local law—

(i) the officer shall, within 20 business days after the date the transferee made the statement on the basis of which the notice was provided, destroy the statement, any record containing information derived from the statement, and any record created as a result of the notice required by paragraph (1)(A)(i)(III);

(ii) the information contained in the statement shall not be conveyed to any person except a person who has a need to know in order to carry out this subsection; and

(iii) the information contained in the statement shall not be used for any purpose other than to carry out this subsection.

(C) If a chief law enforcement officer determines that an individual is ineligible to receive a handgun and the individual requests the officer to provide the reason for such determination, the officer shall provide such reasons to the individual in writing within 20 business days after receipt of the request.

(7) A chief law enforcement officer or other person responsible for providing criminal history background information pursuant to this subsection shall not be liable in an action at law for damages—

(A) for failure to prevent the sale or transfer of a handgun to a person whose receipt or possession of the handgun is unlawful under this section; or

(B) for preventing such a sale or transfer to a person who may lawfully receive or possess a handgun.

(8) For purposes of this subsection, the term "chief law enforcement officer" means the chief of police, the sheriff, or an equivalent officer or the designee of any such individual.

(9) The Attorney General shall take necessary actions to ensure that the provisions of this subsection are published and disseminated to licensed dealers, law enforcement officials, and the public.

(t)(1) Beginning on the date that is 30 days after the Attorney General notifies licensees under section 103(d) of the Brady Handgun Violence Prevention Act that the national instant criminal background check system is established, a licensed importer, licensed manufacturer, or licensed dealer shall not transfer a firearm to any other person who is not licensed under this chapter, unless—

(A) before the completion of the transfer, the licensee contacts the national instant criminal background check system established under section 103 of that Act;

(B)(i) the system provides the licensee with a unique identification number; or

(ii) 3 business days (meaning a day on which State offices are open) have elapsed since the licensee contacted the system, and the system has not notified the licensee that the receipt of a firearm by such other person would violate subsection (g) or (n) of this section; and

(C) the transferor has verified the identity of the transferee by examining a valid identification document (as defined in section 1028(d) of this title) of the transferee containing a photograph of the transferee.

(2) If receipt of a firearm would not violate subsection (g) or (n) or State law, the system shall—

(A) assign a unique identification number to the transfer;

(B) provide the licensee with the number; and

(C) destroy all records of the system with respect to the call (other than the identifying number and the date the number was assigned) and all records of the system relating to the person or the transfer.

(3) Paragraph (1) shall not apply to a firearm transfer between a licensee and another person if—

(A)(i) such other person has presented to the licensee a permit that—

(I) allows such other person to possess or acquire a firearm; and

(II) was issued not more than 5 years earlier by the State in which the transfer is to take place; and

(ii) the law of the State provides that such a permit is to be issued only after an authorized government official has verified that the information available to such official does not indicate that possession of a firearm by such other person would be in violation of law;

(B) the Attorney General has approved the transfer under section 5812 of the Internal Revenue Code of 1986; or

(C) on application of the transferor, the Attorney General has certified that compliance with paragraph (1)(A) is impracticable because—

(i) the ratio of the number of law enforcement officers of the State in which the transfer is to occur to the number of square miles of land area of the State does not exceed 0.0025;

(ii) the business premises of the licensee at which the transfer is to occur are extremely remote in relation to the chief law enforcement officer (as defined in subsection (s)(8)); and

(iii) there is an absence of telecommunications facilities in the geographical area in which the business premises are located.

(4) If the national instant criminal background check system notifies the licensee that the information available to the system does not demonstrate that the receipt of a firearm by such other person would violate subsection (g) or (n) or State law, and the licensee transfers a firearm to such other person, the licensee shall include in the record of the transfer the unique identification number provided by the system with respect to the transfer.

(5) If the licensee knowingly transfers a firearm to such other person and knowingly fails to comply with paragraph (1) of this subsection with respect to the transfer and, at the time such other person most recently proposed the transfer, the national instant criminal background check system was operating and information was available to the system demonstrating that receipt of a firearm by such other person would violate subsection (g) or (n) of this section or State law, the Attorney General may, after notice and opportunity for a hearing, suspend for not more than 6 months or revoke any license issued to the licensee under section 923, and may impose on the licensee a civil fine of not more than $5,000.

(6) Neither a local government nor an employee of the Federal Government or of any State or local government, responsible for

providing information to the national instant criminal background check system shall be liable in an action at law for damages—

(A) for failure to prevent the sale or transfer of a firearm to a person whose receipt or possession of the firearm is unlawful under this section; or

(B) for preventing such a sale or transfer to a person who may lawfully receive or possess a firearm.

(u) It shall be unlawful for a person to steal or unlawfully take or carry away from the person or the premises of a person who is licensed to engage in the business of importing, manufacturing, or dealing in firearms, any firearm in the licensee's business inventory that has been shipped or transported in interstate or foreign commerce.

(v)(1) It shall be unlawful for a person to manufacture, transfer, or possess a semiautomatic assault weapon.

(2) Paragraph (1) shall not apply to the possession or transfer of any semiautomatic assault weapon otherwise lawfully possessed under Federal law on the date of the enactment of this subsection.

(3) Paragraph (1) shall not apply to—

(A) any of the firearms, or replicas or duplicates of the firearms, specified in Appendix A to this section, as such firearms were manufactured on October 1, 1993;

(B) any firearm that—

(i) is manually operated by bolt, pump, lever, or slide action;

(ii) has been rendered permanently inoperable; or

(iii) is an antique firearm;

(C) any semiautomatic rifle that cannot accept a detachable magazine that holds more than 5 rounds of ammunition; or

(D) any semiautomatic shotgun that cannot hold more than 5 rounds of ammunition in a fixed or detachable magazine.

The fact that a firearm is not listed in Appendix A shall not be construed to mean that paragraph (1) applies to such firearm. No firearm exempted by this subsection may be deleted from Appendix A so long as this subsection is in effect.

(4) Paragraph (1) shall not apply to—

(A) the manufacture for, transfer to, or possession by the United States or a department or agency of the United States or a State or a department, agency, or political subdivision of a State, or a transfer to or possession by a law enforcement officer employed by such an entity for purposes of law enforcement (whether on or off duty);

(B) the transfer to a licensee under title I of the Atomic Energy Act of 1954 for purposes of establishing and maintaining an on-site physical protection system and security organization required by Federal law, or possession by an employee or contractor of such licensee on-site for such purposes or off-site for purposes of licensee-authorized training or transportation of nuclear materials;

(C) the possession, by an individual who is retired from service with a law enforcement agency and is not otherwise prohibited from receiving a firearm, of a semiautomatic assault weapon transferred to the individual by the agency upon such retirement; or

(D) the manufacture, transfer, or possession of a semiautomatic assault weapon by a licensed manufacturer or licensed importer for the purposes of testing or experimentation authorized by the Attorney General.

(w)(1) Except as provided in paragraph (2), it shall be unlawful for a person to transfer or possess a large capacity ammunition feeding device.

(2) Paragraph (1) shall not apply to the possession or transfer of any large capacity ammunition feeding device otherwise lawfully possessed on or before the date of the enactment of this subsection.

(3) This subsection shall not apply to—

(A) the manufacture for, transfer to, or possession by the United States or a department or agency of the United States or a State or a department, agency, or political subdivision of a State, or a transfer to or possession by a law enforcement officer employed by such an entity for purposes of law enforcement (whether on or off duty);

(B) the transfer to a licensee under title I of the Atomic Energy Act of 1954 for purposes of establishing and maintaining an on-site physical protection system and security organization required by Federal law, or possession by an employee or contractor of such licensee on-site for such purposes or off-site for purposes of licensee-authorized training or transportation of nuclear materials;

(C) the possession, by an individual who is retired from service with a law enforcement agency and is not otherwise prohibited from receiving ammunition, of a large capacity ammunition feeding device transferred to the individual by the agency upon such retirement; or

(D) the manufacture, transfer, or possession of any large capacity ammunition feeding device by a licensed manufacturer or licensed importer for the purposes of testing or experimentation authorized by the Attorney General.

(4) If a person charged with violating paragraph (1) asserts that paragraph (1) does not apply to such person because of paragraph (2) or (3), the Government shall have the burden of proof to show that such paragraph (1) applies to such person. The lack of a serial number as described in section 923(i) of this title shall be a presumption that the large capacity ammunition feeding device is not subject to the prohibition of possession in paragraph (1).

(x)(1) It shall be unlawful for a person to sell, deliver, or otherwise transfer to a person who the transferor knows or has reasonable cause to believe is a juvenile—

(A) a handgun; or

(B) ammunition that is suitable for use only in a handgun.

(2) It shall be unlawful for any person who is a juvenile to knowingly possess—

(A) a handgun; or

(B) ammunition that is suitable for use only in a handgun.

(3) This subsection does not apply to—

(A) a temporary transfer of a handgun or ammunition to a juvenile or to the possession or use of a handgun or ammunition by a juvenile if the handgun and ammunition are possessed and used by the juvenile—

(i) in the course of employment, in the course of ranching or farming related to activities at the residence of the juvenile (or on property used for ranching or farming at which the juvenile, with the permission of the property owner or lessee, is performing activities related to the operation of the farm or ranch), target practice, hunting, or a course of instruction in the safe and lawful use of a handgun;

(ii) with the prior written consent of the juvenile's parent or guardian who is not prohibited by Federal, State, or local law from possessing a firearm, except—

(I) during transportation by the juvenile of an unloaded handgun in a locked container directly from the place of transfer to a place at which an activity described in clause (i) is to take place and transportation by the juvenile of that handgun, unloaded and in a locked container, directly from the place at which such an activity took place to the transferor; or

(II) with respect to ranching or farming activities as described in clause (i), a juvenile may possess and use a handgun or ammunition with the prior written approval of the juvenile's parent or legal guardian and at the direction of an adult who is not prohibited by Federal, State or local law from possessing a firearm;

(iii) the juvenile has the prior written consent in the juvenile's possession at all times when a handgun is in the possession of the juvenile; and

(iv) in accordance with State and local law;

(B) a juvenile who is a member of the Armed Forces of the United States or the National Guard who possesses or is armed with a handgun in the line of duty;

(C) a transfer by inheritance of title (but not possession) of a handgun or ammunition to a juvenile; or

(D) the possession of a handgun or ammunition by a juvenile taken in defense of the juvenile or other persons against an intruder into the residence of the juvenile or a residence in which the juvenile is an invited guest.

(4) A handgun or ammunition, the possession of which is transferred to a juvenile in circumstances in which the transferor is not in violation of this subsection shall not be subject to permanent confiscation by the Government if its possession by the juvenile subsequently becomes unlawful because of the conduct of the juvenile, but shall be returned to the lawful owner when such handgun or ammunition is no longer required by the Government for the purposes of investigation or prosecution.

(5) For purposes of this subsection, the term "juvenile" means a person who is less than 18 years of age.

(6)(A) In a prosecution of a violation of this subsection, the court shall require the presence of a juvenile defendant's parent or legal guardian at all proceedings.

(B) The court may use the contempt power to enforce subparagraph (A).

(C) The court may excuse attendance of a parent or legal guardian of a juvenile defendant at a proceeding in a prosecution of a violation of this subsection for good cause shown.

(y) Provisions relating to aliens admitted under nonimmigrant visas—

(1) DEFINITIONS.—In this subsection—

(A) the term "alien" has the same meaning as in section 101(a)(3) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(3)); and

(B) the term "nonimmigrant visa" has the same meaning as in section 101(a)(26) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(26)).

(2) EXCEPTIONS.—Subsections (d)(5)(B), (g)(5)(B), and (s)(3)(B)(v)(II) do not apply to any alien who has been lawfully admitted to the United States under a nonimmigrant visa, if that alien is—

(A) admitted to the United States for lawful hunting or sporting purposes or is in possession of a hunting license or permit lawfully issued in the United States;

(B) an official representative of a foreign government who is—

(i) accredited to the United States Government or the Government's mission to an international organization having its headquarters in the United States; or

(ii) en route to or from another country to which that alien is accredited;

(C) an official of a foreign government or a distinguished foreign visitor who has been so designated by the Department of State; or

(D) a foreign law enforcement officer of a friendly foreign government entering the United States on official law enforcement business.

(3) WAIVER—

(A) CONDITIONS FOR WAIVER.—Any individual who has been admitted to the United States under a nonimmigrant visa may receive a waiver from the requirements of subsection (g)(5), if—

(i) the individual submits to the Attorney General a petition that meets the requirements of subparagraph (C); and

(ii) the Attorney General approves the petition.

(B) PETITION.—Each petition under subparagraph (B) shall—

(i) demonstrate that the petitioner has resided in the United States for a continuous period of not less than 180 days before the date on which the petition is submitted under this paragraph; and

(ii) include a written statement from the embassy or consulate of the petitioner, authorizing the petitioner to acquire a firearm or ammunition and certifying that the alien would not, absent the application of subsection (g)(5)(B), otherwise be prohibited from such acquisition under subsection (g).

(C) APPROVAL OF PETITION.—The Attorney General shall approve a petition submitted in accordance with this paragraph,

if the Attorney General determines that waiving the requirements of subsection (g)(5)(B) with respect to the petitioner—

(i) would be in the interests of justice; and

(ii) would not jeopardize the public safety.

APPENDIX A

Centerfire Rifles—Autoloaders

Browning BAR Mark II Safari Semi-Auto Rifle
Browning BAR Mark II Safari Magnum Rifle
Browning High-Power Rifle
Heckler & Koch Model 300 Rifle
Iver Johnson M–1 Carbine
Iver Johnson 50th Anniversary M–1 Carbine
Marlin Model 9 Camp Carbine
Marlin Model 45 Carbine
Remington Nylon 66 Auto-Loading Rifle
Remington Model 7400 Auto Rifle
Remington Model 7400 Rifle
Remington Model 7400 Special Purpose Auto Rifle
Ruger Mini-14 Autoloading Rifle (w/o folding stock)
Ruger Mini Thirty Rifle

Centerfire Rifles—Lever & Slide

Browning Model 81 BLR Lever-Action Rifle
Browning Model 81 Long Action BLR
Browning Model 1886 Lever-Action Carbine
Browning Model 1886 High Grade Carbine
Cimarron 1860 Henry Replica
Cimarron 1866 Winchester Replicas
Cimarron 1873 Short Rifle
Cimarron 1873 Sporting Rifle
Cimarron 1873 30″ Express Rifle
Dixie Engraved 1873 Rifle
E.M.F. 1866 Yellowboy Lever Actions
E.M.F. 1860 Henry Rifle
E.M.F. Model 73 Lever-Action Rifle
Marlin Model 336CS Lever-Action Carbine
Marlin Model 30AS Lever-Action Carbine
Marlin Model 444SS Lever-Action Sporter
Marlin Model 1894S Lever-Action Carbine
Marlin Model 1894CS Carbine
Marlin Model 1894CL Classic
Marlin Model 1895SS Lever-Action Rifle
Mitchell 1858 Henry Replica
Mitchell 1866 Winchester Replica
Mitchell 1873 Winchester Replica
Navy Arms Military Henry Rifle
Navy Arms Henry Trapper
Navy Arms Iron Frame Henry
Navy Arms Henry Carbine
Navy Arms 1866 Yellowboy Rifle
Navy Arms 1873 Winchester-Style Rifle

Navy Arms 1873 Sporting Rifle
Remington 7600 Slide Action
Remington Model 7600 Special Purpose Slide Action
Rossi M92 SRC Saddle-Ring Carbine
Rossi M92 SRS Short Carbine
Savage 99C Lever-Action Rifle
Uberti Henry Rifle
Uberti 1866 Sporting Rifle
Uberti 1873 Sporting Rifle
Winchester Model 94 Side Eject Lever-Action Rifle
Winchester Model 94 Trapper Side Eject
Winchester Model 94 Big Bore Side Eject
Winchester Model 94 Ranger Side Eject Lever-Action Rifle
Winchester Model 94 Wrangler Side Eject

Centerfire Rifles—Bolt Action

Alpine Bolt-Action Rifle
A-Square Caesar Bolt-Action Rifle
A-Square Hannibal Bolt-Action Rifle
Anschutz 1700D Classic Rifles
Anschutz 1700D Custom Rifles
Anschutz 1700D Bavarian Bolt-Action Rifle
Anschutz 1733D Mannlicher Rifle
Barret Model 90 Bolt-Action Rifle
Beeman/HW 60J Bolt-Action Rifle
Blaser R84 Bolt-Action Rifle
BRNO 537 Sporter Bolt-Action Rifle
BRNO ZKB 527 Fox Bolt-Action Rifle
BRNO ZKK 600, 601, 602 Bolt-Action Rifles
Browning A-Bolt Rifle
Browning A-Bolt Stainless Stalker
Browning A-Bolt Left Hand
Browning A-Bolt Short Action
Browning Euro-Bolt Rifle
Browning A-Bolt Gold Medallion
Browning A-Bolt Micro Medallion
Century Centurion 14 Sporter
Century Enfield Sporter #4
Century Swedish Sporter #38
Century Mauser 98 Sporter
Cooper Model 38 Centerfire Sporter
Dakota 22 Sporter Bolt-Action Rifle
Dakota 76 Classic Bolt-Action Rifle
Dakota 76 Short Action Rifles
Dakota 76 Safari Bolt-Action Rifle
Dakota 416 Rigby African
E.A.A./Sabatti Rover 870 Bolt-Action Rifle
Auguste Francotte Bolt-Action Rifles
Carl Gustaf 2000 Bolt-Action Rifle
Heym Magnum Express Series Rifle
Howa Lightning Bolt-Action Rifle
Howa Realtree Camo Rifle
Interarms Mark X Viscount Bolt-Action Rifle

Interarms Mini-Mark X Rifle
Interarms Mark X Whitworth Bolt-Action Rifle
Interarms Whitworth Express Rifle
Iver Johnson Model 5100A1 Long-Range Rifle
KDF K15 American Bolt-Action Rifle
Krico Model 600 Bolt-Action Rifle
Krico Model 700 Bolt-Action Rifles
Mauser Model 66 Bolt-Action Rifle
Mauser Model 99 Bolt-Action Rifle
McMillan Signature Classic Sporter
McMillan Signature Super Varminter
McMillan Signature Alaskan
McMillan Signature Titanium Mountain Rifle
McMillan Classic Stainless Sporter
McMillan Talon Safari Rifle
McMillan Talon Sporter Rifle
Midland 1500S Survivor Rifle
Navy Arms TU–33/40 Carbine
Parker-Hale Model 81 Classic Rifle
Parker-Hale Model 81 Classic African Rifle
Parker-Hale Model 1000 Rifle
Parker-Hale Model 1100M African Magnum
Parker-Hale Model 1100 Lightweight Rifle
Parker-Hale Model 1200 Super Rifle
Parker-Hale Model 1200 Super Clip Rifle
Parker-Hale Model 1300C Scout Rifle
Parker-Hale Model 2100 Midland Rifle
Parker-Hale Model 2700 Lightweight Rifle
Parker-Hale Model 2800 Midland Rifle
Remington Model Seven Bolt-Action Rifle
Remington Model Seven Youth Rifle
Remington Model Seven Custom KS
Remington Model Seven Custom MS Rifle
Remington 700 ADL Bolt-Action Rifle
Remington 700 BDL Bolt-Action Rifle
Remington 700 BDL Varmint Special
Remington 700 BDL European Bolt-Action Rifle
Remington 700 Varmint Synthetic Rifle
Remington 700 BDL SS Rifle
Remington 700 Stainless Synthetic Rifle
Remington 700 MTRSS Rifle
Remington 700 BDL Left Hand
Remington 700 Camo Synthetic Rifle
Remington 700 Safari
Remington 700 Mountain Rifle
Remington 700 Custom KS Mountain Rifle
Remington 700 Classic Rifle
Ruger M77 Mark II Rifle
Ruger M77 Mark II Magnum Rifle
Ruger M77RL Ultra Light
Ruger M77 Mark II All-Weather Stainless Rifle
Ruger M77 RSI International Carbine
Ruger M77 Mark II Express Rifle
Ruger M77VT Target Rifle

Sako Hunter Rifle
Sako FiberClass Sporter
Sako Safari Grade Bolt Action
Sako Hunter Left-Hand Rifle
Sako Classic Bolt Action
Sako Hunter LS Rifle
Sako Deluxe Lightweight
Sako Super Deluxe Sporter
Sako Mannlicher-Style Carbine
Sako Varmint Heavy Barrel
Sako TRG–S Bolt-Action Rifle
Sauer 90 Bolt-Action Rifle
Savage 110G Bolt-Action Rifle
Savage 110CY Youth/Ladies Rifle
Savage 110WLE One of One Thousand Limited Edition Rifle
Savage 110GXP3 Bolt-Action Rifle
Savage 110F Bolt-Action Rifle
Savage 110FXP3 Bolt-Action Rifle
Savage 110GV Varmint Rifle
Savage 112FV Varmint Rifle
Savage Model 112FVS Varmint Rifle
Savage Model 112BV Heavy Barrel Varmint Rifle
Savage 116FSS Bolt-Action Rifle
Savage Model 116FSK Kodiak Rifle
Savage 110FP Police Rifle
Steyr-Mannlicher Sporter Models SL, L, M, S, S/T
Steyr-Mannlicher Luxus Model L, M, S
Steyr-Mannlicher Model M Professional Rifle
Tikka Bolt-Action Rifle
Tikka Premium Grade Rifles
Tikka Varmint/Continental Rifle
Tikka Whitetail/Battue Rifle
Ultra Light Arms Model 20 Rifle
Ultra Light Arms Model 28, Model 40 Rifles
Voere VEC 91 Lightning Bolt-Action Rifle
Voere Model 2165 Bolt-Action Rifle
Voere Model 2155, 2150 Bolt-Action Rifles
Weatherby Mark V Deluxe Bolt-Action Rifle
Weatherby Lasermark V Rifle
Weatherby Mark V Crown Custom Rifles
Weatherby Mark V Sporter Rifle
Weatherby Mark V Safari Grade Custom Rifles
Weatherby Weathermark Rifle
Weatherby Weathermark Alaskan Rifle
Weatherby Classicmark No. 1 Rifle
Weatherby Weatherguard Alaskan Rifle
Weatherby Vanguard VGX Deluxe Rifle
Weatherby Vanguard Classic Rifle
Weatherby Vanguard Classic No. 1 Rifle
Weatherby Vanguard Weatherguard Rifle
Wichita Classic Rifle
Wichita Varmint Rifle
Winchester Model 70 Sporter
Winchester Model 70 Sporter WinTuff

Winchester Model 70 SM Sporter
Winchester Model 70 Stainless Rifle
Winchester Model 70 Varmint
Winchester Model 70 Synthetic Heavy Varmint Rifle
Winchester Model 70 DBM Rifle
Winchester Model 70 DBM-S Rifle
Winchester Model 70 Featherweight
Winchester Model 70 Featherweight WinTuff
Winchester Model 70 Featherweight Classic
Winchester Model 70 Lightweight Rifle
Winchester Ranger Rifle
Winchester Model 70 Super Express Magnum
Winchester Model 70 Super Grade
Winchester Model 70 Custom Sharpshooter
Winchester Model 70 Custom Sporting Sharpshooter Rifle

Centerfire Rifles—Single Shot

Armsport 1866 Sharps Rifle, Carbine
Brown Model One Single Shot Rifle
Browning Model 1885 Single Shot Rifle
Dakota Single Shot Rifle
Desert Industries G–90 Single Shot Rifle
Harrington & Richardson Ultra Varmint Rifle
Model 1885 High Wall Rifle
Navy Arms Rolling Block Buffalo Rifle
Navy Arms #2 Creedmoor Rifle
Navy Arms Sharps Cavalry Carbine
Navy Arms Sharps Plains Rifle
New England Firearms Handi-Rifle
Red Willow Armory Ballard No. 5 Pacific
Red Willow Armory Ballard No. 1.5 Hunting Rifle
Red Willow Armory Ballard No. 8 Union Hill Rifle
Red Willow Armory Ballard No. 4.5 Target Rifle
Remington-Style Rolling Block Carbine
Ruger No. 1B Single Shot
Ruger No. 1A Light Sporter
Ruger No. 1H Tropical Rifle
Ruger No. 1S Medium Sporter
Ruger No. 1 RSI International
Ruger No. 1V Special Varminter
C.Sharps Arms New Model 1874 Old Reliable
C.Sharps Arms New Model 1875 Rifle
C.Sharps Arms 1875 Classic Sharps
C.Sharps Arms New Model 1875 Target & Long Range
Shiloh Sharps 1874 Long Range Express
Shiloh Sharps 1874 Montana Roughrider
Shiloh Sharps 1874 Military Carbine
Shiloh Sharps 1874 Business Rifle
Shiloh Sharps 1874 Military Rifle
Sharps 1874 Old Reliable
Thompson/Center Contender Carbine
Thompson/Center Stainless Contender Carbine
Thompson/Center Contender Carbine Survival System

Thompson/Center Contender Carbine Youth Model
Thompson/Center TCR '87 Single Shot Rifle
Uberti Rolling Block Baby Carbine

Drillings, Combination Guns, Double Rifles

Beretta Express SSO O/U Double Rifles
Beretta Model 455 SxS Express Rifle
Chapuis RGExpress Double Rifle
Auguste Francotte Sidelock Double Rifles
Auguste Francotte Boxlock Double Rifle
Heym Model 55B O/U Double Rifle
Heym Model 55FW O/U Combo Gun
Heym Model 88b Side-by-Side Double Rifle
Kodiak Mk. IV Double Rifle
Kreighoff Teck O/U Combination Gun
Kreighoff Trumpf Drilling
Merkel Over/Under Combination Guns
Merkel Drillings
Merkel Model 160 Side-by-Side Double Rifles
Merkel Over/Under Double Rifles
Savage 24F O/U Combination Gun
Savage 24F–12T Turkey Gun
Springfield Inc. M6 Scout Rifle/Shotgun
Tikka Model 412s Combination Gun
Tikka Model 412S Double Fire
A. Zoli Rifle-Shotgun O/U Combo

Rimfire Rifles—Autoloaders

AMT Lightning 25/22 Rifle
AMT Lightning Small-Game Hunting Rifle II
AMT Magnum Hunter Auto Rifle
Anschutz 525 Deluxe Auto
Armscor Model 20P Auto Rifle
Browning Auto-22 Rifle
Browning Auto-22 Grade VI
Krico Model 260 Auto Rifle
Lakefield Arms Model 64B Auto Rifle
Marlin Model 60 Self-Loading Rifle
Marlin Model 60ss Self-Loading Rifle
Marlin Model 70 HC Auto
Marlin Model 990l Self-Loading Rifle
Marlin Model 70P Papoose
Marlin Model 922 Magnum Self-Loading Rifle
Marlin Model 995 Self-Loading Rifle
Norinco Model 22 ATD Rifle
Remington Model 522 Viper Autoloading Rifle
Remington 552BDL Speedmaster Rifle
Ruger 10/22 Autoloading Carbine (w/o folding stock)
Survival Arms AR–7 Explorer Rifle
Texas Remington Revolving Carbine
Voere Model 2115 Auto Rifle

Rimfire Rifles—Lever & Slide Action

Browning BL–22 Lever-Action Rifle
Marlin 39TDS Carbine
Marlin Model 39AS Golden Lever-Action Rifle
Remington 572BDL Fieldmaster Pump Rifle
Norinco EM–321 Pump Rifle
Rossi Model 62 SA Pump Rifle
Rossi Model 62 SAC Carbine
Winchester Model 9422 Lever-Action Rifle
Winchester Model 9422 Magnum Lever-Action Rifle

Rimfire Rifles—Bolt Actions & Single Shots

Anschutz Achiever Bolt-Action Rifle
Anschutz 1416D/1516D Classic Rifles
Anschutz 1418D/1518D Mannlicher Rifles
Anschutz 1700D Classic Rifles
Anschutz 1700D Custom Rifles
Anschutz 1700 FWT Bolt-Action Rifle
Anschutz 1700D Graphite Custom Rifle
Anschutz 1700D Bavarian Bolt-Action Rifle
Armscor Model 14P Bolt-Action Rifle
Armscor Model 1500 Rifle
BRNO ZKM–452 Deluxe Bolt-Action Rifle
BRNO ZKM 452 Deluxe
Beeman/HW 60–J–ST Bolt-Action Rifle
Browning A-Bolt 22 Bolt-Action Rifle
Browning A-Bolt Gold Medallion
Cabanas Phaser Rifle
Cabanas Master Bolt-Action Rifle
Cabanas Espronceda IV Bolt-Action Rifle
Cabanas Leyre Bolt-Action Rifle
Chipmunk Single Shot Rifle
Cooper Arms Model 36S Sporter Rifle
Dakota 22 Sporter Bolt-Action Rifle
Krico Model 300 Bolt-Action Rifles
Lakefield Arms Mark II Bolt-Action Rifle
Lakefield Arms Mark I Bolt-Action Rifle
Magtech Model MT–22C Bolt-Action Rifle
Marlin Model 880 Bolt-Action Rifle
Marlin Model 881 Bolt-Action Rifle
Marlin Model 882 Bolt-Action Rifle
Marlin Model 883 Bolt-Action Rifle
Marlin Model 883SS Bolt-Action Rifle
Marlin Model 25MN Bolt-Action Rifle
Marlin Model 25N Bolt-Action Repeater
Marlin Model 15YN "Little Buckaroo"
Mauser Model 107 Bolt-Action Rifle
Mauser Model 201 Bolt-Action Rifle
Navy Arms TU–KKW Training Rifle
Navy Arms TU–33/40 Carbine
Navy Arms TU–KKW Sniper Trainer
Norinco JW–27 Bolt-Action Rifle
Norinco JW–15 Bolt-Action Rifle

Remington 541–T
Remington 40–XR Rimfire Custom Sporter
Remington 541–T HB Bolt-Action Rifle
Remington 581–S Sportsman Rifle
Ruger 77/22 Rimfire Bolt-Action Rifle
Ruger K77/22 Varmint Rifle
Ultra Light Arms Model 20 RF Bolt-Action Rifle
Winchester Model 52B Sporting Rifle

Competition Rifles—Centerfire & Rimfire

Anschutz 64–MS Left Silhouette
Anschutz 1808D RT Super Match 54 Target
Anschutz 1827B Biathlon Rifle
Anschutz 1903D Match Rifle
Anschutz 1803D Intermediate Match
Anschutz 1911 Match Rifle
Anschutz 54.18MS REP Deluxe Silhouette Rifle
Anschutz 1913 Super Match Rifle
Anschutz 1907 Match Rifle
Anschutz 1910 Super Match II
Anschutz 54.18MS Silhouette Rifle
Anschutz Super Match 54 Target Model 2013
Anschutz Super Match 54 Target Model 2007
Beeman/Feinwerkbau 2600 Target Rifle
Cooper Arms Model TRP–1 ISU Standard Rifle
E.A.A./Weihrauch HW 60 Target Rifle
E.A.A./HW 660 Match Rifle
Finnish Lion Standard Target Rifle
Krico Model 360 S2 Biathlon Rifle
Krico Model 400 Match Rifle
Krico Model 360S Biathlon Rifle
Krico Model 500 Kricotronic Match Rifle
Krico Model 600 Sniper Rifle
Krico Model 600 Match Rifle
Lakefield Arms Model 90B Target Rifle
Lakefield Arms Model 91T Target Rifle
Lakefield Arms Model 92S Silhouette Rifle
Marlin Model 2000 Target Rifle
Mauser Model 86–SR Specialty Rifle
McMillan M–86 Sniper Rifle
McMillan Combo M–87/M–88 50-Caliber Rifle
McMillan 300 Phoenix Long Range Rifle
McMillan M–89 Sniper Rifle
McMillan National Match Rifle
McMillan Long Range Rifle
Parker-Hale M–87 Target Rifle
Parker-Hale M–85 Sniper Rifle
Remington 40–XB Rangemaster Target Centerfire
Remington 40–XR KS Rimfire Position Rifle
Remington 40–XBBR KS
Remington 40–XC KS National Match Course Rifle
Sako TRG–21 Bolt-Action Rifle
Steyr-Mannlicher Match SPG–UIT Rifle

Steyr-Mannlicher SSG P–I Rifle
Steyr-Mannlicher SSG P–III Rifle
Steyr-Mannlicher SSG P–IV Rifle
Tanner Standard UIT Rifle
Tanner 50 Meter Free Rifle
Tanner 300 Meter Free Rifle
Wichita Silhouette Rifle

Shotguns—Autoloaders

American Arms/Franchi Black Magic 48/AL
Benelli Super Black Eagle Shotgun
Benelli Super Black Eagle Slug Gun
Benelli M1 Super 90 Field Auto Shotgun
Benelli Montefeltro Super 90 20-Gauge Shotgun
Benelli Montefeltro Super 90 Shotgun
Benelli M1 Sporting Special Auto Shotgun
Benelli Black Eagle Competition Auto Shotgun
Beretta A–303 Auto Shotgun
Beretta 390 Field Auto Shotgun
Beretta 390 Super Trap, Super Skeet Shotguns
Beretta Vittoria Auto Shotgun
Beretta Model 1201F Auto Shotgun
Browning BSA 10 Auto Shotgun
Browning BSA 10 Stalker Auto Shotgun
Browning A–500R Auto Shotgun
Browning A–500G Auto Shotgun
Browning A–500G Sporting Clays
Browning Auto-5 Light 12 and 20
Browning Auto-5 Stalker
Browning Auto-5 Magnum 20
Browning Auto-5 Magnum 12
Churchill Turkey Automatic Shotgun
Cosmi Automatic Shotgun
Maverick Model 60 Auto Shotgun
Mossberg Model 5500 Shotgun
Mossberg Model 9200 Regal Semi-Auto Shotgun
Mossberg Model 9200 USST Auto Shotgun
Mossberg Model 9200 Camo Shotgun
Mossberg Model 6000 Auto Shotgun
Remington Model 1100 Shotgun
Remington 11–87 Premier Shotgun
Remington 11–87 Sporting Clays
Remington 11–87 Premier Skeet
Remington 11–87 Premier Trap
Remington 11–87 Special Purpose Magnum
Remington 11–87 SPS–T Camo Auto Shotgun
Remington 11–87 Special Purpose Deer Gun
Remington 11–87 SPS–BG-Camo Deer/Turkey Shotgun
Remington 11–87 SPS-Deer Shotgun
Remington 11–87 Special Purpose Synthetic Camo
Remington SP–10 Magnum-Camo Auto Shotgun
Remington SP–10 Magnum Auto Shotgun
Remington SP–10 Magnum Turkey Combo

Remington 1100 LT–20 Auto
Remington 1100 Special Field
Remington 1100 20-Gauge Deer Gun
Remington 1100 LT–20 Tournament Skeet
Winchester Model 1400 Semi-Auto Shotgun

Shotguns—Slide Actions

Browning Model 42 Pump Shotgun
Browning BPS Pump Shotgun
Browning BPS Stalker Pump Shotgun
Browning BPS Pigeon Grade Pump Shotgun
Browning BPS Pump Shotgun (Ladies and Youth Model)
Browning BPS Game Gun Turkey Special
Browning BPS Game Gun Deer Special
Ithaca Model 87 Supreme Pump Shotgun
Ithaca Model 87 Deerslayer Shotgun
Ithaca Deerslayer II Rifled Shotgun
Ithaca Model 87 Turkey Gun
Ithaca Model 87 Deluxe Pump Shotgun
Magtech Model 586–VR Pump Shotgun
Maverick Models 88, 91 Pump Shotguns
Mossberg Model 500 Sporting Pump
Mossberg Model 500 Camo Pump
Mossberg Model 500 Muzzleloader Combo
Mossberg Model 500 Trophy Slugster
Mossberg Turkey Model 500 Pump
Mossberg Model 500 Bantam Pump
Mossberg Field Grade Model 835 Pump Shotgun
Mossberg Model 835 Regal Ulti-Mag Pump
Remington 870 Wingmaster
Remington 870 Special Purpose Deer Gun
Remington 870 SPS–BG-Camo Deer/Turkey Shotgun
Remington 870 SPS-Deer Shotgun
Remington 870 Marine Magnum
Remington 870 TC Trap
Remington 870 Special Purpose Synthetic Camo
Remington 870 Wingmaster Small Gauges
Remington 870 Express Rifle Sighted Deer Gun
Remington 870 SPS Special Purpose Magnum
Remington 870 SPS–T Camo Pump Shotgun
Remington 870 Special Field
Remington 870 Express Turkey
Remington 870 High Grades
Remington 870 Express
Remington Model 870 Express Youth Gun
Winchester Model 12 Pump Shotgun
Winchester Model 42 High Grade Shotgun
Winchester Model 1300 Walnut Pump
Winchester Model 1300 Slug Hunter Deer Gun
Winchester Model 1300 Ranger Pump Gun Combo & Deer Gun
Winchester Model 1300 Turkey Gun
Winchester Model 1300 Ranger Pump Gun

Shotguns—Over/Unders

American Arms/Franchi Falconet 2000 O/U
American Arms Silver I O/U
American Arms Silver II Shotgun
American Arms Silver Skeet O/U
American Arms/Franchi Sporting 2000 O/U
American Arms Silver Sporting O/U
American Arms Silver Trap O/U
American Arms WS/OU 12, TS/OU 12 Shotguns
American Arms WT/OU 10 Shotgun
Armsport 2700 O/U Goose Gun
Armsport 2700 Series O/U
Armsport 2900 Tri-Barrel Shotgun
Baby Bretton Over/Under Shotgun
Beretta Model 686 Ultralight O/U
Beretta ASE 90 Competition O/U Shotgun
Beretta Over/Under Field Shotguns
Beretta Onyx Hunter Sport O/U Shotgun
Beretta Model SO5, SO6, SO9 Shotguns
Beretta Sporting Clay Shotguns
Beretta 687EL Sporting O/U
Beretta 682 Super Sporting O/U
Beretta Series 682 Competition Over/Unders
Browning Citori O/U Shotgun
Browning Superlight Citori Over/Under
Browning Lightning Sporting Clays
Browning Micro Citori Lightning
Browning Citori Plus Trap Combo
Browning Citori Plus Trap Gun
Browning Citori O/U Skeet Models
Browning Citori O/U Trap Models
Browning Special Sporting Clays
Browning Citori GTI Sporting Clays
Browning 325 Sporting Clays
Centurion Over/Under Shotgun
Chapuis Over/Under Shotgun
Connecticut Valley Classics Classic Sporter O/U
Connecticut Valley Classics Classic Field Waterfowler
Charles Daly Field Grade O/U
Charles Daly Lux Over/Under
E.A.A./Sabatti Sporting Clays Pro-Gold O/U
E.A.A./Sabatti Falcon-Mon Over/Under
Kassnar Grade I O/U Shotgun
Krieghoff K–80 Sporting Clays O/U
Krieghoff K–80 Skeet Shotgun
Krieghoff K–80 International Skeet
Krieghoff K–80 Four-Barrel Skeet Set
Krieghoff K–80/RT Shotguns
Krieghoff K–80 O/U Trap Shotgun
Laurona Silhouette 300 Sporting Clays
Laurona Silhouette 300 Trap
Laurona Super Model Over/Unders
Ljutic LM–6 Deluxe O/U Shotgun

Marocchi Conquista Over/Under Shotgun
Marocchi Avanza O/U Shotgun
Merkel Model 200E O/U Shotgun
Merkel Model 200E Skeet, Trap Over/Unders
Merkel Model 203E, 303E Over/Under Shotguns
Perazzi Mirage Special Sporting O/U
Perazzi Mirage Special Four-Gauge Skeet
Perazzi Sporting Classic O/U
Perazzi MX7 Over/Under Shotguns
Perazzi Mirage Special Skeet Over/Under
Perazzi MX8/MX8 Special Trap, Skeet
Perazzi MX8/20 Over/Under Shotgun
Perazzi MX9 Single Over/Under Shotguns
Perazzi MX12 Hunting Over/Under
Perazzi MX28, MX410 Game O/U Shotguns
Perazzi MX20 Hunting Over/Under
Piotti Boss Over/Under Shotgun
Remington Peerless Over/Under Shotgun
Ruger Red Label O/U Shotgun
Ruger Sporting Clays O/U Shotgun
San Marco 12-Ga. Wildflower Shotgun
San Marco Field Special O/U Shotgun
San Marco 10-Ga. O/U Shotgun
SKB Model 505 Deluxe Over/Under Shotgun
SKB Model 685 Over/Under Shotgun
SKB Model 885 Over/Under Trap, Skeet, Sporting Clays
Stoeger/IGA Condor I O/U Shotgun
Stoeger/IGA ERA 2000 Over/Under Shotgun
Techni-Mec Model 610 Over/Under
Tikka Model 412S Field Grade Over/Under
Weatherby Athena Grade IV O/U Shotguns
Weatherby Athena Grade V Classic Field O/U
Weatherby Orion O/U Shotguns
Weatherby II, III Classic Field O/Us
Weatherby Orion II Classic Sporting Clays O/U
Weatherby Orion II Sporting Clays O/U
Winchester Model 1001 O/U Shotgun
Winchester Model 1001 Sporting Clays O/U
Pietro Zanoletti Model 2000 Field O/U

Shotguns—Side by Sides

American Arms Brittany Shotgun
American Arms Gentry Double Shotgun
American Arms Derby Side-by-Side
American Arms Grulla #2 Double Shotgun
American Arms WS/SS 10
American Arms TS/SS 10 Double Shotgun
American Arms TS/SS 12 Side-by-Side
Arrieta Sidelock Double Shotguns
Armsport 1050 Series Double Shotguns
Arizaga Model 31 Double Shotgun
AYA Boxlock Shotguns
AYA Sidelock Double Shotguns

Beretta Model 452 Sidelock Shotgun
Beretta Side-by-Side Field Shotguns
Crucelegui Hermanos Model 150 Double
Chapuis Side-by-Side Shotgun
E.A.A./Sabatti Saba-Mon Double Shotgun
Charles Daly Model Dss Double
Ferlib Model F VII Double Shotgun
Auguste Francotte Boxlock Shotgun
Auguste Francotte Sidelock Shotgun
Garbi Model 100 Double
Garbi Model 101 Side-by-Side
Garbi Model 103A, B Side-by-Side
Garbi Model 200 Side-by-Side
Bill Hanus Birdgun Doubles
Hatfield Uplander Shotgun
Merkel Model 8, 47E Side-by-Side Shotguns
Merkel Model 47LSC Sporting Clays Double
Merkel Model 47S, 147S Side-by-Sides
Parker Reproductions Side-by-Side
Piotti King No. 1 Side-by-Side
Piotti Lunik Side-by-Side
Piotti King Extra Side-by-Side
Piotti Piuma Side-by-Side
Precision Sports Model 600 Series Doubles
Rizzini Boxlock Side-by-Side
Rizzini Sidelock Side-by-Side
Stoeger/IGA Uplander Side-by-Side Shotgun
Ugartechea 10-Ga. Magnum Shotgun

Shotguns—Bolt Actions & Single Shots

Armsport Single Barrel Shotgun
Browning BT–99 Competition Trap Special
Browning BT–99 Plus Trap Gun
Browning BT–99 Plus Micro
Browning Recoilless Trap Shotgun
Browning Micro Recoilless Trap Shotgun
Desert Industries Big Twenty Shotgun
Harrington & Richardson Topper Model 098
Harrington & Richardson Topper Classic Youth Shotgun
Harrington & Richardson N.W.T.F. Turkey Mag
Harrington & Richardson Topper Deluxe Model 098
Krieghoff KS–5 Trap Gun
Krieghoff KS–5 Special
Krieghoff K–80 Single Barrel Trap Gun
Ljutic Mono Gun Single Barrel
Ljutic LTX Super Deluxe Mono Gun
Ljutic Recoilless Space Gun Shotgun
Marlin Model 55 Goose Gun Bolt Action
New England Firearms Turkey and Goose Gun
New England Firearms N.W.T.F. Shotgun
New England Firearms Tracker Slug Gun
New England Firearms Standard Pardner
New England Firearms Survival Gun

Perazzi TM1 Special Single Trap
Remington 90–T Super Single Shotgun
Snake Charmer II Shotgun
Stoeger/IGA Reuna Single Barrel Shotgun
Thompson/Center TCR '87 Hunter Shotgun.

§ 924. Penalties[1]

(a)(1) Except as otherwise provided in this subsection, subsection (b), (c), or (f) of this section, or in section 929, whoever—

(A) knowingly makes any false statement or representation with respect to the information required by this chapter to be kept in the records of a person licensed under this chapter or in applying for any license or exemption or relief from disability under the provisions of this chapter;

(B) knowingly violates subsection (a)(4), (f), (k), (r), (v), or (w) of section 922;

(C) knowingly imports or brings into the United States or any possession thereof any firearm or ammunition in violation of section 922(l); or

(D) willfully violates any other provision of this chapter,

shall be fined under this title, imprisoned not more than five years, or both.

(2) Whoever knowingly violates subsection (a)(6), (d), (g), (h), (i), (j), or (o) of section 922 shall be fined as provided in this title, imprisoned not more than 10 years, or both.

(3) Any licensed dealer, licensed importer, licensed manufacturer, or licensed collector who knowingly—

(A) makes any false statement or representation with respect to the information required by the provisions of this chapter to be kept in the records of a person licensed under this chapter, or

(B) violates subsection (m) of section 922,

shall be fined under this title, imprisoned not more than one year, or both.

(4) Whoever violates section 922(q) shall be fined under this title, imprisoned for not more than 5 years, or both. Notwithstanding any other provision of law, the term of imprisonment imposed

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[1] Added by Public Law 90–351, Title IV, § 902, June 19, 1968, 82 Stat. 233, and amended by Public Law 90–618, Title I, § 102, Oct. 22, 1968, 82 Stat. 1223; Public Law 91–644, Title II, § 13, Jan. 2, 1971, 84 Stat. 1889; Public Law 98–473, Title II, §§ 223(a), 1005(a), Oct. 12, 1984, 98 Stat. 2028, 2138; Public Law 99–308, § 104(a), May 19, 1986, 100 Stat. 456; Public Law 99–570, Title I, § 1402, Oct. 27, 1986, 100 Stat. 3207–39; Public Law 100–649, § 2(b), (f)(2)(B), (D), Nov. 10, 1988, 102 Stat. 3817, 3818; Public Law 100–690, Title VI, §§ 6211, 6212, 6451, 6460, 6462, Title VII, §§ 7056, 7060(a), Nov. 18, 1988, 102 Stat. 4359, 4360, 4371, 4373, 4374, 4402, 4403; Public Law 101–647, Title XI, § 1101, Title XVII, § 1702(b)(3), Title XXII, §§ 2203(d), 2204(c), Title XXXV, §§ 3526, 3527, 3528, 3529, Nov. 29, 1990, 104 Stat. 4829, 4845, 4857, 4924; Public Law 103–159, Title I, § 102(c), Title III, § 302(d), Nov. 30, 1993, 107 Stat. 1541, 1545; Public Law 103–322, Title VI, § 60013, Title XI, §§ 110102(c), 110103(c), 110201(b), 110401(e), 110503, 110504(a), 110507, 110510, 110515(a), 110517, 110518(a), Title XXXIII, §§ 330002(h), 330003(f)(2), 330011(i), (j), 330016(1)(H), (K), (L), Sept. 13, 1994, 108 Stat. 1973, 1998, 1999, 2011, 2015, 2016, 2018, 2019, 2020, 2140, 2141, 2145, 2147; Public Law 104–294, Title VI, § 603(m)(1), (n) to (p)(1), (q) to (s), Oct. 11, 1996, 110 Stat. 3505; Public Law 105–386, § 1(a), Nov. 13, 1998, 112 Stat. 3469; Public Law 107–273, Div. B, Title IV, § 4002(d)(1)(E), Div. C, Title I, § 11009(e)(3), Nov. 2, 2002, 116 Stat. 1809, 1821.

under this paragraph shall not run concurrently with any other term of imprisonment imposed under any other provision of law. Except for the authorization of a term of imprisonment of not more than 5 years made in this paragraph, for the purpose of any other law a violation of section 922(q) shall be deemed to be a misdemeanor.

(5) Whoever knowingly violates subsection (s) or (t) of section 922 shall be fined under this title, imprisoned for not more than 1 year, or both.

(6)(A)(i) A juvenile who violates section 922(x) shall be fined under this title, imprisoned not more than 1 year, or both, except that a juvenile described in clause (ii) shall be sentenced to probation on appropriate conditions and shall not be incarcerated unless the juvenile fails to comply with a condition of probation.

(ii) A juvenile is described in this clause if—

(I) the offense of which the juvenile is charged is possession of a handgun or ammunition in violation of section 922(x)(2); and

(II) the juvenile has not been convicted in any court of an offense (including an offense under section 922(x) or a similar State law, but not including any other offense consisting of conduct that if engaged in by an adult would not constitute an offense) or adjudicated as a juvenile delinquent for conduct that if engaged in by an adult would constitute an offense.

(B) A person other than a juvenile who knowingly violates section 922(x)—

(i) shall be fined under this title, imprisoned not more than 1 year, or both; and

(ii) if the person sold, delivered, or otherwise transferred a handgun or ammunition to a juvenile knowing or having reasonable cause to know that the juvenile intended to carry or otherwise possess or discharge or otherwise use the handgun or ammunition in the commission of a crime of violence, shall be fined under this title, imprisoned not more than 10 years, or both.

(7) Whoever knowingly violates section 931 shall be fined under this title, imprisoned not more than 3 years, or both.

(b) Whoever, with intent to commit therewith an offense punishable by imprisonment for a term exceeding one year, or with knowledge or reasonable cause to believe that an offense punishable by imprisonment for a term exceeding one year is to be committed therewith, ships, transports, or receives a firearm or any ammunition in interstate or foreign commerce shall be fined under this title, or imprisoned not more than ten years, or both.

(c)(1)(A) Except to the extent that a greater minimum sentence is otherwise provided by this subsection or by any other provision of law, any person who, during and in relation to any crime of violence or drug trafficking crime (including a crime of violence or drug trafficking crime that provides for an enhanced punishment if committed by the use of a deadly or dangerous weapon or device) for which the person may be prosecuted in a court of the United States, uses or carries a firearm, or who, in furtherance of any such crime, possesses a firearm, shall, in addition to the punishment provided for such crime of violence or drug trafficking crime—

(i) be sentenced to a term of imprisonment of not less than 5 years;

(ii) if the firearm is brandished, be sentenced to a term of imprisonment of not less than 7 years; and

(iii) if the firearm is discharged, be sentenced to a term of imprisonment of not less than 10 years.

(B) If the firearm possessed by a person convicted of a violation of this subsection—

(i) is a short-barreled rifle, short-barreled shotgun, or semi-automatic assault weapon, the person shall be sentenced to a term of imprisonment of not less than 10 years; or

(ii) is a machinegun or a destructive device, or is equipped with a firearm silencer or firearm muffler, the person shall be sentenced to a term of imprisonment of not less than 30 years.

(C) In the case of a second or subsequent conviction under this subsection, the person shall—

(i) be sentenced to a term of imprisonment of not less than 25 years; and

(ii) if the firearm involved is a machinegun or a destructive device, or is equipped with a firearm silencer or firearm muffler, be sentenced to imprisonment for life.

(D) Notwithstanding any other provision of law—

(i) a court shall not place on probation any person convicted of a violation of this subsection; and

(ii) no term of imprisonment imposed on a person under this subsection shall run concurrently with any other term of imprisonment imposed on the person, including any term of imprisonment imposed for the crime of violence or drug trafficking crime during which the firearm was used, carried, or possessed.

(2) For purposes of this subsection, the term ''drug trafficking crime'' means any felony punishable under the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), or the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.).

(3) For purposes of this subsection the term ''crime of violence'' means an offense that is a felony and—

(A) has as an element the use, attempted use, or threatened use of physical force against the person or property of another, or

(B) that by its nature, involves a substantial risk that physical force against the person or property of another may be used in the course of committing the offense.

(4) For purposes of this subsection, the term ''brandish'' means, with respect to a firearm, to display all or part of the firearm, or otherwise make the presence of the firearm known to another person, in order to intimidate that person, regardless of whether the firearm is directly visible to that person.

(d)(1) Any firearm or ammunition involved in or used in any knowing violation of subsection (a)(4), (a)(6), (f), (g), (h), (i), (j), or (k) of section 922, or knowing importation or bringing into the United States or any possession thereof any firearm or ammunition in violation of section 922(l), or knowing violation of section 924, or willful violation of any other provision of this chapter or any

rule or regulation promulgated thereunder, or any violation of any other criminal law of the United States, or any firearm or ammunition intended to be used in any offense referred to in paragraph (3) of this subsection, where such intent is demonstrated by clear and convincing evidence, shall be subject to seizure and forfeiture, and all provisions of the Internal Revenue Code of 1986 relating to the seizure, forfeiture, and disposition of firearms, as defined in section 5845(a) of that Code, shall, so far as applicable, extend to seizures and forfeitures under the provisions of this chapter: *Provided,* That upon acquittal of the owner or possessor, or dismissal of the charges against him other than upon motion of the Government prior to trial, or lapse of or court termination of the restraining order to which he is subject, the seized or relinquished firearms or ammunition shall be returned forthwith to the owner or possessor or to a person delegated by the owner or possessor unless the return of the firearms or ammunition would place the owner or possessor or his delegate in violation of law. Any action or proceeding for the forfeiture of firearms or ammunition shall be commenced within one hundred and twenty days of such seizure.

(2)(A) In any action or proceeding for the return of firearms or ammunition seized under the provisions of this chapter, the court shall allow the prevailing party, other than the United States, a reasonable attorney's fee, and the United States shall be liable therefor.

(B) In any other action or proceeding under the provisions of this chapter, the court, when it finds that such action was without foundation, or was initiated vexatiously, frivolously, or in bad faith, shall allow the prevailing party, other than the United States, a reasonable attorney's fee, and the United States shall be liable therefor.

(C) Only those firearms or quantities of ammunition particularly named and individually identified as involved in or used in any violation of the provisions of this chapter or any rule or regulation issued thereunder, or any other criminal law of the United States or as intended to be used in any offense referred to in paragraph (3) of this subsection, where such intent is demonstrated by clear and convincing evidence, shall be subject to seizure, forfeiture, and disposition.

(D) The United States shall be liable for attorneys' fees under this paragraph only to the extent provided in advance by appropriation Acts.

(3) The offenses referred to in paragraphs (1) and (2)(C) of this subsection are—

(A) any crime of violence, as that term is defined in section 924(c)(3) of this title;

(B) any offense punishable under the Controlled Substances Act (21 U.S.C. 801 et seq.) or the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.);

(C) any offense described in section 922(a)(1), 922(a)(3), 922(a)(5), or 922(b)(3) of this title, where the firearm or ammunition intended to be used in any such offense is involved in a pattern of activities which includes a violation of any offense described in section 922(a)(1), 922(a)(3), 922(a)(5), or 922(b)(3) of this title;

(D) any offense described in section 922(d) of this title where the firearm or ammunition is intended to be used in such offense by the transferor of such firearm or ammunition;

(E) any offense described in section 922(i), 922(j), 922(l), 922(n), or 924(b) of this title; and

(F) any offense which may be prosecuted in a court of the United States which involves the exportation of firearms or ammunition.

(e)(1) In the case of a person who violates section 922(g) of this title and has three previous convictions by any court referred to in section 922(g)(1) of this title for a violent felony or a serious drug offense, or both, committed on occasions different from one another, such person shall be fined under this title and imprisoned not less than fifteen years, and, notwithstanding any other provision of law, the court shall not suspend the sentence of, or grant a probationary sentence to, such person with respect to the conviction under section 922(g).

(2) As used in this subsection—

(A) the term "serious drug offense" means—

(i) an offense under the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), or the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.), for which a maximum term of imprisonment of ten years or more is prescribed by law; or

(ii) an offense under State law, involving manufacturing, distributing, or possessing with intent to manufacture or distribute, a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)), for which a maximum term of imprisonment of ten years or more is prescribed by law;

(B) the term "violent felony" means any crime punishable by imprisonment for a term exceeding one year, or any act of juvenile delinquency involving the use or carrying of a firearm, knife, or destructive device that would be punishable by imprisonment for such term if committed by an adult, that—

(i) has as an element the use, attempted use, or threatened use of physical force against the person of another; or

(ii) is burglary, arson, or extortion, involves use of explosives, or otherwise involves conduct that presents a serious potential risk of physical injury to another; and

(C) the term "conviction" includes a finding that a person has committed an act of juvenile delinquency involving a violent felony.

(f) In the case of a person who knowingly violates section 922(p), such person shall be fined under this title, or imprisoned not more than 5 years, or both.

(g) Whoever, with the intent to engage in conduct which—

(1) constitutes an offense listed in section 1961(1),

(2) is punishable under the Controlled Substances Act (21 U.S.C. 802 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), or the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.),

(3) violates any State law relating to any controlled substance (as defined in section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))), or

(4) constitutes a crime of violence (as defined in subsection (c)(3)),

travels from any State or foreign country into any other State and acquires, transfers, or attempts to acquire or transfer, a firearm in such other State in furtherance of such purpose, shall be imprisoned not more than 10 years, fined in accordance with this title, or both.

(h) Whoever knowingly transfers a firearm, knowing that such firearm will be used to commit a crime of violence (as defined in subsection (c)(3)) or drug trafficking crime (as defined in subsection (c)(2)) shall be imprisoned not more than 10 years, fined in accordance with this title, or both.

(i)(1) A person who knowingly violates section 922(u) shall be fined under this title, imprisoned not more than 10 years, or both.

(2) Nothing contained in this subsection shall be construed as indicating an intent on the part of Congress to occupy the field in which provisions of this subsection operate to the exclusion of State laws on the same subject matter, nor shall any provision of this subsection be construed as invalidating any provision of State law unless such provision is inconsistent with any of the purposes of this subsection.

(j) A person who, in the course of a violation of subsection (c), causes the death of a person through the use of a firearm, shall—

(1) if the killing is a murder (as defined in section 1111), be punished by death or by imprisonment for any term of years or for life; and

(2) if the killing is manslaughter (as defined in section 1112), be punished as provided in that section.

(k) A person who, with intent to engage in or to promote conduct that—

(1) is punishable under the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), or the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.);

(2) violates any law of a State relating to any controlled substance (as defined in section 102 of the Controlled Substances Act, 21 U.S.C. 802); or

(3) constitutes a crime of violence (as defined in subsection (c)(3)),

smuggles or knowingly brings into the United States a firearm, or attempts to do so, shall be imprisoned not more than 10 years, fined under this title, or both.

(l) A person who steals any firearm which is moving as, or is a part of, or which has moved in, interstate or foreign commerce shall be imprisoned for not more than 10 years, fined under this title, or both.

(m) A person who steals any firearm from a licensed importer, licensed manufacturer, licensed dealer, or licensed collector shall be fined under this title, imprisoned not more than 10 years, or both.

(n) A person who, with the intent to engage in conduct that constitutes a violation of section 922(a)(1)(A), travels from any State

or foreign country into any other State and acquires, or attempts to acquire, a firearm in such other State in furtherance of such purpose shall be imprisoned for not more than 10 years.

(o) A person who conspires to commit an offense under subsection (c) shall be imprisoned for not more than 20 years, fined under this title, or both; and if the firearm is a machinegun or destructive device, or is equipped with a firearm silencer or muffler, shall be imprisoned for any term of years or life.

18 U.S.C. § 929

Possession of restricted ammunition during the commission of a drug trafficking offense

§ 929. Use of restricted ammunition [1]

(a)(1) Whoever, during and in relation to the commission of a crime of violence or drug trafficking crime (including a crime of violence or drug trafficking crime which provides for an enhanced punishment if committed by the use of a deadly or dangerous weapon or device) for which he may be prosecuted in a court of the United States, uses or carries a firearm and is in possession of armor piercing ammunition capable of being fired in that firearm, shall, in addition to the punishment provided for the commission of such crime of violence or drug trafficking crime be sentenced to a term of imprisonment for not less than five years.

(2) For purposes of this subsection, the term ''drug trafficking crime'' means any felony punishable under the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), or the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.).

(b) Notwithstanding any other provision of law, the court shall not suspend the sentence of any person convicted of a violation of this section, nor place the person on probation, nor shall the terms of imprisonment run concurrently with any other terms of imprisonment, including that imposed for the crime in which the armor piercing ammunition was used or possessed.

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[1] Added by Public Law 98–473, Title II, § 1006(a), Oct. 12, 1984, 98 Stat. 2139, and amended by Public Law 99–308, § 108, May 19, 1986, 100 Stat. 460; Public Law 99–408, § 8, Aug. 28, 1986, 100 Stat. 921; Public Law 100–690, Title VI, § 6212, Title VII, § 7060(b), Nov. 18, 1988, 102 Stat. 4360, 4404; Public Law 107–273, Div. B, Title IV, § 4002(c)(4), Nov. 2, 2002, 116 Stat. 1809.)

18 U.S.C. §§ 981–986
Civil and criminal forfeiture procedure for confiscation related to controlled substance and money laundering violations

Chapter 46. Forfeiture

§ 981. Civil forfeiture [1]

(a)(1) The following property is subject to forfeiture to the United States:

(A) Any property, real or personal, involved in a transaction or attempted transaction in violation of section 1956, 1957 or 1960 of this title, or any property traceable to such property.

(B) Any property, real or personal, within the jurisdiction of the United States, constituting, derived from, or traceable to, any proceeds obtained directly or indirectly from an offense against a foreign nation, or any property used to facilitate such an offense, if the offense—

(i) involves the manufacture, importation, sale, or distribution of a controlled substance (as that term is defined for purposes of the Controlled Substances Act), or any other conduct described in section 1956(c) (7)(B);

(ii) would be punishable within the jurisdiction of the foreign nation by death or imprisonment for a term exceeding 1 year; and

(iii) would be punishable under the laws of the United States by imprisonment for a term exceeding 1 year, if the act or activity constituting the offense had occurred within the jurisdiction of the United States.

(C) Any property, real or personal, which constitutes or is derived from proceeds traceable to a violation of section 215, 471, 472, 473, 474, 476, 477, 478, 479, 480, 481, 485, 486, 487, 488, 501, 502, 510, 542, 545, 656, 657, 842, 844, 1005, 1006, 1007, 1014, 1028, 1029, 1030, 1032, or 1344 of this title or any offense constituting "specified unlawful activity" (as defined in section 1956(c)(7) of this title), or a conspiracy to commit such offense.

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[1] Added by Public Law 99–570, Title I, § 1366(a), Oct. 27, 1986, 100 Stat. 3207–35, and amended by Public Law 100–690, Title VI, §§ 6463(a), (b), 6469(b), 6470(b), (e), (f), 6471(c), Nov. 18, 1988, 102 Stat. 4374, 4377, 4378; Public Law 101–73, Title IX, § 963(a), (b), Aug. 9, 1989, 103 Stat. 504; Public Law 101–647, Title I, § 103, Title XXV, §§ 2508, 2524, 2525(a), Title XXXV, § 3531, Nov. 29, 1990, 104 Stat. 4791, 4862, 4873, 4874, 4924; Public Law 102–393, Title VI, § 638(d), Oct. 6, 1992, 106 Stat. 1788; Public Law 102–519, Title I, § 104(a), Oct. 25, 1992, 106 Stat. 3385; Public Law 102–550, Title XV, §§ 1525(c)(1), 1533, Oct. 28, 1992, 106 Stat. 4065, 4066; Public Law 103–322, Title XXXIII, § 330011(s)(2), Sept. 13, 1994, 108 Stat. 2146; Public Law 103–447, Title I, § 102(b), Nov. 2, 1994, 108 Stat. 4693; Public Law 106–185, §§ 2(c)(1), 5(a), 6, 8(a), 20, Apr. 25, 2000, 114 Stat. 210, 213 to 215, 224; Public Law 107–56, Title III, §§ 319(a), 320, 372(b)(1), 373(b), Title VIII, § 806, Oct. 26, 2001, 115 Stat. 311, 315, 339, 340, 378; Public Law 107–197, Title III, § 301(d), June 25, 2002, 116 Stat. 728; Public Law 107–273, Div. B, Title IV, § 4002(a)(2), Nov. 2, 2002, 116 Stat. 1806.

(D) Any property, real or personal, which represents or is traceable to the gross receipts obtained, directly or indirectly, from a violation of—

(i) section 666(a)(1) (relating to Federal program fraud);

(ii) section 1001 (relating to fraud and false statements);

(iii) section 1031 (relating to major fraud against the United States);

(iv) section 1032 (relating to concealment of assets from conservator or receiver of insured financial institution);

(v) section 1341 (relating to mail fraud); or

(vi) section 1343 (relating to wire fraud),

if such violation relates to the sale of assets acquired or held by the Resolution Trust Corporation, the Federal Deposit Insurance Corporation, as conservator or receiver for a financial institution, or any other conservator for a financial institution appointed by the Office of the Comptroller of the Currency or the Office of Thrift Supervision or the National Credit Union Administration, as conservator or liquidating agent for a financial institution.

(E) With respect to an offense listed in subsection (a)(1)(D) committed for the purpose of executing or attempting to execute any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent statements, pretenses, representations or promises, the gross receipts of such an offense shall include all property, real or personal, tangible or intangible, which thereby is obtained, directly or indirectly.

(F) Any property, real or personal, which represents or is traceable to the gross proceeds obtained, directly or indirectly, from a violation of—

(i) section 511 (altering or removing motor vehicle identification numbers);

(ii) section 553 (importing or exporting stolen motor vehicles);

(iii) section 2119 (armed robbery of automobiles);

(iv) section 2312 (transporting stolen motor vehicles in interstate commerce); or

(v) section 2313 (possessing or selling a stolen motor vehicle that has moved in interstate commerce).

(G) All assets, foreign or domestic—

(i) of any individual, entity, or organization engaged in planning or perpetrating any act of domestic or international terrorism (as defined in section 2331) against the United States, citizens or residents of the United States, or their property, and all assets, foreign or domestic, affording any person a source of influence over any such entity or organization;

(ii) acquired or maintained by any person with the intent and for the purpose of supporting, planning, conducting, or concealing an act of domestic or international terrorism (as defined in section 2331) against the United States, citizens or residents of the United States, or their property; or

(iii) derived from, involved in, or used or intended to be used to commit any act of domestic or international terrorism (as defined in section 2331) against the United States, citizens or residents of the United States, or their property.

(H) Any property, real or personal, involved in a violation or attempted violation, or which constitutes or is derived from proceeds traceable to a violation, of section 2339C of this title.

(2) For purposes of paragraph (1), the term "proceeds" is defined as follows:

(A) In cases involving illegal goods, illegal services, unlawful activities, and telemarketing and health care fraud schemes, the term "proceeds" means property of any kind obtained directly or indirectly, as the result of the commission of the offense giving rise to forfeiture, and any property traceable thereto, and is not limited to the net gain or profit realized from the offense.

(B) In cases involving lawful goods or lawful services that are sold or provided in an illegal manner, the term "proceeds" means the amount of money acquired through the illegal transactions resulting in the forfeiture, less the direct costs incurred in providing the goods or services. The claimant shall have the burden of proof with respect to the issue of direct costs. The direct costs shall not include any part of the overhead expenses of the entity providing the goods or services, or any part of the income taxes paid by the entity.

(C) In cases involving fraud in the process of obtaining a loan or extension of credit, the court shall allow the claimant a deduction from the forfeiture to the extent that the loan was repaid, or the debt was satisfied, without any financial loss to the victim.

(b)(1) Except as provided in section 985, any property subject to forfeiture to the United States under subsection (a) may be seized by the Attorney General and, in the case of property involved in a violation investigated by the Secretary of the Treasury or the United States Postal Service, the property may also be seized by the Secretary of the Treasury or the Postal Service, respectively.

(2) Seizures pursuant to this section shall be made pursuant to a warrant obtained in the same manner as provided for a search warrant under the Federal Rules of Criminal Procedure, except that a seizure may be made without a warrant if—

(A) a complaint for forfeiture has been filed in the United States district court and the court issued an arrest warrant in rem pursuant to the Supplemental Rules for Certain Admiralty and Maritime Claims;

(B) there is probable cause to believe that the property is subject to forfeiture and—

(i) the seizure is made pursuant to a lawful arrest or search; or

(ii) another exception to the Fourth Amendment warrant requirement would apply; or

(C) the property was lawfully seized by a State or local law enforcement agency and transferred to a Federal agency.

(3) Notwithstanding the provisions of rule 41(a) of the Federal Rules of Criminal Procedure, a seizure warrant may be issued pursuant to this subsection by a judicial officer in any district in which a forfeiture action against the property may be filed under section 1355(b) of title 28, and may be executed in any district in which the property is found, or transmitted to the central authority of any foreign state for service in accordance with any treaty or other international agreement. Any motion for the return of property seized under this section shall be filed in the district court in which the seizure warrant was issued or in the district court for the district in which the property was seized.

(4)(A) If any person is arrested or charged in a foreign country in connection with an offense that would give rise to the forfeiture of property in the United States under this section or under the Controlled Substances Act, the Attorney General may apply to any Federal judge or magistrate judge in the district in which the property is located for an ex parte order restraining the property subject to forfeiture for not more than 30 days, except that the time may be extended for good cause shown at a hearing conducted in the manner provided in rule 43(e) of the Federal Rules of Civil Procedure.

(B) The application for the restraining order shall set forth the nature and circumstances of the foreign charges and the basis for belief that the person arrested or charged has property in the United States that would be subject to forfeiture, and shall contain a statement that the restraining order is needed to preserve the availability of property for such time as is necessary to receive evidence from the foreign country or elsewhere in support of probable cause for the seizure of the property under this subsection.

(c) Property taken or detained under this section shall not be repleviable, but shall be deemed to be in the custody of the Attorney General, the Secretary of the Treasury, or the Postal Service, as the case may be, subject only to the orders and decrees of the court or the official having jurisdiction thereof. Whenever property is seized under this subsection, the Attorney General, the Secretary of the Treasury, or the Postal Service, as the case may be, may—

(1) place the property under seal;

(2) remove the property to a place designated by him; or

(3) require that the General Services Administration take custody of the property and remove it, if practicable, to an appropriate location for disposition in accordance with law.

(d) For purposes of this section, the provisions of the customs laws relating to the seizure, summary and judicial forfeiture, condemnation of property for violation of the customs laws, the disposition of such property or the proceeds from the sale of such property under this section, the remission or mitigation of such forfeitures, and the compromise of claims (19 U.S.C. 1602 et seq.), insofar as they are applicable and not inconsistent with the provisions of this section, shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under this section, except that such duties as are imposed upon the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws shall be performed with respect to seizures and forfeitures of property under this section by such officers,

agents, or other persons as may be authorized or designated for that purpose by the Attorney General, the Secretary of the Treasury, or the Postal Service, as the case may be. The Attorney General shall have sole responsibility for disposing of petitions for remission or mitigation with respect to property involved in a judicial forfeiture proceeding.

(e) Notwithstanding any other provision of the law, except section 3 of the Anti Drug Abuse Act of 1986, the Attorney General, the Secretary of the Treasury, or the Postal Service, as the case may be, is authorized to retain property forfeited pursuant to this section, or to transfer such property on such terms and conditions as he may determine—

(1) to any other Federal agency;

(2) to any State or local law enforcement agency which participated directly in any of the acts which led to the seizure or forfeiture of the property;

(3) in the case of property referred to in subsection (a)(1)(C), to any Federal financial institution regulatory agency—

(A) to reimburse the agency for payments to claimants or creditors of the institution; and

(B) to reimburse the insurance fund of the agency for losses suffered by the fund as a result of the receivership or liquidation;

(4) in the case of property referred to in subsection (a)(1)(C), upon the order of the appropriate Federal financial institution regulatory agency, to the financial institution as restitution, with the value of the property so transferred to be set off against any amount later recovered by the financial institution as compensatory damages in any State or Federal proceeding;

(5) in the case of property referred to in subsection (a)(1)(C), to any Federal financial institution regulatory agency, to the extent of the agency's contribution of resources to, or expenses involved in, the seizure and forfeiture, and the investigation leading directly to the seizure and forfeiture, of such property;

(6) as restoration to any victim of the offense giving rise to the forfeiture, including, in the case of a money laundering offense, any offense constituting the underlying specified unlawful activity; or

(7) In[2] the case of property referred to in subsection (a)(1)(D), to the Resolution Trust Corporation, the Federal Deposit Insurance Corporation, or any other Federal financial institution regulatory agency (as defined in section 8(e)(7)(D) of the Federal Deposit Insurance Act).

The Attorney General, the Secretary of the Treasury, or the Postal Service, as the case may be, shall ensure the equitable transfer pursuant to paragraph (2) of any forfeited property to the appropriate State or local law enforcement agency so as to reflect generally the contribution of any such agency participating directly in any of the acts which led to the seizure or forfeiture of such property. A decision by the Attorney General, the Secretary of the Treasury, or the Postal Service pursuant to paragraph (2) shall not be subject to review. The United States shall not be liable in any

[2] So in original. Probably should not be capitalized.

action arising out of the use of any property the custody of which was transferred pursuant to this section to any non-Federal agency. The Attorney General, the Secretary of the Treasury, or the Postal Service may order the discontinuance of any forfeiture proceedings under this section in favor of the institution of forfeiture proceedings by State or local authorities under an appropriate State or local statute. After the filing of a complaint for forfeiture under this section, the Attorney General may seek dismissal of the complaint in favor of forfeiture proceedings under State or local law. Whenever forfeiture proceedings are discontinued by the United States in favor of State or local proceedings, the United States may transfer custody and possession of the seized property to the appropriate State or local official immediately upon the initiation of the proper actions by such officials. Whenever forfeiture proceedings are discontinued by the United States in favor of State or local proceedings, notice shall be sent to all known interested parties advising them of the discontinuance or dismissal. The United States shall not be liable in any action arising out of the seizure, detention, and transfer of seized property to State or local officials. The United States shall not be liable in any action arising out of a transfer under paragraph (3), (4), or (5) of this subsection.

(f) All right, title, and interest in property described in subsection (a) of this section shall vest in the United States upon commission of the act giving rise to forfeiture under this section.

(g)(1) Upon the motion of the United States, the court shall stay the civil forfeiture proceeding if the court determines that civil discovery will adversely affect the ability of the Government to conduct a related criminal investigation or the prosecution of a related criminal case.

(2) Upon the motion of a claimant, the court shall stay the civil forfeiture proceeding with respect to that claimant if the court determines that—

(A) the claimant is the subject of a related criminal investigation or case;

(B) the claimant has standing to assert a claim in the civil forfeiture proceeding; and

(C) continuation of the forfeiture proceeding will burden the right of the claimant against self-incrimination in the related investigation or case.

(3) With respect to the impact of civil discovery described in paragraphs (1) and (2), the court may determine that a stay is unnecessary if a protective order limiting discovery would protect the interest of one party without unfairly limiting the ability of the opposing party to pursue the civil case. In no case, however, shall the court impose a protective order as an alternative to a stay if the effect of such protective order would be to allow one party to pursue discovery while the other party is substantially unable to do so.

(4) In this subsection, the terms ''related criminal case'' and ''related criminal investigation'' mean an actual prosecution or investigation in progress at the time at which the request for the stay, or any subsequent motion to lift the stay is made. In determining whether a criminal case or investigation is ''related'' to a civil forfeiture proceeding, the court shall consider the degree of similarity between the parties, witnesses, facts, and circumstances involved

in the two proceedings, without requiring an identity with respect to any one or more factors.

(5) In requesting a stay under paragraph (1), the Government may, in appropriate cases, submit evidence ex parte in order to avoid disclosing any matter that may adversely affect an ongoing criminal investigation or pending criminal trial.

(6) Whenever a civil forfeiture proceeding is stayed pursuant to this subsection, the court shall enter any order necessary to preserve the value of the property or to protect the rights of lienholders or other persons with an interest in the property while the stay is in effect.

(7) A determination by the court that the claimant has standing to request a stay pursuant to paragraph (2) shall apply only to this subsection and shall not preclude the Government from objecting to the standing of the claimant by dispositive motion or at the time of trial.

(h) In addition to the venue provided for in section 1395 of title 28 or any other provision of law, in the case of property of a defendant charged with a violation that is the basis for forfeiture of the property under this section, a proceeding for forfeiture under this section may be brought in the judicial district in which the defendant owning such property is found or in the judicial district in which the criminal prosecution is brought.

(i)(1) Whenever property is civilly or criminally forfeited under this chapter, the Attorney General or the Secretary of the Treasury, as the case may be, may transfer the forfeited personal property or the proceeds of the sale of any forfeited personal or real property to any foreign country which participated directly or indirectly in the seizure or forfeiture of the property, if such a transfer—

(A) has been agreed to by the Secretary of State;

(B) is authorized in an international agreement between the United States and the foreign country; and

(C) is made to a country which, if applicable, has been certified under section 481(h) of the Foreign Assistance Act of 1961.

A decision by the Attorney General or the Secretary of the Treasury pursuant to this paragraph shall not be subject to review. The foreign country shall, in the event of a transfer of property or proceeds of sale of property under this subsection, bear all expenses incurred by the United States in the seizure, maintenance, inventory, storage, forfeiture, and disposition of the property, and all transfer costs. The payment of all such expenses, and the transfer of assets pursuant to this paragraph, shall be upon such terms and conditions as the Attorney General or the Secretary of the Treasury may, in his discretion, set.

(2) The provisions of this section shall not be construed as limiting or superseding any other authority of the United States to provide assistance to a foreign country in obtaining property related to a crime committed in the foreign country, including property which is sought as evidence of a crime committed in the foreign country.

(3) A certified order or judgment of forfeiture by a court of competent jurisdiction of a foreign country concerning property which

is the subject of forfeiture under this section and was determined by such court to be the type of property described in subsection (a)(1)(B) of this section, and any certified recordings or transcripts of testimony taken in a foreign judicial proceeding concerning such order or judgment of forfeiture, shall be admissible in evidence in a proceeding brought pursuant to this section. Such certified order or judgment of forfeiture, when admitted into evidence, shall constitute probable cause that the property forfeited by such order or judgment of forfeiture is subject to forfeiture under this section and creates a rebuttable presumption of the forfeitability of such property under this section.

(4) A certified order or judgment of conviction by a court of competent jurisdiction of a foreign country concerning an unlawful drug activity which gives rise to forfeiture under this section and any certified recordings or transcripts of testimony taken in a foreign judicial proceeding concerning such order or judgment of conviction shall be admissible in evidence in a proceeding brought pursuant to this section. Such certified order or judgment of conviction, when admitted into evidence, creates a rebuttable presumption that the unlawful drug activity giving rise to forfeiture under this section has occurred.

(5) The provisions of paragraphs (3) and (4) of this subsection shall not be construed as limiting the admissibility of any evidence otherwise admissible, nor shall they limit the ability of the United States to establish probable cause that property is subject to forfeiture by any evidence otherwise admissible.

(j) For purposes of this section—

(1) the term "Attorney General" means the Attorney General or his delegate; and

(2) the term "Secretary of the Treasury" means the Secretary of the Treasury or his delegate.

(k) INTERBANK ACCOUNTS.—

(1) IN GENERAL.—

(A) IN GENERAL.—For the purpose of a forfeiture under this section or under the Controlled Substances Act (21 U.S.C. 801 et seq.), if funds are deposited into an account at a foreign bank, and that foreign bank has an interbank account in the United States with a covered financial institution (as defined in section 5318(j)(1) of title 31), the funds shall be deemed to have been deposited into the interbank account in the United States, and any restraining order, seizure warrant, or arrest warrant in rem regarding the funds may be served on the covered financial institution, and funds in the interbank account, up to the value of the funds deposited into the account at the foreign bank, may be restrained, seized, or arrested.

(B) AUTHORITY TO SUSPEND.—The Attorney General, in consultation with the Secretary of the Treasury, may suspend or terminate a forfeiture under this section if the Attorney General determines that a conflict of law exists between the laws of the jurisdiction in which the foreign

bank is located and the laws of the United States with respect to liabilities arising from the restraint, seizure, or arrest of such funds, and that such suspension or termination would be in the interest of justice and would not harm the national interests of the United States.

(2) NO REQUIREMENT FOR GOVERNMENT TO TRACE FUNDS.—If a forfeiture action is brought against funds that are restrained, seized, or arrested under paragraph (1), it shall not be necessary for the Government to establish that the funds are directly traceable to the funds that were deposited into the foreign bank, nor shall it be necessary for the Government to rely on the application of section 984.

(3) CLAIMS BROUGHT BY OWNER OF THE FUNDS.—If a forfeiture action is instituted against funds restrained, seized, or arrested under paragraph (1), the owner of the funds deposited into the account at the foreign bank may contest the forfeiture by filing a claim under section 983.

(4) DEFINITIONS.—For purposes of this subsection, the following definitions shall apply:

(A) INTERBANK ACCOUNT.—The term "interbank account" has the same meaning as in section 984(c)(2)(B).

(B) OWNER.—

(i) IN GENERAL.—Except as provided in clause (ii), the term "owner"—

(I) means the person who was the owner, as that term is defined in section 983(d)(6), of the funds that were deposited into the foreign bank at the time such funds were deposited; and

(II) does not include either the foreign bank or any financial institution acting as an intermediary in the transfer of the funds into the interbank account.

(ii) EXCEPTION.—The foreign bank may be considered the "owner" of the funds (and no other person shall qualify as the owner of such funds) only if—

(I) the basis for the forfeiture action is wrongdoing committed by the foreign bank; or

(II) the foreign bank establishes, by a preponderance of the evidence, that prior to the restraint, seizure, or arrest of the funds, the foreign bank had discharged all or part of its obligation to the prior owner of the funds, in which case the foreign bank shall be deemed the owner of the funds to the extent of such discharged obligation.

§ 982. Criminal forfeiture [3]

(a)(1) The court, in imposing sentence on a person convicted of an offense in violation of section 1956, 1957, or 1960 of this title,

[3] Added by Public Law 99–570, Title I, § 1366(a), Oct. 27, 1986, 100 Stat. 3707–39, and amended by Public Law 100–690, Title VI, § § 6463(c), 6464, Nov. 18, 1988, 102 Stat. 4374, 4375; Public Law 101–73, Title IX, § 963(c), Aug. 9, 1989, 103 Stat. 504; Public Law 101–647, Title XIV, § § 1401, 1403, Title XXV, § 2525(b), Nov. 29, 1990, 104 Stat. 4835, 4874; Public Law 102–393, Title VI, § 638(e), Oct. 6, 1992, 106 Stat. 1788; Public Law 102–519, Title I, § 104(b), Oct. 25, 1992, 106 Stat. 3385; Public Law 102–550, Title XV, § 1512(c), Oct. 28, 1992, 106 Stat. 4058; Public Law 103–322, Title XXXIII, § 330011(s)(1), Sept. 13, 1994, 108 Stat. 2145; Public Law 104–191, Title II, § 249(a), (b), Aug. 21, 1996, 110 Stat. 2020; Public Law 104–208, Div. C, Title

shall order that the person forfeit to the United States any property, real or personal, involved in such offense, or any property traceable to such property.

(2) The court, in imposing sentence on a person convicted of a violation of, or a conspiracy to violate—

(A) section 215, 656, 657, 1005, 1006, 1007, 1014, 1341, 1343, or 1344 of this title, affecting a financial institution, or

(B) section 471, 472, 473, 474, 476, 477, 478, 479, 480, 481, 485, 486, 487, 488, 501, 502, 510, 542, 545, 842, 844, 1028, 1029, or 1030 of this title,

shall order that the person forfeit to the United States any property constituting, or derived from, proceeds the person obtained directly or indirectly, as the result of such violation.

(3) The court, in imposing a sentence on a person convicted of an offense under—

(A) section 666(a)(1) (relating to Federal program fraud);

(B) section 1001 (relating to fraud and false statements);

(C) section 1031 (relating to major fraud against the United States);

(D) section 1032 (relating to concealment of assets from conservator, receiver, or liquidating agent of insured financial institution);

(E) section 1341 (relating to mail fraud); or

(F) section 1343 (relating to wire fraud),

involving the sale of assets acquired or held by the Resolution Trust Corporation, the Federal Deposit Insurance Corporation, as conservator or receiver for a financial institution or any other conservator for a financial institution appointed by the Office of the Comptroller of the Currency or the Office of Thrift Supervision, or the National Credit Union Administration, as conservator or liquidating agent for a financial institution, shall order that the person forfeit to the United States any property, real or personal, which represents or is traceable to the gross receipts obtained, directly or indirectly, as a result of such violation.

(4) With respect to an offense listed in subsection (a)(3) committed for the purpose of executing or attempting to execute any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent statements, pretenses, representations, or promises, the gross receipts of such an offense shall include any property, real or personal, tangible or intangible, which is obtained, directly or indirectly, as a result of such offense.

(5) The court, in imposing sentence on a person convicted of a violation or conspiracy to violate—

(A) section 511 (altering or removing motor vehicle identification numbers);

(B) section 553 (importing or exporting stolen motor vehicles);

(C) section 2119 (armed robbery of automobiles);

(D) section 2312 (transporting stolen motor vehicles in interstate commerce); or

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II, § 217, Sept. 30, 1996, 110 Stat. 3009–573; Public Law 105–184, § 2, June 23, 1998, 112 Stat. 520; Public Law 105–318, § 6(a), Oct. 30, 1998, 112 Stat. 3010; Public Law 106–185, § 18(b), Apr. 25, 2000, 114 Stat. 223; Public Law 107–56, Title III, § 372(b)(2), Oct. 26, 2001, 115 Stat. 339; Public Law 107–273, Div. B, Title IV, § 4002(b)(10), Nov. 2, 2002, 116 Stat. 1808.

(E) section 2313 (possessing or selling a stolen motor vehicle that has moved in interstate commerce);

shall order that the person forfeit to the United States any property, real or personal, which represents or is traceable to the gross proceeds obtained, directly or indirectly, as a result of such violation.

(6)(A) The court, in imposing sentence on a person convicted of a violation of, or conspiracy to violate, section 274(a), 274A(a)(1), or 274A(a)(2) of the Immigration and Nationality Act or section 1425, 1426, 1427, 1541, 1542, 1543, 1544, or 1546 of this title, or a violation of, or conspiracy to violate, section 1028 of this title if committed in connection with passport or visa issuance or use, shall order that the person forfeit to the United States, regardless of any provision of State law—

(i) any conveyance, including any vessel, vehicle, or aircraft used in the commission of the offense of which the person is convicted; and

(ii) any property real or personal—

(I) that constitutes, or is derived from or is traceable to the proceeds obtained directly or indirectly from the commission of the offense of which the person is convicted; or

(II) that is used to facilitate, or is intended to be used to facilitate, the commission of the offense of which the person is convicted.

(B) The court, in imposing sentence on a person described in subparagraph (A), shall order that the person forfeit to the United States all property described in that subparagraph.

(7) The court, in imposing sentence on a person convicted of a Federal health care offense, shall order the person to forfeit property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

(8) The court, in sentencing a defendant convicted of an offense under section 1028, 1029, 1341, 1342, 1343, or 1344, or of a conspiracy to commit such an offense, if the offense involves telemarketing (as that term is defined in section 2325), shall order that the defendant forfeit to the United States any real or personal property—

(A) used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and

(B) constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense.

(b)(1) The forfeiture of property under this section, including any seizure and disposition of the property and any related judicial or administrative proceeding, shall be governed by the provisions of section 413 (other than subsection (d) of that section) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853).

(2) The substitution of assets provisions of subsection 413(p) shall not be used to order a defendant to forfeit assets in place of the actual property laundered where such defendant acted merely as an intermediary who handled but did not retain the property in the course of the money laundering offense unless the defendant,

in committing the offense or offenses giving rise to the forfeiture, conducted three or more separate transactions involving a total of $100,000 or more in any twelve month period.

§ 983. General rules for civil forfeiture proceedings[4]

(a) NOTICE; CLAIM; COMPLAINT.—

(1)(A)(i) Except as provided in clauses (ii) through (v), in any nonjudicial civil forfeiture proceeding under a civil forfeiture statute, with respect to which the Government is required to send written notice to interested parties, such notice shall be sent in a manner to achieve proper notice as soon as practicable, and in no case more than 60 days after the date of the seizure.

(ii) No notice is required if, before the 60-day period expires, the Government files a civil judicial forfeiture action against the property and provides notice of that action as required by law.

(iii) If, before the 60-day period expires, the Government does not file a civil judicial forfeiture action, but does obtain a criminal indictment containing an allegation that the property is subject to forfeiture, the Government shall either—

(I) send notice within the 60 days and continue the nonjudicial civil forfeiture proceeding under this section; or

(II) terminate the nonjudicial civil forfeiture proceeding, and take the steps necessary to preserve its right to maintain custody of the property as provided in the applicable criminal forfeiture statute.

(iv) In a case in which the property is seized by a State or local law enforcement agency and turned over to a Federal law enforcement agency for the purpose of forfeiture under Federal law, notice shall be sent not more than 90 days after the date of seizure by the State or local law enforcement agency.

(v) If the identity or interest of a party is not determined until after the seizure or turnover but is determined before a declaration of forfeiture is entered, notice shall be sent to such interested party not later than 60 days after the determination by the Government of the identity of the party or the party's interest.

(B) A supervisory official in the headquarters office of the seizing agency may extend the period for sending notice under subparagraph (A) for a period not to exceed 30 days (which period may not be further extended except by a court), if the official determines that the conditions in subparagraph (D) are present.

(C) Upon motion by the Government, a court may extend the period for sending notice under subparagraph (A) for a period not to exceed 60 days, which period may be further extended by the court for 60-day periods, as necessary, if the court determines, based on a written certification of a supervisory official in the headquarters office of the seizing agency, that the conditions in subparagraph (D) are present.

[4] Added by Public Law 106–185, § 2(a), Apr. 25, 2000, 114 Stat. 202, and amended by Public Law 106–185, § 9, Apr. 25, 2000, 114 Stat. 216; Public Law 106–561, § 3(a), Dec. 21, 2000, 114 Stat. 2791; Public Law 107–56, Title III, § 316(d), Oct. 26, 2001, 115 Stat. 310.

(D) The period for sending notice under this paragraph may be extended only if there is reason to believe that notice may have an adverse result, including—

(i) endangering the life or physical safety of an individual;

(ii) flight from prosecution;

(iii) destruction of or tampering with evidence;

(iv) intimidation of potential witnesses; or

(v) otherwise seriously jeopardizing an investigation or unduly delaying a trial.

(E) Each of the Federal seizing agencies conducting nonjudicial forfeitures under this section shall report periodically to the Committees on the Judiciary of the House of Representatives and the Senate the number of occasions when an extension of time is granted under subparagraph (B).

(F) If the Government does not send notice of a seizure of property in accordance with subparagraph (A) to the person from whom the property was seized, and no extension of time is granted, the Government shall return the property to that person without prejudice to the right of the Government to commence a forfeiture proceeding at a later time. The Government shall not be required to return contraband or other property that the person from whom the property was seized may not legally possess.

(2)(A) Any person claiming property seized in a nonjudicial civil forfeiture proceeding under a civil forfeiture statute may file a claim with the appropriate official after the seizure.

(B) A claim under subparagraph (A) may be filed not later than the deadline set forth in a personal notice letter (which deadline may be not earlier than 35 days after the date the letter is mailed), except that if that letter is not received, then a claim may be filed not later than 30 days after the date of final publication of notice of seizure.

(C) A claim shall—

(i) identify the specific property being claimed;

(ii) state the claimant's interest in such property; and

(iii) be made under oath, subject to penalty of perjury.

(D) A claim need not be made in any particular form. Each Federal agency conducting nonjudicial forfeitures under this section shall make claim forms generally available on request, which forms shall be written in easily understandable language.

(E) Any person may make a claim under subparagraph (A) without posting bond with respect to the property which is the subject of the claim.

(3)(A) Not later than 90 days after a claim has been filed, the Government shall file a complaint for forfeiture in the manner set forth in the Supplemental Rules for Certain Admiralty and Maritime Claims or return the property pending the filing of a complaint, except that a court in the district in which the complaint will be filed may extend the period for filing a complaint for good cause shown or upon agreement of the parties.

(B) If the Government does not—

(i) file a complaint for forfeiture or return the property, in accordance with subparagraph (A); or

(ii) before the time for filing a complaint has expired—

(I) obtain a criminal indictment containing an allegation that the property is subject to forfeiture; and

(II) take the steps necessary to preserve its right to maintain custody of the property as provided in the applicable criminal forfeiture statute,

the Government shall promptly release the property pursuant to regulations promulgated by the Attorney General, and may not take any further action to effect the civil forfeiture of such property in connection with the underlying offense.

(C) In lieu of, or in addition to, filing a civil forfeiture complaint, the Government may include a forfeiture allegation in a criminal indictment. If criminal forfeiture is the only forfeiture proceeding commenced by the Government, the Government's right to continued possession of the property shall be governed by the applicable criminal forfeiture statute.

(D) No complaint may be dismissed on the ground that the Government did not have adequate evidence at the time the complaint was filed to establish the forfeitability of the property.

(4)(A) In any case in which the Government files in the appropriate United States district court a complaint for forfeiture of property, any person claiming an interest in the seized property may file a claim asserting such person's interest in the property in the manner set forth in the Supplemental Rules for Certain Admiralty and Maritime Claims, except that such claim may be filed not later than 30 days after the date of service of the Government's complaint or, as applicable, not later than 30 days after the date of final publication of notice of the filing of the complaint.

(B) A person asserting an interest in seized property, in accordance with subparagraph (A), shall file an answer to the Government's complaint for forfeiture not later than 20 days after the date of the filing of the claim.

(b) REPRESENTATION.—

(1)(A) If a person with standing to contest the forfeiture of property in a judicial civil forfeiture proceeding under a civil forfeiture statute is financially unable to obtain representation by counsel, and the person is represented by counsel appointed under section 3006A of this title in connection with a related criminal case, the court may authorize counsel to represent that person with respect to the claim.

(B) In determining whether to authorize counsel to represent a person under subparagraph (A), the court shall take into account such factors as—

(i) the person's standing to contest the forfeiture; and

(ii) whether the claim appears to be made in good faith.

(2)(A) If a person with standing to contest the forfeiture of property in a judicial civil forfeiture proceeding under a civil forfeiture statute is financially unable to obtain representation

by counsel, and the property subject to forfeiture is real property that is being used by the person as a primary residence, the court, at the request of the person, shall insure that the person is represented by an attorney for the Legal Services Corporation with respect to the claim.

(B)(i) At appropriate times during a representation under subparagraph (A), the Legal Services Corporation shall submit a statement of reasonable attorney fees and costs to the court.

(ii) The court shall enter a judgment in favor of the Legal Services Corporation for reasonable attorney fees and costs submitted pursuant to clause (i) and treat such judgment as payable under section 2465 of title 28, United States Code, regardless of the outcome of the case.

(3) The court shall set the compensation for representation under this subsection, which shall be equivalent to that provided for court-appointed representation under section 3006A of this title.

(c) BURDEN OF PROOF.—In a suit or action brought under any civil forfeiture statute for the civil forfeiture of any property—

(1) the burden of proof is on the Government to establish, by a preponderance of the evidence, that the property is subject to forfeiture;

(2) the Government may use evidence gathered after the filing of a complaint for forfeiture to establish, by a preponderance of the evidence, that property is subject to forfeiture; and

(3) if the Government's theory of forfeiture is that the property was used to commit or facilitate the commission of a criminal offense, or was involved in the commission of a criminal offense, the Government shall establish that there was a substantial connection between the property and the offense.

(d) INNOCENT OWNER DEFENSE.—

(1) An innocent owner's interest in property shall not be forfeited under any civil forfeiture statute. The claimant shall have the burden of proving that the claimant is an innocent owner by a preponderance of the evidence.

(2)(A) With respect to a property interest in existence at the time the illegal conduct giving rise to forfeiture took place, the term "innocent owner" means an owner who—

(i) did not know of the conduct giving rise to forfeiture; or

(ii) upon learning of the conduct giving rise to the forfeiture, did all that reasonably could be expected under the circumstances to terminate such use of the property.

(B)(i) For the purposes of this paragraph, ways in which a person may show that such person did all that reasonably could be expected may include demonstrating that such person, to the extent permitted by law—

(I) gave timely notice to an appropriate law enforcement agency of information that led the person to know the conduct giving rise to a forfeiture would occur or has occurred; and

(II) in a timely fashion revoked or made a good faith attempt to revoke permission for those engaging in such conduct to use the property or took reasonable actions in consultation with a law enforcement agency to discourage or prevent the illegal use of the property.

(ii) A person is not required by this subparagraph to take steps that the person reasonably believes would be likely to subject any person (other than the person whose conduct gave rise to the forfeiture) to physical danger.

(3)(A) With respect to a property interest acquired after the conduct giving rise to the forfeiture has taken place, the term "innocent owner" means a person who, at the time that person acquired the interest in the property—

(i) was a bona fide purchaser or seller for value (including a purchaser or seller of goods or services for value); and

(ii) did not know and was reasonably without cause to believe that the property was subject to forfeiture.

(B) An otherwise valid claim under subparagraph (A) shall not be denied on the ground that the claimant gave nothing of value in exchange for the property if—

(i) the property is the primary residence of the claimant;

(ii) depriving the claimant of the property would deprive the claimant of the means to maintain reasonable shelter in the community for the claimant and all dependents residing with the claimant;

(iii) the property is not, and is not traceable to, the proceeds of any criminal offense; and

(iv) the claimant acquired his or her interest in the property through marriage, divorce, or legal separation, or the claimant was the spouse or legal dependent of a person whose death resulted in the transfer of the property to the claimant through inheritance or probate,

except that the court shall limit the value of any real property interest for which innocent ownership is recognized under this subparagraph to the value necessary to maintain reasonable shelter in the community for such claimant and all dependents residing with the claimant.

(4) Notwithstanding any provision of this subsection, no person may assert an ownership interest under this subsection in contraband or other property that it is illegal to possess.

(5) If the court determines, in accordance with this section, that an innocent owner has a partial interest in property otherwise subject to forfeiture, or a joint tenancy or tenancy by the entirety in such property, the court may enter an appropriate order—

(A) severing the property;

(B) transferring the property to the Government with a provision that the Government compensate the innocent owner to the extent of his or her ownership interest once a final order of forfeiture has been entered and the property has been reduced to liquid assets; or

(C) permitting the innocent owner to retain the property subject to a lien in favor of the Government to the extent of the forfeitable interest in the property.

(6) In this subsection, the term "owner"—

(A) means a person with an ownership interest in the specific property sought to be forfeited, including a leasehold, lien, mortgage, recorded security interest, or valid assignment of an ownership interest; and

(B) does not include—

(i) a person with only a general unsecured interest in, or claim against, the property or estate of another;

(ii) a bailee unless the bailor is identified and the bailee shows a colorable legitimate interest in the property seized; or

(iii) a nominee who exercises no dominion or control over the property.

(e) MOTION TO SET ASIDE FORFEITURE.—

(1) Any person entitled to written notice in any nonjudicial civil forfeiture proceeding under a civil forfeiture statute who does not receive such notice may file a motion to set aside a declaration of forfeiture with respect to that person's interest in the property, which motion shall be granted if—

(A) the Government knew, or reasonably should have known, of the moving party's interest and failed to take reasonable steps to provide such party with notice; and

(B) the moving party did not know or have reason to know of the seizure within sufficient time to file a timely claim.

(2)(A) Notwithstanding the expiration of any applicable statute of limitations, if the court grants a motion under paragraph (1), the court shall set aside the declaration of forfeiture as to the interest of the moving party without prejudice to the right of the Government to commence a subsequent forfeiture proceeding as to the interest of the moving party.

(B) Any proceeding described in subparagraph (A) shall be commenced—

(i) if nonjudicial, within 60 days of the entry of the order granting the motion; or

(ii) if judicial, within 6 months of the entry of the order granting the motion.

(3) A motion under paragraph (1) may be filed not later than 5 years after the date of final publication of notice of seizure of the property.

(4) If, at the time a motion made under paragraph (1) is granted, the forfeited property has been disposed of by the Government in accordance with law, the Government may institute proceedings against a substitute sum of money equal to the value of the moving party's interest in the property at the time the property was disposed of.

(5) A motion filed under this subsection shall be the exclusive remedy for seeking to set aside a declaration of forfeiture under a civil forfeiture statute.

(f) RELEASE OF SEIZED PROPERTY.—

(1) A claimant under subsection (a) is entitled to immediate release of seized property if—

(A) the claimant has a possessory interest in the property;

(B) the claimant has sufficient ties to the community to provide assurance that the property will be available at the time of the trial;

(C) the continued possession by the Government pending the final disposition of forfeiture proceedings will cause substantial hardship to the claimant, such as preventing the functioning of a business, preventing an individual from working, or leaving an individual homeless;

(D) the claimant's likely hardship from the continued possession by the Government of the seized property outweighs the risk that the property will be destroyed, damaged, lost, concealed, or transferred if it is returned to the claimant during the pendency of the proceeding; and

(E) none of the conditions set forth in paragraph (8) applies.

(2) A claimant seeking release of property under this subsection must request possession of the property from the appropriate official, and the request must set forth the basis on which the requirements of paragraph (1) are met.

(3)(A) If not later than 15 days after the date of a request under paragraph (2) the property has not been released, the claimant may file a petition in the district court in which the complaint has been filed or, if no complaint has been filed, in the district court in which the seizure warrant was issued or in the district court for the district in which the property was seized.

(B) The petition described in subparagraph (A) shall set forth—

(i) the basis on which the requirements of paragraph (1) are met; and

(ii) the steps the claimant has taken to secure release of the property from the appropriate official.

(4) If the Government establishes that the claimant's claim is frivolous, the court shall deny the petition. In responding to a petition under this subsection on other grounds, the Government may in appropriate cases submit evidence ex parte in order to avoid disclosing any matter that may adversely affect an ongoing criminal investigation or pending criminal trial.

(5) The court shall render a decision on a petition filed under paragraph (3) not later than 30 days after the date of the filing, unless such 30-day limitation is extended by consent of the parties or by the court for good cause shown.

(6) If—

(A) a petition is filed under paragraph (3); and

(B) the claimant demonstrates that the requirements of paragraph (1) have been met,

the district court shall order that the property be returned to the claimant, pending completion of proceedings by the Government to obtain forfeiture of the property.

(7) If the court grants a petition under paragraph (3)—

(A) the court may enter any order necessary to ensure that the value of the property is maintained while the forfeiture action is pending, including—

(i) permitting the inspection, photographing, and inventory of the property;

(ii) fixing a bond in accordance with rule E(5) of the Supplemental Rules for Certain Admiralty and Maritime Claims; and

(iii) requiring the claimant to obtain or maintain insurance on the subject property; and

(B) the Government may place a lien against the property or file a lis pendens to ensure that the property is not transferred to another person.

(8) This subsection shall not apply if the seized property—

(A) is contraband, currency, or other monetary instrument, or electronic funds unless such currency or other monetary instrument or electronic funds constitutes the assets of a legitimate business which has been seized;

(B) is to be used as evidence of a violation of the law;

(C) by reason of design or other characteristic, is particularly suited for use in illegal activities; or

(D) is likely to be used to commit additional criminal acts if returned to the claimant.

(g) PROPORTIONALITY.—

(1) The claimant under subsection (a)(4) may petition the court to determine whether the forfeiture was constitutionally excessive.

(2) In making this determination, the court shall compare the forfeiture to the gravity of the offense giving rise to the forfeiture.

(3) The claimant shall have the burden of establishing that the forfeiture is grossly disproportional by a preponderance of the evidence at a hearing conducted by the court without a jury.

(4) If the court finds that the forfeiture is grossly disproportional to the offense it shall reduce or eliminate the forfeiture as necessary to avoid a violation of the Excessive Fines Clause of the Eighth Amendment of the Constitution.

(h) CIVIL FINE.—

(1) In any civil forfeiture proceeding under a civil forfeiture statute in which the Government prevails, if the court finds that the claimant's assertion of an interest in the property was frivolous, the court may impose a civil fine on the claimant of an amount equal to 10 percent of the value of the forfeited property, but in no event shall the fine be less than $250 or greater than $5,000.

(2) Any civil fine imposed under this subsection shall not preclude the court from imposing sanctions under rule 11 of the Federal Rules of Civil Procedure.

(3) In addition to the limitations of section 1915 of title 28, United States Code, in no event shall a prisoner file a claim under a civil forfeiture statute or appeal a judgment in a civil action or proceeding based on a civil forfeiture statute if the

prisoner has, on three or more prior occasions, while incarcerated or detained in any facility, brought an action or appeal in a court of the United States that was dismissed on the grounds that it is frivolous or malicious, unless the prisoner shows extraordinary and exceptional circumstances.

(i) CIVIL FORFEITURE STATUTE DEFINED.—In this section, the term "civil forfeiture statute"—

(1) means any provision of Federal law providing for the forfeiture of property other than as a sentence imposed upon conviction of a criminal offense; and

(2) does not include—

(A) the Tariff Act of 1930 or any other provision of law codified in title 19;

(B) the Internal Revenue Code of 1986;

(C) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(D) the Trading with the Enemy Act (50 U.S.C. App. 1 et seq.) or the International Emergency Economic Powers Act (IEEPA) (50 U.S.C. 1701 et seq.); or

(E) section 1 of title VI of the Act of June 15, 1917 (40 Stat. 233; 22 U.S.C. 401).

(j) RESTRAINING ORDERS; PROTECTIVE ORDERS.—

(1) Upon application of the United States, the court may enter a restraining order or injunction, require the execution of satisfactory performance bonds, create receiverships, appoint conservators, custodians, appraisers, accountants, or trustees, or take any other action to seize, secure, maintain, or preserve the availability of property subject to civil forfeiture—

(A) upon the filing of a civil forfeiture complaint alleging that the property with respect to which the order is sought is subject to civil forfeiture; or

(B) prior to the filing of such a complaint, if, after notice to persons appearing to have an interest in the property and opportunity for a hearing, the court determines that—

(i) there is a substantial probability that the United States will prevail on the issue of forfeiture and that failure to enter the order will result in the property being destroyed, removed from the jurisdiction of the court, or otherwise made unavailable for forfeiture; and

(ii) the need to preserve the availability of the property through the entry of the requested order outweighs the hardship on any party against whom the order is to be entered.

(2) An order entered pursuant to paragraph (1)(B) shall be effective for not more than 90 days, unless extended by the court for good cause shown, or unless a complaint described in paragraph (1)(A) has been filed.

(3) A temporary restraining order under this subsection may be entered upon application of the United States without notice or opportunity for a hearing when a complaint has not yet been filed with respect to the property, if the United States demonstrates that there is probable cause to believe that the property with respect to which the order is sought is subject to civil

forfeiture and that provision of notice will jeopardize the availability of the property for forfeiture. Such a temporary order shall expire not more than 10 days after the date on which it is entered, unless extended for good cause shown or unless the party against whom it is entered consents to an extension for a longer period. A hearing requested concerning an order entered under this paragraph shall be held at the earliest possible time and prior to the expiration of the temporary order.

(4) The court may receive and consider, at a hearing held pursuant to this subsection, evidence and information that would be inadmissible under the Federal Rules of Evidence.

§ 984. Civil forfeiture of fungible property [5]

(a)(1) In any forfeiture action in rem in which the subject property is cash, monetary instruments in bearer form, funds deposited in an account in a financial institution (as defined in section 20 of this title), or precious metals—

(A) it shall not be necessary for the Government to identify the specific property involved in the offense that is the basis for the forfeiture; and

(B) it shall not be a defense that the property involved in such an offense has been removed and replaced by identical property.

(2) Except as provided in subsection (b), any identical property found in the same place or account as the property involved in the offense that is the basis for the forfeiture shall be subject to forfeiture under this section.

(b) No action pursuant to this section to forfeit property not traceable directly to the offense that is the basis for the forfeiture may be commenced more than 1 year from the date of the offense.

(c)(1) Subsection (a) does not apply to an action against funds held by a financial institution in an interbank account unless the account holder knowingly engaged in the offense that is the basis for the forfeiture.

(2) In this subsection—

(A) the term ''financial institution'' includes a foreign bank (as defined in section 1(b)(7) of the International Banking Act of 1978 (12 U.S.C. 3101(b)(7)) [6]; and

(B) the term ''interbank account'' means an account held by one financial institution at another financial institution primarily for the purpose of facilitating customer transactions.

(d) Nothing in this section may be construed to limit the ability of the Government to forfeit property under any provision of law if the property involved in the offense giving rise to the forfeiture or property traceable thereto is available for forfeiture.

§ 985. Civil forfeiture of real property [7]

(a) Notwithstanding any other provision of law, all civil forfeitures of real property and interests in real property shall proceed as judicial forfeitures.

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[5] Added by Public Law 102–550, Title XV, § 1522(a), Oct. 28, 1992, 106 Stat. 4063, and amended by Public Law 103–325, Title IV, § 411(c)(2)(E), Sept. 23, 1994, 108 Stat. 2253; Public Law 106–185, § 13(a), Apr. 25, 2000, 114 Stat. 218.

[6] So in original. Probably should be ''(12 U.S.C. 3101(7))''.

[7] Added by Public Law 106–185, § 7(a), Apr. 25, 2000, 114 Stat. 214.

(b)(1) Except as provided in this section—

(A) real property that is the subject of a civil forfeiture action shall not be seized before entry of an order of forfeiture; and

(B) the owners or occupants of the real property shall not be evicted from, or otherwise deprived of the use and enjoyment of, real property that is the subject of a pending forfeiture action.

(2) The filing of a lis pendens and the execution of a writ of entry for the purpose of conducting an inspection and inventory of the property shall not be considered a seizure under this subsection.

(c)(1) The Government shall initiate a civil forfeiture action against real property by—

(A) filing a complaint for forfeiture;

(B) posting a notice of the complaint on the property; and

(C) serving notice on the property owner, along with a copy of the complaint.

(2) If the property owner cannot be served with the notice under paragraph (1) because the owner—

(A) is a fugitive;

(B) resides outside the United States and efforts at service pursuant to rule 4 of the Federal Rules of Civil Procedure are unavailing; or

(C) cannot be located despite the exercise of due diligence, constructive service may be made in accordance with the laws of the State in which the property is located.

(3) If real property has been posted in accordance with this subsection, it shall not be necessary for the court to issue an arrest warrant in rem, or to take any other action to establish in rem jurisdiction over the property.

(d)(1) Real property may be seized prior to the entry of an order of forfeiture if—

(A) the Government notifies the court that it intends to seize the property before trial; and

(B) the court—

(i) issues a notice of application for warrant, causes the notice to be served on the property owner and posted on the property, and conducts a hearing in which the property owner has a meaningful opportunity to be heard; or

(ii) makes an ex parte determination that there is probable cause for the forfeiture and that there are exigent circumstances that permit the Government to seize the property without prior notice and an opportunity for the property owner to be heard.

(2) For purposes of paragraph (1)(B)(ii), to establish exigent circumstances, the Government shall show that less restrictive measures such as a lis pendens, restraining order, or bond would not suffice to protect the Government's interests in preventing the sale, destruction, or continued unlawful use of the real property.

(e) If the court authorizes a seizure of real property under subsection (d)(1)(B)(ii), it shall conduct a prompt post-seizure hearing during which the property owner shall have an opportunity to contest the basis for the seizure.

(f) This section—

(1) applies only to civil forfeitures of real property and interests in real property;

(2) does not apply to forfeitures of the proceeds of the sale of such property or interests, or of money or other assets intended to be used to acquire such property or interests; and

(3) shall not affect the authority of the court to enter a restraining order relating to real property.

§ 986. Subpoenas for bank records[8]

(a) At any time after the commencement of any action for forfeiture in rem brought by the United States under section 1956, 1957, or 1960 of this title, section 5322 or 5324 of title 31, United States Code, or the Controlled Substances Act, any party may request the Clerk of the Court in the district in which the proceeding is pending to issue a subpoena duces tecum to any financial institution, as defined in section 5312(a) of title 31, United States Code, to produce books, records and any other documents at any place designated by the requesting party. All parties to the proceeding shall be notified of the issuance of any such subpoena. The procedures and limitations set forth in section 985 of this title shall apply to subpoenas issued under this section.

(b) Service of a subpoena issued pursuant to this section shall be by certified mail. Records produced in response to such a subpoena may be produced in person or by mail, common carrier, or such other method as may be agreed upon by the party requesting the subpoena and the custodian of records. The party requesting the subpoena may require the custodian of records to submit an affidavit certifying the authenticity and completeness of the records and explaining the omission of any record called for in the subpoena.

(c) Nothing in this section shall preclude any party from pursuing any form of discovery pursuant to the Federal Rules of Civil Procedure.

(d) ACCESS TO RECORDS IN BANK SECRECY JURISDICTIONS.—

(1) IN GENERAL.—In any civil forfeiture case, or in any ancillary proceeding in any criminal forfeiture case governed by section 413(n) of the Controlled Substances Act (21 U.S.C. 853(n)), in which—

(A) financial records located in a foreign country may be material—

(i) to any claim or to the ability of the Government to respond to such claim; or

(ii) in a civil forfeiture case, to the ability of the Government to establish the forfeitability of the property; and

(B) it is within the capacity of the claimant to waive the claimant's rights under applicable financial secrecy laws, or to obtain the records so that such records can be made available notwithstanding such secrecy laws,

the refusal of the claimant to provide the records in response to a discovery request or to take the action necessary otherwise

[8] Added by Public Law 102–550, Title XV, § 1523(a), Oct. 28, 1992, 106 Stat. 4063, and amended by Public Law 103–325, Title IV, § 411(c)(2)(E), Sept. 23, 1994, 108 Stat. 2253; Public Law 106–185, § 17, Apr. 25, 2000, 114 Stat. 221.

to make the records available shall be grounds for judicial sanctions, up to and including dismissal of the claim with prejudice.

(2) PRIVILEGE.—This subsection shall not affect the right of the claimant to refuse production on the basis of any privilege guaranteed by the Constitution of the United States or any other provision of Federal law.

18 U.S.C. § 1001
False statement of material matter within the jurisdiction of a Federal agency or department

Chapter 47. Fraud and False Statements

§ 1001. Statements or entries generally [1]

(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation; or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both.

(b) Subsection (a) does not apply to a party to a judicial proceeding, or that party's counsel, for statements, representations, writings or documents submitted by such party or counsel to a judge or magistrate in that proceeding.

(c) With respect to any matter within the jurisdiction of the legislative branch, subsection (a) shall apply only to—

(1) administrative matters, including a claim for payment, a matter related to the procurement of property or services, personnel or employment practices, or support services, or a document required by law, rule, or regulation to be submitted to the Congress or any office or officer within the legislative branch; or

(2) any investigation or review, conducted pursuant to the authority of any committee, subcommittee, commission or office of the Congress, consistent with applicable rules of the House or Senate.

[1] June 25, 1948, c. 645, 62 Stat. 749; Sept. 13, 1994, Public Law 103–322, Title XXXIII, § 330016(1)(L), 108 Stat. 2147; Oct. 11, 1996, Public Law 104–292, § 2, 110 Stat. 3459; Dec. 17, 2004, Public Law 108–458, § 6703(a), 118 Stat. 3766.

18 U.S.C. § 1114
Killing or attempting to kill a Federal official

Chapter 51. Homicide

§ 1114. Protection of officers and employees of the United States[1]

Whoever kills or attempts to kill any officer or employee of the United States or of any agency in any branch of the United States Government (including any member of the uniformed services) while such officer or employee is engaged in or on account of the performance of official duties, or any person assisting such an officer or employee in the performance of such duties or on account of that assistance, shall be punished—

(1) in the case of murder, as provided under section 1111;

(2) in the case of manslaughter, as provided under section 1112; or

(3) in the case of attempted murder or manslaughter, as provided in section 1113.

[1] June 25, 1948, c. 645, 62 Stat. 756; May 24, 1949, c. 139, § 24, 63 Stat. 93; Oct. 31, 1951, c. 655, § 28, 65 Stat. 721; June 27, 1952, c. 477, Title IV, § 402(c), 66 Stat. 276; July 29, 1958, Public Law 85–568, Title III, § 304(d), 72 Stat. 434; July 2, 1962, Public Law 87–518, § 10, 76 Stat. 132; Aug. 27, 1964, Public Law 88–493, § 3, 78 Stat. 610; July 15, 1965, Public Law 89–74, § 8(b), 79 Stat. 234; Aug. 2, 1968, Public Law 90–449, § 2, 82 Stat. 611; Aug. 12, 1970, Public Law 91–375, § 6(j) (9), 84 Stat. 777; Oct. 27, 1970, Public Law 91–513, Title II, § 701(i) (1), 84 Stat. 1282; Dec. 29, 1970, Public Law 91–596, § 17(h) (1), 84 Stat. 1607; Oct. 26, 1974, Public Law 93–481, § 5, 88 Stat. 1456; May 11, 1976, Public Law 94–284, § 18, 90 Stat. 514; Oct. 21, 1976, Public Law 94–582, § 16, 90 Stat. 2883; Aug. 3, 1977, Public Law 95–87, Title VII, § 704, 91 Stat. 520; Nov. 8, 1978, Public Law 95–616, § 3(j) (2), 92 Stat. 3112; Nov. 10, 1978, Public Law 95–630, Title III, § 307, 92 Stat. 3677; July 1, 1980, Public Law 96–296, § 26(c), 94 Stat. 819; Oct. 17, 1980, Public Law 96–466, Title VII, § 704, 94 Stat. 2216; Dec. 29, 1981, Public Law 97–143, § 1(b), 95 Stat. 1724; Sept. 13, 1982, Public Law 97–259, Title I, § 128, 96 Stat. 1099; Oct. 25, 1982, Public Law 97–365, § 6, 96 Stat. 1752; Jan. 12, 1983, Public Law 97–452, § 2(b), 96 Stat. 2478; July 30, 1983, Public Law 98–63, Title I, § 101, 97 Stat. 313; Oct. 12, 1984, Public Law 98–473, Title II, § 1012, 98 Stat. 2142; Oct. 30, 1984, Public Law 98–557, § 17(c), 98 Stat. 2868; Nov. 18, 1988, Public Law 100–690, Title VII, § 7026, 102 Stat. 4397; Aug. 9, 1989, Public Law 101–73, Title IX, § 962(a)(6), 103 Stat. 502; Nov. 29, 1990, Public Law 101–647, Title XII, § 1205(h), Title XVI, § 1606, Title XXXV, § 3535, 104 Stat. 4831, 4843, 4925; June 13, 1991, Public Law 102–54, § 13(f)(2), 105 Stat. 275; Sept. 3, 1992, Public Law 102–365, § 6, 106 Stat. 975; Sept. 13, 1994, Public Law 103–322, Title VI, § 60007, Title XXXIII, §§ 330009(c), 330011(g), 108 Stat. 1971, 2143, 2145; Apr. 24, 1996, Public Law 104–132, Title VII, § 727(a), 110 Stat. 1302; Oct. 11, 1996, Public Law 104–294, Title VI, § 601(f)(2), 110 Stat. 3499; Nov. 2, 2002, Public Law 107–273, Div. B, Title IV, § 4002(c)(1), 116 Stat. 1808.

Chapter 63. Mail Fraud

§ 1341. Frauds and swindles[1]

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, or to sell, dispose of, loan, exchange, alter, give away, distribute, supply, or furnish or procure for unlawful use any counterfeit or spurious coin, obligation, security, or other article, or anything represented to be or intimated or held out to be such counterfeit or spurious article, for the purpose of executing such scheme or artifice or attempting so to do, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or deposits or causes to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier, or takes or receives therefrom, any such matter or thing, or knowingly causes to be delivered by mail or such carrier according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter or thing, shall be fined under this title or imprisoned not more than 20 years, or both. If the violation affects a financial institution, such person shall be fined not more than $1,000,000 or imprisoned not more than 30 years, or both.

[1] June 25, 1948, c. 645, 62 Stat. 763; May 24, 1949, c. 139, § 34, 63 Stat. 94; Aug. 12, 1970, Public Law 91–375, § 6(j)(11), 84 Stat. 778; Aug. 9, 1989, Public Law 101–73, Title IX, § 961(i), 103 Stat. 500; Nov. 29, 1990, Public Law 101–647, Title XXV, § 2504(h), 104 Stat. 4861; Sept. 13, 1994, Public Law 103–322, Title XXV, § 250006, Title XXXIII, 330016(1)(H), 108 Stat. 2087, 2147; July 30, 2002, Public Law 107–204, Title IX, § 903(a), 116 Stat. 805.

18 U.S.C. § 1343
Wire fraud

§ 1343. Fraud by wire, radio, or television [1]

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice, shall be fined under this title or imprisoned not more than 20 years, or both. If the violation affects a financial institution, such person shall be fined not more than $1,000,000 or imprisoned not more than 30 years, or both.

[1] Added July 16, 1952, c. 879, § 18(a), 66 Stat. 722, and amended July 11, 1956, c. 561, 70 Stat. 523; Aug. 9, 1989, Public Law 101–73, Title IX, § 961(j), 103 Stat. 500; Nov. 29, 1990, Public Law 101–647, Title XXV, § 2504(i), 104 Stat. 4861; Sept. 13, 1994, Public Law 103–322, Title XXXIII, § 330016(1)(H), 108 Stat. 2147; July 30, 2002, Public Law 107–204, Title IX, § 903(b), 116 Stat. 805.

Chapter 73. Obstruction of Justice

§ 1505. Obstruction of proceedings before departments, agencies, and committees[1]

Whoever, with intent to avoid, evade, prevent, or obstruct compliance, in whole or in part, with any civil investigative demand duly and properly made under the Antitrust Civil Process Act, willfully withholds, misrepresents, removes from any place, conceals, covers up, destroys, mutilates, alters, or by other means falsifies any documentary material, answers to written interrogatories, or oral testimony, which is the subject of such demand; or attempts to do so or solicits another to do so; or

Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress—

Shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both.

[1] June 25, 1948, c. 645, 62 Stat. 770; Sept. 19, 1962, Public Law 87–664, § 6(a), 76 Stat. 551; Oct. 15, 1970, Public Law 91–452, Title IX, § 903, 84 Stat. 947; Sept. 30, 1976, Public Law 94–435, Title I, § 105, 90 Stat. 1389; Oct. 12, 1982, Public Law 97–291, § 4(d), 96 Stat. 1253; Sept. 13, 1994, Public Law 103–322, Title XXXIII, § 330016(1)(K), 108 Stat. 2147; Dec. 17, 2004, Public Law 108–458, § 6703(a), 118 Stat. 3766.

§ 1512. Tampering with a witness, victim, or an informant[1]

(a)(1) Whoever kills or attempts to kill another person, with intent to—

(A) prevent the attendance or testimony of any person in an official proceeding;

(B) prevent the production of a record, document, or other object, in an official proceeding; or

(C) prevent the communication by any person to a law enforcement officer or judge of the United States of information relating to the commission or possible commission of a Federal offense or a violation of conditions of probation, parole, or release pending judicial proceedings;

shall be punished as provided in paragraph (3).

(2) Whoever uses physical force or the threat of physical force against any person, or attempts to do so, with intent to—

(A) influence, delay, or prevent the testimony of any person in an official proceeding;

(B) cause or induce any person to—

(i) withhold testimony, or withhold a record, document, or other object, from an official proceeding;

(ii) alter, destroy, mutilate, or conceal an object with intent to impair the integrity or availability of the object for use in an official proceeding;

(iii) evade legal process summoning that person to appear as a witness, or to produce a record, document, or other object, in an official proceeding; or

(iv) be absent from an official proceeding to which that person has been summoned by legal process; or

(C) hinder, delay, or prevent the communication to a law enforcement officer or judge of the United States of information relating to the commission or possible commission of a Federal offense or a violation of conditions of probation, supervised release, parole, or release pending judicial proceedings;

shall be punished as provided in paragraph (3).

(3) The punishment for an offense under this subsection is—

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[1] Added by Public Law 97–291, § 4(a), Oct. 12, 1982, 96 Stat. 1249, and amended by Public Law 99–646, § 61, Nov. 10, 1986, 100 Stat. 3614; Public Law 100–690, Title VII, § 7029(a), (c), Nov. 18, 1988, 102 Stat. 4397, 4398; Public Law 101–650, Title III, § 321, Dec. 1, 1990, 104 Stat. 5117; Public Law 103–322, Title VI, § 60018, Title XXXIII, § 330016(1)(O), (U), Sept. 13, 1994, 108 Stat. 1975, 2148; Public Law 104–214, § 1(2), Oct. 1, 1996, 110 Stat. 3017; Public Law 104–294, Title VI, § 604(b)(31), Oct. 11, 1996, 110 Stat. 3508; Public Law 107–204, Title XI, § 1102, July 30, 2002, 116 Stat. 807; Public Law 107–273, Div. B, Title III, § 3001(a), (c)(1), Nov. 2, 2002, 116 Stat. 1803, 1804.

(A) in the case of murder (as defined in section 1111), the death penalty or imprisonment for life, and in the case of any other killing, the punishment provided in section 1112;

(B) in the case of—

(i) an attempt to murder; or

(ii) the use or attempted use of physical force against any person; imprisonment for not more than 20 years; and

(C) in the case of the threat of use of physical force against any person, imprisonment for not more than 10 years.

(b) Whoever knowingly uses intimidation, threatens, or corruptly persuades another person, or attempts to do so, or engages in misleading conduct toward another person, with intent to—

(1) influence, delay, or prevent the testimony of any person in an official proceeding;

(2) cause or induce any person to—

(A) withhold testimony, or withhold a record, document, or other object, from an official proceeding;

(B) alter, destroy, mutilate, or conceal an object with intent to impair the object's integrity or availability for use in an official proceeding;

(C) evade legal process summoning that person to appear as a witness, or to produce a record, document, or other object, in an official proceeding; or

(D) be absent from an official proceeding to which such person has been summoned by legal process; or

(3) hinder, delay, or prevent the communication to a law enforcement officer or judge of the United States of information relating to the commission or possible commission of a Federal offense or a violation of conditions of probation [2] supervised release,,[3] parole, or release pending judicial proceedings;

shall be fined under this title or imprisoned not more than ten years, or both.

(c) Whoever corruptly—

(1) alters, destroys, mutilates, or conceals a record, document, or other object, or attempts to do so, with the intent to impair the object's integrity or availability for use in an official proceeding; or

(2) otherwise obstructs, influences, or impedes any official proceeding, or attempts to do so,

shall be fined under this title or imprisoned not more than 20 years, or both.

(d) Whoever intentionally harasses another person and thereby hinders, delays, prevents, or dissuades any person from—

(1) attending or testifying in an official proceeding;

(2) reporting to a law enforcement officer or judge of the United States the commission or possible commission of a Federal offense or a violation of conditions of probation [4] supervised release,,[5] parole, or release pending judicial proceedings;

(3) arresting or seeking the arrest of another person in connection with a Federal offense; or

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[2] So in original. A comma probably should appear.
[3] So in original. The second comma probably should not appear.
[4] So in original. A comma probably should appear.
[5] So in original. The second comma probably should not appear.

(4) causing a criminal prosecution, or a parole or probation revocation proceeding, to be sought or instituted, or assisting in such prosecution or proceeding;

or attempts to do so, shall be fined under this title or imprisoned not more than one year, or both.

(e) In a prosecution for an offense under this section, it is an affirmative defense, as to which the defendant has the burden of proof by a preponderance of the evidence, that the conduct consisted solely of lawful conduct and that the defendant's sole intention was to encourage, induce, or cause the other person to testify truthfully.

(f) For the purposes of this section—

(1) an official proceeding need not be pending or about to be instituted at the time of the offense; and

(2) the testimony, or the record, document, or other object need not be admissible in evidence or free of a claim of privilege.

(g) In a prosecution for an offense under this section, no state of mind need be proved with respect to the circumstance—

(1) that the official proceeding before a judge, court, magistrate judge, grand jury, or government agency is before a judge or court of the United States, a United States magistrate judge, a bankruptcy judge, a Federal grand jury, or a Federal Government agency; or

(2) that the judge is a judge of the United States or that the law enforcement officer is an officer or employee of the Federal Government or a person authorized to act for or on behalf of the Federal Government or serving the Federal Government as an adviser or consultant.

(h) There is extraterritorial Federal jurisdiction over an offense under this section.

(i) A prosecution under this section or section 1503 may be brought in the district in which the official proceeding (whether or not pending or about to be instituted) was intended to be affected or in the district in which the conduct constituting the alleged offense occurred.

(j) If the offense under this section occurs in connection with a trial of a criminal case, the maximum term of imprisonment which may be imposed for the offense shall be the higher of that otherwise provided by law or the maximum term that could have been imposed for any offense charged in such case.

(k) Whoever conspires to commit any offense under this section shall be subject to the same penalties as those prescribed for the offense the commission of which was the object of the conspiracy.

§ 1513. Retaliating against a witness, victim, or an informant[1]

(a)(1) Whoever kills or attempts to kill another person with intent to retaliate against any person for—

(A) the attendance of a witness or party at an official proceeding, or any testimony given or any record, document, or other object produced by a witness in an official proceeding; or

(B) providing to a law enforcement officer any information relating to the commission or possible commission of a Federal offense or a violation of conditions of probation[2] supervised release,,[3] parole, or release pending judicial proceedings,

shall be punished as provided in paragraph (2).

(2) The punishment for an offense under this subsection is—

(A) in the case of a killing, the punishment provided in sections 1111 and 1112; and

(B) in the case of an attempt, imprisonment for not more than 20 years.

(b) Whoever knowingly engages in any conduct and thereby causes bodily injury to another person or damages the tangible property of another person, or threatens to do so, with intent to retaliate against any person for—

(1) the attendance of a witness or party at an official proceeding, or any testimony given or any record, document, or other object produced by a witness in an official proceeding; or

(2) any information relating to the commission or possible commission of a Federal offense or a violation of conditions of probation[4] supervised release,,[5] parole, or release pending judicial proceedings given by a person to a law enforcement officer;

or attempts to do so, shall be fined under this title or imprisoned not more than ten years, or both.

(c) If the retaliation occurred because of attendance at or testimony in a criminal case, the maximum term of imprisonment which may be imposed for the offense under this section shall be the higher of that otherwise provided by law or the maximum term that could have been imposed for any offense charged in such case.

(d) There is extraterritorial Federal jurisdiction over an offense under this section.

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[1] Added by Public Law 97–291, § 4(a), Oct. 12, 1982, 96 Stat. 1250, and amended by Public Law 103–322, Title VI, § 60017, Title XXXIII, § 330016(1)(U), Sept. 13, 1994, 108 Stat. 1975, 2148; Public Law 104–214, § 1(1), Oct. 1, 1996, 110 Stat. 3017; Public Law 107–204, Title XI, § 1107(a), July 30, 2002, 116 Stat. 810; Public Law 107–273, Div. B, Title III, § 3001(b), (c)(2), Title IV, § 4002(b)(4), Nov. 2, 2002, 116 Stat. 1804, 1807.

[2] So in original. A comma probably should appear.

[3] So in original. The second comma probably should not appear.

[4] So in original. A comma probably should appear.

[5] So in original. The second comma probably should not appear.

(e)[6] Whoever knowingly, with the intent to retaliate, takes any action harmful to any person, including interference with the lawful employment or livelihood of any person, for providing to a law enforcement officer any truthful information relating to the commission or possible commission of any Federal offense, shall be fined under this title or imprisoned not more than 10 years, or both.

(e)[7] Whoever conspires to commit any offense under this section shall be subject to the same penalties as those prescribed for the offense the commission of which was the object of the conspiracy.

[6] So in original. Two subsecs. (e) have been enacted.
[7] So in original. Two subsecs. (e) have been enacted.

18 U.S.C. § 1515
General provisions relating to obstruction of administrative proceedings

§ 1515. Definitions for certain provisions; general provision [1]

(a) As used in sections 1512 and 1513 of this title and in this section—

(1) the term "official proceeding" means—

(A) a proceeding before a judge or court of the United States, a United States magistrate judge, a bankruptcy judge, a judge of the United States Tax Court, a special trial judge of the Tax Court, a judge of the United States Court of Federal Claims, or a Federal grand jury;

(B) a proceeding before the Congress;

(C) a proceeding before a Federal Government agency which is authorized by law; or

(D) a proceeding involving the business of insurance whose activities affect interstate commerce before any insurance regulatory official or agency or any agent or examiner appointed by such official or agency to examine the affairs of any person engaged in the business of insurance whose activities affect interstate commerce;

(2) the term "physical force" means physical action against another, and includes confinement;

(3) the term "misleading conduct" means—

(A) knowingly making a false statement;

(B) intentionally omitting information from a statement and thereby causing a portion of such statement to be misleading, or intentionally concealing a material fact, and thereby creating a false impression by such statement;

(C) with intent to mislead, knowingly submitting or inviting reliance on a writing or recording that is false, forged, altered, or otherwise lacking in authenticity;

(D) with intent to mislead, knowingly submitting or inviting reliance on a sample, specimen, map, photograph, boundary mark, or other object that is misleading in a material respect; or

(E) knowingly using a trick, scheme, or device with intent to mislead;

(4) the term "law enforcement officer" means an officer or employee of the Federal Government, or a person authorized to

[1] Added by Public Law 97–291, § 4(a), Oct. 12, 1982, 96 Stat. 1252, and amended by Public Law 99–646, § 50(b), Nov. 10, 1986, 100 Stat. 3605; Public Law 100–690, Title VII, § 7029(b), (d), Nov. 18, 1988, 102 Stat. 4398; Public Law 101–650, Title III, § 321, Dec. 1, 1990, 104 Stat. 5117; Public Law 103–322, Title XXXII, § 320604(a), Sept. 13, 1994, 108 Stat. 2118; Public Law 104–292, § 3, Oct. 11, 1996, 110 Stat. 3460; Public Law 104–294, Title VI, § 604(b)(39), Oct. 11, 1996, 110 Stat. 3509.

act for or on behalf of the Federal Government or serving the Federal Government as an adviser or consultant—

(A) authorized under law to engage in or supervise the prevention, detection, investigation, or prosecution of an offense; or

(B) serving as a probation or pretrial services officer under this title;

(5) the term "bodily injury" means—

(A) a cut, abrasion, bruise, burn, or disfigurement;

(B) physical pain;

(C) illness;

(D) impairment of the function of a bodily member, organ, or mental faculty; or

(E) any other injury to the body, no matter how temporary; and

(6) the term "corruptly persuades" does not include conduct which would be misleading conduct but for a lack of a state of mind.

(b) As used in section 1505, the term "corruptly" means acting with an improper purpose, personally or by influencing another, including making a false or misleading statement, or withholding, concealing, altering, or destroying a document or other information.

(c) This chapter does not prohibit or punish the providing of lawful, bona fide, legal representation services in connection with or anticipation of an official proceeding.

18 U.S.C. § 1791
Possession of contraband (including controlled substances) in Federal prisons

Chapter 87. Prisons

§ 1791. Providing or possessing contraband in prison [1]

(a) OFFENSE.—Whoever—

(1) in violation of a statute or a rule or order issued under a statute, provides to an inmate of a prison a prohibited object, or attempts to do so; or

(2) being an inmate of a prison, makes, possesses, or obtains, or attempts to make or obtain, a prohibited object;

shall be punished as provided in subsection (b) of this section.

(b) PUNISHMENT.—The punishment for an offense under this section is a fine under this title or—

(1) imprisonment for not more than 20 years, or both, if the object is specified in subsection (d)(1)(C) of this section;

(2) imprisonment for not more than 10 years, or both, if the object is specified in subsection (d)(1)(A) of this section;

(3) imprisonment for not more than 5 years, or both, if the object is specified in subsection (d)(1)(B) of this section;

(4) imprisonment for not more than one year, or both, if the object is specified in subsection (d)(1)(D) or (d)(1)(E) of this section; and

(5) imprisonment for not more than 6 months, or both, if the object is specified in subsection (d)(1)(F) of this section.

(c) CONSECUTIVE PUNISHMENT REQUIRED IN CERTAIN CASES.—Any punishment imposed under subsection (b) for a violation of this section involving a controlled substance shall be consecutive to any other sentence imposed by any court for an offense involving such a controlled substance. Any punishment imposed under subsection (b) for a violation of this section by an inmate of a prison shall be consecutive to the sentence being served by such inmate at the time the inmate commits such violation.

(d) DEFINITIONS.—As used in this section—

(1) the term "prohibited object" means—

(A) a firearm or destructive device or a controlled substance in schedule I or II, other than marijuana or a controlled substance referred to in subparagraph (C) of this subsection;

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[1] June 25, 1948, c. 645, 62 Stat. 786; Oct. 12, 1984, Public Law 98–473, Title II, § 1109(a), 98 Stat. 2147; Nov. 10, 1986, Public Law 99–646, § 52(a), 100 Stat. 3606; Nov. 18, 1988, Public Law 100–690, Title VI, § 6468(a), (b), 102 Stat. 4376; Sept. 13, 1994, Public Law 103–322, Title IX, § 90101, Title XXXIII, § 330003(a), 108 Stat. 1986, 2140; Oct. 11, 1996, Public Law 104–294, Title VI, § 601(m), 110 Stat. 3502.

(B) marijuana or a controlled substance in schedule III, other than a controlled substance referred to in subparagraph (C) of this subsection, ammunition, a weapon (other than a firearm or destructive device), or an object that is designed or intended to be used as a weapon or to facilitate escape from a prison;

(C) a narcotic drug, methamphetamine, its salts, isomers, and salts of its isomers, lysergic acid diethylamide, or phencyclidine;

(D) a controlled substance (other than a controlled substance referred to in subparagraph (A), (B), or (C) of this subsection) or an alcoholic beverage;

(E) any United States or foreign currency; and

(F) any other object that threatens the order, discipline, or security of a prison, or the life, health, or safety of an individual;

(2) the terms "ammunition", "firearm", and "destructive device" have, respectively, the meanings given those terms in section 921 of this title;

(3) the terms "controlled substance" and "narcotic drug" have, respectively, the meanings given those terms in section 102 of the Controlled Substances Act (21 U.S.C. 802); and

(4) the term "prison" means a Federal correctional, detention, or penal facility.

18 U.S.C. § 1832
Theft of trade secrets

Chapter 90. Protection of Trade Secrets

§ 1832. Theft of trade secrets [1]

(a) Whoever, with intent to convert a trade secret, that is related to or included in a product that is produced for or placed in interstate or foreign commerce, to the economic benefit of anyone other than the owner thereof, and intending or knowing that the offense will, injure any owner of that trade secret, knowingly—

(1) steals, or without authorization appropriates, takes, carries away, or conceals, or by fraud, artifice, or deception obtains such information;

(2) without authorization copies, duplicates, sketches, draws, photographs, downloads, uploads, alters, destroys, photocopies, replicates, transmits, delivers, sends, mails, communicates, or conveys such information;

(3) receives, buys, or possesses such information, knowing the same to have been stolen or appropriated, obtained, or converted without authorization;

(4) attempts to commit any offense described in paragraphs (1) through (3); or

(5) conspires with one or more other persons to commit any offense described in paragraphs (1) through (3), and one or more of such persons do any act to effect the object of the conspiracy,

shall, except as provided in subsection (b), be fined under this title or imprisoned not more than 10 years, or both.

(b) Any organization that commits any offense described in subsection (a) shall be fined not more than $5,000,000.

[1] Added by Public Law 104–294, Title I, § 101(a), Oct. 11, 1996, 110 Stat. 3489.

18 U.S.C. § 1864
Hazardous or injurious devices on Federal lands in furtherance of a controlled substance offense

Chapter 91. Public Lands

§ 1864. Hazardous or injurious devices on Federal lands [1]

(a) Whoever—

(1) with the intent to violate the Controlled Substances Act,

(2) with the intent to obstruct or harass the harvesting of timber, or

(3) with reckless disregard to the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk,

uses a hazardous or injurious device on Federal land, on an Indian reservation, or on an Indian allotment while the title to such allotment is held in trust by the United States or while such allotment remains inalienable by the allottee without the consent of the United States shall be punished under subsection (b).

(b) An individual who violates subsection (a) shall—

(1) if death of an individual results, be fined under this title or imprisoned for any term of years or for life, or both;

(2) if serious bodily injury to any individual results, be fined under this title or imprisoned for not more than 40 years, or both;

(3) if bodily injury to any individual results, be fined under this title or imprisoned for not more than 20 years, or both;

(4) if damage to the property of any individual results or if avoidance costs have been incurred exceeding $10,000, in the aggregate, be fined under this title or imprisoned for not more than 20 years, or both; and

(5) in any other case, be fined under this title or imprisoned for not more than one year.

(c) Any individual who is punished under subsection (b)(5) after one or more prior convictions under any such subsection shall be fined under this title or imprisoned for not more than 20 years, or both.

(d) As used in this section—

(1) the term "serious bodily injury" means bodily injury which involves—

(A) a substantial risk of death;

(B) extreme physical pain;

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[1] Added by Public Law 100–690, Title VI, § 6254(f), Nov. 18, 1988, 102 Stat. 4366, and amended by Public Law 101–647, Title XXXV, § 3555, Nov. 29, 1990, 104 Stat. 4927; Public Law 103–322, Title XXXIII, § 330007, Sept. 13, 1994, 108 Stat. 2142; Public Law 104–134, Title I, § 101(c) [Title III, § 330], Apr. 26, 1996, 110 Stat. 1321–208; renumbered Title I, Public Law 104–140, § 1(a), May 2, 1996, 110 Stat. 1327.

(C) protracted and obvious disfigurement; and

(D) protracted loss or impairment of the function of bodily member, organ, or mental faculty;

(2) the term ''bodily injury'' means—

(A) a cut, abrasion, bruise, burn, or disfigurement;

(B) physical pain;

(C) illness;

(D) impairment of the function of a bodily member, organ, or mental faculty; or

(E) any other injury to the body, no matter how temporary;

(3) the term ''hazardous or injurious device'' means a device, which when assembled or placed, is capable of causing bodily injury, or damage to property, by the action of any person making contact with such device subsequent to the assembly or placement. Such term includes guns attached to trip wires or other triggering mechanisms, ammunition attached to trip wires or other triggering mechanisms, or explosive devices attached to trip wires or other triggering mechanisms, sharpened stakes, lines or wires, lines or wires with hooks attached, nails placed so that the sharpened ends are positioned in an upright manner, or tree spiking devices including spikes, nails, or other objects hammered, driven, fastened, or otherwise placed into or on any timber, whether or not severed from the stump; and

(4) the term ''avoidance costs'' means costs incurred by any individual for the purpose of—

(A) detecting a hazardous or injurious device; or

(B) preventing death, serious bodily injury, bodily injury, or property damage likely to result from the use of a hazardous or injurious device in violation of subsection (a).

(e) Any person injured as the result of a violation of subsection (a) may commence a civil action on his own behalf against any person who is alleged to be in violation of subsection (a). The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, in such civil actions. The court may award, in addition to monetary damages for any injury resulting from an alleged violation of subsection (a), costs of litigation, including reasonable attorney and expert witness fees, to any prevailing or substantially prevailing party, whenever the court determines such award is appropriate.

18 U.S.C. § 1905
Trade secret disclosure

Chapter 93. Public Officers and Employees

§ 1905. Disclosure of confidential information generally [1]

Whoever, being an officer or employee of the United States or of any department or agency thereof, any person acting on behalf of the Office of Federal Housing Enterprise Oversight, or agent of the Department of Justice as defined in the Antitrust Civil Process Act (15 U.S.C. 1311–1314), or being an employee of a private sector organization who is or was assigned to an agency under chapter 37 of title 5, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.

[1] June 25, 1948, c. 645, 62 Stat. 791; Sept. 12, 1980, Public Law 96–349, § 7(b), 94 Stat. 1158; Oct. 28, 1992, Public Law 102–550, Title XIII, § 1353, 106 Stat. 3970; Oct. 11, 1996, Public Law 104–294, Title VI, § 601(a)(8), 110 Stat. 3498; Dec. 17, 2002, Public Law 107–347, Title II, § 209(d)(2), 116 Stat. 2930.

18 U.S.C. § 1951
Hobbs Act; extortion under color of official right

Chapter 95. Racketeering

§ 1951. Interference with commerce by threats or violence[1]

(a) Whoever in any way or degree obstructs, delays, or affects commerce or the movement of any article or commodity in commerce, by robbery or extortion or attempts or conspires so to do, or commits or threatens physical violence to any person or property in furtherance of a plan or purpose to do anything in violation of this section shall be fined under this title or imprisoned not more than twenty years, or both.

(b) As used in this section—

(1) The term "robbery" means the unlawful taking or obtaining of personal property from the person or in the presence of another, against his will, by means of actual or threatened force, or violence, or fear of injury, immediate or future, to his person or property, or property in his custody or possession, or the person or property of a relative or member of his family or of anyone in his company at the time of the taking or obtaining.

(2) The term "extortion" means the obtaining of property from another, with his consent, induced by wrongful use of actual or threatened force, violence, or fear, or under color of official right.

(3) The term "commerce" means commerce within the District of Columbia, or any Territory or Possession of the United States; all commerce between any point in a State, Territory, Possession, or the District of Columbia and any point outside thereof; all commerce between points within the same State through any place outside such State; and all other commerce over which the United States has jurisdiction.

(c) This section shall not be construed to repeal, modify or affect section 17 of Title 15, sections 52, 101–115, 151–166 of Title 29 or sections 151–188 of Title 45.

[1] June 25, 1948, c. 645, 62 Stat. 793; Sept. 13, 1994, Public Law 103–322, Title XXXIII, § 330016(1)(L), 108 Stat. 2147.

18 U.S.C. § 1952
Travel Act violations involving controlled substances

§ 1952. Interstate and foreign travel or transportation in aid of racketeering enterprises [1]

(a) Whoever travels in interstate or foreign commerce or uses the mail or any facility in interstate or foreign commerce, with intent to—

(1) distribute the proceeds of any unlawful activity; or

(2) commit any crime of violence to further any unlawful activity; or

(3) otherwise promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on, of any unlawful activity,

and thereafter performs or attempts to perform—

(A) an act described in paragraph (1) or (3) shall be fined under this title, imprisoned not more than 5 years, or both; or

(B) an act described in paragraph (2) shall be fined under this title, imprisoned for not more than 20 years, or both, and if death results shall be imprisoned for any term of years or for life.

(b) As used in this section (i) "unlawful activity" means (1) any business enterprise involving gambling, liquor on which the Federal excise tax has not been paid, narcotics or controlled substances (as defined in section 102(6) of the Controlled Substances Act), or prostitution offenses in violation of the laws of the State in which they are committed or of the United States, (2) extortion, bribery, or arson in violation of the laws of the State in which committed or of the United States, or (3) any act which is indictable under subchapter II of chapter 53 of title 31, United States Code, or under section 1956 or 1957 of this title and (ii) the term "State" includes a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(c) Investigations of violations under this section involving liquor shall be conducted under the supervision of the Attorney General.

[1] Added by Public Law 87–228 § 1(a), Sept. 13, 1961, 75 Stat. 498, and amended by Public Law 89–68, July 7, 1965, 79 Stat. 212; Public Law 91–513, Title II, § 701(i) (2), Oct. 27, 1970, 84 Stat. 1282; Public Law 99–570, Title XIII, § 1365(a), Oct. 27, 1986, 100 Stat. 3207–35; Public Law 101–647, Title XII, § 1205(i), Title XVI, § 1604, Nov. 29, 1990, 104 Stat. 4831, 4843; Public Law 103–322, Title XIV, § 140007(a), Title XXXIII, § 330016(1)(L), Sept. 13, 1994, 108 Stat. 2033, 2147; Public Law 107–296, Title XI, § 1112(h), Nov. 25, 2002, 116 Stat. 2277.

§ 1956. Laundering of monetary instruments[1]

(a)(1) Whoever, knowing that the property involved in a financial transaction represents the proceeds of some form of unlawful activity, conducts or attempts to conduct such a financial transaction which in fact involves the proceeds of specified unlawful activity—

(A)(i) with the intent to promote the carrying on of specified unlawful activity; or

(ii) with intent to engage in conduct constituting a violation of section 7201 or 7206 of the Internal Revenue Code of 1986; or

(B) knowing that the transaction is designed in whole or in part—

(i) to conceal or disguise the nature, the location, the source, the ownership, or the control of the proceeds of specified unlawful activity; or

(ii) to avoid a transaction reporting requirement under State or Federal law,

shall be sentenced to a fine of not more than $500,000 or twice the value of the property involved in the transaction, whichever is greater, or imprisonment for not more than twenty years, or both.

(2) Whoever transports, transmits, or transfers, or attempts to transport, transmit, or transfer a monetary instrument or funds from a place in the United States to or through a place outside the United States or to a place in the United States from or through a place outside the United States—

(A) with the intent to promote the carrying on of specified unlawful activity; or

(B) knowing that the monetary instrument or funds involved in the transportation, transmission, or transfer represent the proceeds of some form of unlawful activity and knowing that such transportation, transmission, or transfer is designed in whole or in part—

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[1] Added by Public Law 99–570, Title XIII, § 1352(a), Oct. 27, 1986, 100 Stat. 3207–18, and amended by Public Law 100–690, Title VI, §§ 6183, 6465, 6466, 6469(a)(1), 6471(a), (b), Title VII, § 7031, Nov. 18, 1988, 102 Stat. 4354, 4375, 4377, 4378, 4398; Public Law 101–647, Title I, §§ 105 to 108, Title XII, § 1205(j), Title XIV, §§ 1402, 1404, Title XXV, § 2506, Title XXXV, § 3557, Nov. 29, 1990, 104 Stat. 4791, 4792, 4831, 4835, 4862, 4927; Public Law 102–550, Title XV, §§ 1504(c), 1524, 1526(a), 1527(a), 1530, 1531, 1534, 1536, Oct. 28, 1992, 106 Stat. 4055, 4064 to 4067; Public Law 103–322, Title XXXII, § 320104(b), Title XXXIII, §§ 330008(2), 330011(l), 330012, 330019, 330021(1), Sept. 13, 1994, 108 Stat. 2111, 2142, 2145, 2146, 2149, 2150; Public Law 103–325, Title IV, §§ 411(c)(2)(E), 413(c)(1), (d), Sept. 23, 1994, 108 Stat. 2253, 2254, 2255; Public Law 104–132, Title VII, § 726, Apr. 24, 1996, 110 Stat. 1301; Public Law 104–191, Title II, § 246, Aug. 21, 1996, 110 Stat. 2018; Public Law 104–294, Title VI, §§ 601(f)(6), 604(b)(38), Oct. 11, 1996, 110 Stat. 3499, 3509; Public Law 106–569, Title VII, § 709(a), Dec. 27, 2000, 114 Stat. 3018; Public Law 107–56, Title III, §§ 315, 317, 318, 376, Title VIII, § 805(b), Title X, § 1004, Oct. 26, 2001, 115 Stat. 308, 310, 311, 342, 378, 392; Public Law 107–273, Div. B, Title IV, § 4002(a)(11), (b)(5), (c)(2), 4005(d)(1), (e), Nov. 2, 2002, 116 Stat. 1807, 1809, 1812, 1813; Public Law 108–458, § 6909, Dec. 17, 2004, 118 Stat. 3774.

(i) to conceal or disguise the nature, the location, the source, the ownership, or the control of the proceeds of specified unlawful activity; or

(ii) to avoid a transaction reporting requirement under State or Federal law,

shall be sentenced to a fine of not more than $500,000 or twice the value of the monetary instrument or funds involved in the transportation, transmission, or transfer whichever is greater, or imprisonment for not more than twenty years, or both. For the purpose of the offense described in subparagraph (B), the defendant's knowledge may be established by proof that a law enforcement officer represented the matter specified in subparagraph (B) as true, and the defendant's subsequent statements or actions indicate that the defendant believed such representations to be true.

(3) Whoever, with the intent—

(A) to promote the carrying on of specified unlawful activity;

(B) to conceal or disguise the nature, location, source, ownership, or control of property believed to be the proceeds of specified unlawful activity; or

(C) to avoid a transaction reporting requirement under State or Federal law,

conducts or attempts to conduct a financial transaction involving property represented to be the proceeds of specified unlawful activity, or property used to conduct or facilitate specified unlawful activity, shall be fined under this title or imprisoned for not more than 20 years, or both. For purposes of this paragraph and paragraph (2), the term "represented" means any representation made by a law enforcement officer or by another person at the direction of, or with the approval of, a Federal official authorized to investigate or prosecute violations of this section.

(b) PENALTIES.—

(1) IN GENERAL.—Whoever conducts or attempts to conduct a transaction described in subsection (a)(1) or (a)(3), or section 1957, or a transportation, transmission, or transfer described in subsection (a)(2), is liable to the United States for a civil penalty of not more than the greater of—

(A) the value of the property, funds, or monetary instruments involved in the transaction; or

(B) $10,000.

(2) JURISDICTION OVER FOREIGN PERSONS.—For purposes of adjudicating an action filed or enforcing a penalty ordered under this section, the district courts shall have jurisdiction over any foreign person, including any financial institution authorized under the laws of a foreign country, against whom the action is brought, if service of process upon the foreign person is made under the Federal Rules of Civil Procedure or the laws of the country in which the foreign person is found, and—

(A) the foreign person commits an offense under subsection (a) involving a financial transaction that occurs in whole or in part in the United States;

(B) the foreign person converts, to his or her own use, property in which the United States has an ownership interest by virtue of the entry of an order of forfeiture by a court of the United States; or

(C) the foreign person is a financial institution that maintains a bank account at a financial institution in the United States.

(3) COURT AUTHORITY OVER ASSETS.—A court described in paragraph (2) may issue a pretrial restraining order or take any other action necessary to ensure that any bank account or other property held by the defendant in the United States is available to satisfy a judgment under this section.

(4) FEDERAL RECEIVER.—

(A) IN GENERAL.—A court described in paragraph (2) may appoint a Federal Receiver, in accordance with subparagraph (B) of this paragraph, to collect, marshal, and take custody, control, and possession of all assets of the defendant, wherever located, to satisfy a civil judgment under this subsection, a forfeiture judgment under section 981 or 982, or a criminal sentence under section 1957 or subsection (a) of this section, including an order of restitution to any victim of a specified unlawful activity.

(B) APPOINTMENT AND AUTHORITY.—A Federal Receiver described in subparagraph (A)—

(i) may be appointed upon application of a Federal prosecutor or a Federal or State regulator, by the court having jurisdiction over the defendant in the case;

(ii) shall be an officer of the court, and the powers of the Federal Receiver shall include the powers set out in section 754 of title 28, United States Code; and

(iii) shall have standing equivalent to that of a Federal prosecutor for the purpose of submitting requests to obtain information regarding the assets of the defendant—

(I) from the Financial Crimes Enforcement Network of the Department of the Treasury; or

(II) from a foreign country pursuant to a mutual legal assistance treaty, multilateral agreement, or other arrangement for international law enforcement assistance, provided that such requests are in accordance with the policies and procedures of the Attorney General.

(c) As used in this section—

(1) the term "knowing that the property involved in a financial transaction represents the proceeds of some form of unlawful activity" means that the person knew the property involved in the transaction represented proceeds from some form, though not necessarily which form, of activity that constitutes a felony under State, Federal, or foreign law, regardless of whether or not such activity is specified in paragraph (7);

(2) the term "conducts" includes initiating, concluding, or participating in initiating, or concluding a transaction;

(3) the term "transaction" includes a purchase, sale, loan, pledge, gift, transfer, delivery, or other disposition, and with respect to a financial institution includes a deposit, withdrawal, transfer between accounts, exchange of currency, loan,

extension of credit, purchase or sale of any stock, bond, certificate of deposit, or other monetary instrument, use of a safe deposit box, or any other payment, transfer, or delivery by, through, or to a financial institution, by whatever means effected;

(4) the term "financial transaction" means (A) a transaction which in any way or degree affects interstate or foreign commerce (i) involving the movement of funds by wire or other means or (ii) involving one or more monetary instruments, or (iii) involving the transfer of title to any real property, vehicle, vessel, or aircraft, or (B) a transaction involving the use of a financial institution which is engaged in, or the activities of which affect, interstate or foreign commerce in any way or degree;

(5) the term "monetary instruments" means (i) coin or currency of the United States or of any other country, travelers' checks, personal checks, bank checks, and money orders, or (ii) investment securities or negotiable instruments, in bearer form or otherwise in such form that title thereto passes upon delivery;

(6) the term "financial institution" includes—

(A) any financial institution, as defined in section 5312(a)(2) of title 31, United States Code, or the regulations promulgated thereunder; and

(B) any foreign bank, as defined in section 1[2] of the International Banking Act of 1978 (12 U.S.C. 3101);

(7) the term "specified unlawful activity" means—

(A) any act or activity constituting an offense listed in section 1961(1) of this title except an act which is indictable under subchapter II of chapter 53 of title 31;

(B) with respect to a financial transaction occurring in whole or in part in the United States, an offense against a foreign nation involving—

(i) the manufacture, importation, sale, or distribution of a controlled substance (as such term is defined for the purposes of the Controlled Substances Act);

(ii) murder, kidnapping, robbery, extortion, destruction of property by means of explosive or fire, or a crime of violence (as defined in section 16);

(iii) fraud, or any scheme or attempt to defraud, by or against a foreign bank (as defined in paragraph 7 of section 1(b) of the International Banking Act of 1978));[3]

(iv) bribery of a public official, or the misappropriation, theft, or embezzlement of public funds by or for the benefit of a public official;

(v) smuggling or export control violations involving—

(I) an item controlled on the United States Munitions List established under section 38 of the Arms Export Control Act (22 U.S.C. 2778); or

[2] So in original. Probably should read "section 1(b)".
[3] So in original. The second closing parenthesis probably should not appear.

(II) an item controlled under regulations under the Export Administration Regulations (15 C.F.R. Parts 730–774); or

(vi) an offense with respect to which the United States would be obligated by a multilateral treaty, either to extradite the alleged offender or to submit the case for prosecution, if the offender were found within the territory of the United States;

(C) any act or acts constituting a continuing criminal enterprise, as that term is defined in section 408 of the Controlled Substances Act (21 U.S.C. 848);

(D) an offense under section 32 (relating to the destruction of aircraft), section 37 (relating to violence at international airports), section 115 (relating to influencing, impeding, or retaliating against a Federal official by threatening or injuring a family member), section 152 (relating to concealment of assets; false oaths and claims; bribery), section 175c (relating to the variola virus), section 215 (relating to commissions or gifts for procuring loans), section 351 (relating to congressional or Cabinet officer assassination), any of sections 500 through 503 (relating to certain counterfeiting offenses), section 513 (relating to securities of States and private entities), section 541 (relating to goods falsely classified), section 542 (relating to entry of goods by means of false statements), section 545 (relating to smuggling goods into the United States), section 549 (relating to removing goods from Customs custody), section 641 (relating to public money, property, or records), section 656 (relating to theft, embezzlement, or misapplication by bank officer or employee), section 657 (relating to lending, credit, and insurance institutions), section 658 (relating to property mortgaged or pledged to farm credit agencies), section 666 (relating to theft or bribery concerning programs receiving Federal funds), section 793, 794, or 798 (relating to espionage), section 831 (relating to prohibited transactions involving nuclear materials), section 844(f) or (i) (relating to destruction by explosives or fire of Government property or property affecting interstate or foreign commerce), section 875 (relating to interstate communications), section 922(1) (relating to the unlawful importation of firearms), section 924(n) (relating to firearms trafficking), section 956 (relating to conspiracy to kill, kidnap, maim, or injure certain property in a foreign country), section 1005 (relating to fraudulent bank entries), 1006[4] (relating to fraudulent Federal credit institution entries), 1007[5] (relating to fraudulent Federal Deposit Insurance transactions), 1014[6] (relating to fraudulent loan or credit applications), section 1030 (relating to computer fraud and

[4] So in original. Probably should be preceded by "section".
[5] So in original. Probably should be preceded by "section".
[6] So in original. Probably should be preceded by "section".

abuse), 1032[7] (relating to concealment of assets from conservator, receiver, or liquidating agent of financial institution), section 1111 (relating to murder), section 1114 (relating to murder of United States law enforcement officials), section 1116 (relating to murder of foreign officials, official guests, or internationally protected persons), section 1201 (relating to kidnaping), section 1203 (relating to hostage taking), section 1361 (relating to willful injury of Government property), section 1363 (relating to destruction of property within the special maritime and territorial jurisdiction), section 1708 (theft from the mail), section 1751 (relating to Presidential assassination), section 2113 or 2114 (relating to bank and postal robbery and theft), section 2280 (relating to violence against maritime navigation), section 2281 (relating to violence against maritime fixed platforms), section 2319 (relating to copyright infringement), section 2320 (relating to trafficking in counterfeit goods and services), section 2332 (relating to terrorist acts abroad against United States nationals), section 2332a (relating to use of weapons of mass destruction), section 2332b (relating to international terrorist acts transcending national boundaries), section 2332g (relating to missile systems designed to destroy aircraft), section 2332h (relating to radiological dispersal devices), or section 2339A or 2339B (relating to providing material support to terrorists) of this title, section 46502 of title 49, United States Code, a felony violation of the Chemical Diversion and Trafficking Act of 1988 (relating to precursor and essential chemicals), section 590 of the Tariff Act of 1930 (19 U.S.C. 1590) (relating to aviation smuggling), section 422 of the Controlled Substances Act (relating to transportation of drug paraphernalia), section 38(c) (relating to criminal violations) of the Arms Export Control Act, section 11 (relating to violations) of the Export Administration Act of 1979, section 206 (relating to penalties) of the International Emergency Economic Powers Act, section 16 (relating to offenses and punishment) of the Trading with the Enemy Act, any felony violation of section 15 of the Food Stamp Act of 1977[8] (relating to food stamp fraud) involving a quantity of coupons having a value of not less than $5,000, any violation of section 543(a)(1) of the Housing Act of 1949[9] (relating to equity skimming), any felony violation of the Foreign Agents Registration Act of 1938, any felony violation of the Foreign Corrupt Practices Act, or section 92 of the Atomic Energy Act of 1954 (42 U.S.C. 2122) (relating to prohibitions governing atomic weapons)

(E) a felony violation of the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.), the Ocean Dumping Act (33 U.S.C. 1401 et seq.), the Act to Prevent Pollution from Ships (33 U.S.C. 1901 et seq.), the Safe Drinking

[7] So in original. Probably should be preceded by "section".
[8] 7 U.S.C. § 2024.
[9] 42 U.S.C. § 1490s(a)(1).

Water Act (42 U.S.C. 300f et seq.), or the Resources Conservation and Recovery Act (42 U.S.C. 6901 et seq.); or

(F) any act or activity constituting an offense involving a Federal health care offense;

(8) the term "State" includes a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(d) Nothing in this section shall supersede any provision of Federal, State, or other law imposing criminal penalties or affording civil remedies in addition to those provided for in this section.

(e) Violations of this section may be investigated by such components of the Department of Justice as the Attorney General may direct, and by such components of the Department of the Treasury as the Secretary of the Treasury may direct, as appropriate and, with respect to offenses over which the United States Postal Service has jurisdiction, by the Postal Service. Such authority of the Secretary of the Treasury and the Postal Service shall be exercised in accordance with an agreement which shall be entered into by the Secretary of the Treasury, the Postal Service, and the Attorney General. Violations of this section involving offenses described in paragraph (c)(7)(E) may be investigated by such components of the Department of Justice as the Attorney General may direct, and the National Enforcement Investigations Center of the Environmental Protection Agency.

(f) There is extraterritorial jurisdiction over the conduct prohibited by this section if—

(1) the conduct is by a United States citizen or, in the case of a non-United States citizen, the conduct occurs in part in the United States; and

(2) the transaction or series of related transactions involves funds or monetary instruments of a value exceeding $10,000.

(g) NOTICE OF CONVICTION OF FINANCIAL INSTITUTIONS.—If any financial institution or any officer, director, or employee of any financial institution has been found guilty of an offense under this section, section 1957 or 1960 of this title, or section 5322 or 5324 of title 31, the Attorney General shall provide written notice of such fact to the appropriate regulatory agency for the financial institution.

(h) Any person who conspires to commit any offense defined in this section or section 1957 shall be subject to the same penalties as those prescribed for the offense the commission of which was the object of the conspiracy.

(i) VENUE.—(1) Except as provided in paragraph (2), a prosecution for an offense under this section or section 1957 may be brought in—

(A) any district in which the financial or monetary transaction is conducted; or

(B) any district where a prosecution for the underlying specified unlawful activity could be brought, if the defendant participated in the transfer of the proceeds of the specified unlawful activity from that district to the district where the financial or monetary transaction is conducted.

(2) A prosecution for an attempt or conspiracy offense under this section or section 1957 may be brought in the district where venue

would lie for the completed offense under paragraph (1), or in any other district where an act in furtherance of the attempt or conspiracy took place.

(3) For purposes of this section, a transfer of funds from 1 place to another, by wire or any other means, shall constitute a single, continuing transaction. Any person who conducts (as that term is defined in subsection (c)(2)) any portion of the transaction may be charged in any district in which the transaction takes place.

§ 1957. Engaging in monetary transactions in property derived from specified unlawful activity [1]

(a) Whoever, in any of the circumstances set forth in subsection (d), knowingly engages or attempts to engage in a monetary transaction in criminally derived property of a value greater than $10,000 and is derived from specified unlawful activity, shall be punished as provided in subsection (b).

(b)(1) Except as provided in paragraph (2), the punishment for an offense under this section is a fine under title 18, United States Code, or imprisonment for not more than ten years or both.

(2) The court may impose an alternate fine to that imposable under paragraph (1) of not more than twice the amount of the criminally derived property involved in the transaction.

(c) In a prosecution for an offense under this section, the Government is not required to prove the defendant knew that the offense from which the criminally derived property was derived was specified unlawful activity.

(d) The circumstances referred to in subsection (a) are—

(1) that the offense under this section takes place in the United States or in the special maritime and territorial jurisdiction of the United States; or

(2) that the offense under this section takes place outside the United States and such special jurisdiction, but the defendant is a United States person (as defined in section 3077 of this title, but excluding the class described in paragraph (2)(D) of such section).

(e) Violations of this section may be investigated by such components of the Department of Justice as the Attorney General may direct, and by such components of the Department of the Treasury as the Secretary of the Treasury may direct, as appropriate and, with respect to offenses over which the United States Postal Service has jurisdiction, by the Postal Service. Such authority of the Secretary of the Treasury and the Postal Service shall be exercised in accordance with an agreement which shall be entered into by the Secretary of the Treasury, the Postal Service, and the Attorney General.

(f) As used in this section—

(1) the term "monetary transaction" means the deposit, withdrawal, transfer, or exchange, in or affecting interstate or foreign commerce, of funds or a monetary instrument (as defined

[1] Added by Public Law 99–570, Title XIII, § 1352(a), Oct. 27, 1986, 100 Stat. 3207–21, and amended by Public Law 100–690, Title VI, §§ 6182, 6184, 6469(a)(2), Nov. 18, 1988, 102 Stat. 4354, 4377; Public Law 102–550, Title XV, §§ 1526(b), 1527(b), Oct. 28, 1992, 106 Stat. 4065; Public Law 103–322, Title XXXIII, § 330020, Sept. 13, 1994, 108 Stat. 2149; Public Law 103–325, Title IV, § 413(c)(2), Sept. 23, 1994, 108 Stat. 2255.

in section 1956(c)(5) of this title) by, through, or to a financial institution (as defined in section 1956 of this title), including any transaction that would be a financial transaction under section 1956(c)(4)(B) of this title, but such term does not include any transaction necessary to preserve a person's right to representation as guaranteed by the sixth amendment to the Constitution;

(2) the term "criminally derived property" means any property constituting, or derived from, proceeds obtained from a criminal offense; and

(3) the term "specified unlawful activity" has the meaning given that term in section 1956 of this title.

18 U.S.C. § 1959

Violent crimes in aid of racketeering relating to controlled substances

§ 1959. Violent crimes in aid of racketeering activity [1]

(a) Whoever, as consideration for the receipt of, or as consideration for a promise or agreement to pay, anything of pecuniary value from an enterprise engaged in racketeering activity, or for the purpose of gaining entrance to or maintaining or increasing position in an enterprise engaged in racketeering activity, murders, kidnaps, maims, assaults with a dangerous weapon, commits assault resulting in serious bodily injury upon, or threatens to commit a crime of violence against any individual in violation of the laws of any State or the United States, or attempts or conspires so to do, shall be punished—

(1) for murder, by death or life imprisonment, or a fine under this title, or both; and for kidnapping, by imprisonment for any term of years or for life, or a fine under this title, or both;

(2) for maiming, by imprisonment for not more than thirty years or a fine under this title, or both;

(3) for assault with a dangerous weapon or assault resulting in serious bodily injury, by imprisonment for not more than twenty years or a fine under this title, or both;

(4) for threatening to commit a crime of violence, by imprisonment for not more than five years or a fine under this title, or both;

(5) for attempting or conspiring to commit murder or kidnapping, by imprisonment for not more than ten years or a fine under this title, or both; and

(6) for attempting or conspiring to commit a crime involving maiming, assault with a dangerous weapon, or assault resulting in serious bodily injury, by imprisonment for not more than three years or a fine of [2] under this title, or both.

(b) As used in this section—

(1) ''racketeering activity'' has the meaning set forth in section 1961 of this title; and

(2) ''enterprise'' includes any partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity, which is engaged in, or the activities of which affect, interstate or foreign commerce.

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[1] Added by Public Law 98–473, Title II, § 1002(a), Oct. 12, 1984, 98 Stat. 2137, § 1952B; renumbered § 1959, Public Law 100–690, Title VII, § 7053(b), Nov. 18, 1988, 102 Stat. 4402, and amended by Public Law 103–322, Title VI, § 60003(a)(12), Title XXXIII, §§ 330016(1)(J), (2)(C), 330021(1), Sept. 13, 1994, 108 Stat. 1969, 2147, 2148, 2150.

[2] So in original. The word ''of'' probably should not appear.

18 U.S.C. § § 1961–1968
Racketeer influenced and corrupt organization (RICO) offenses relating to controlled substance offenses

Chapter 96. Racketeer Influenced and Corrupt Organizations

§ 1961. Definitions [1]

As used in this chapter—

(1) "racketeering activity" means (A) any act or threat involving murder, kidnapping, gambling, arson, robbery, bribery, extortion, dealing in obscene matter, or dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), which is chargeable under State law and punishable by imprisonment for more than one year; (B) any act which is indictable under any of the following provisions of title 18, United States Code: Section 201 (relating to bribery), section 224 (relating to sports bribery), sections 471, 472, and 473 (relating to counterfeiting), section 659 (relating to theft from interstate shipment) if the act indictable under section 659 is felonious, section 664 (relating to embezzlement from pension and welfare funds), sections 891–894 (relating to extortionate credit transactions), section 1028 (relating to fraud and related activity in connection with identification documents), section 1029 (relating to fraud and related activity in connection with access devices), section 1084 (relating to the transmission of gambling information), section 1341 (relating to mail fraud), section 1343 (relating to wire fraud), section 1344 (relating to financial institution fraud), section 1425 (relating to the procurement of citizenship or nationalization unlawfully), section 1426 (relating to the reproduction of naturalization or citizenship papers), section 1427 (relating to the sale of naturalization or citizenship papers), sections 1461–

[1] Added by Public Law 91–452, Title IX, § 901(a), Oct. 15, 1970, 84 Stat. 941, and amended by Public Law 95–575, § 3(c), Nov. 2, 1978, 92 Stat. 2465; Public Law 95–598, Title III, § 314(g), Nov. 6, 1978, 92 Stat. 2677; Public Law 98–473, Title II, § § 901(g), 1020, Oct. 12, 1984, 98 Stat. 2136, 2143; Public Law 98–547, Title II, § 205, Oct. 25, 1984, 98 Stat. 2770; Public Law 99–570, Title XIII, § 1365(b), Oct. 27, 1986, 100 Stat. 3207–35; Public Law 99–646, § 50(a), Nov. 10, 1986, 100 Stat. 3605; Public Law 100–690, Title VII, § § 7013, 7020(c), 7032, 7054, 7514, Nov. 18, 1988, 102 Stat. 4395, 4396, 4398, 4402, 4489; Public Law 101–73, Title IX, § 968, Aug. 9, 1989, 103 Stat. 506; Public Law 101–647, Title XXXV, § 3560, Nov. 29, 1990, 104 Stat. 4927; Public Law 103–322, Title IX, § 90104, Title XVI, § 160001(f), Title XXXIII, § 330021(1), Sept. 13, 1994, 108 Stat. 1987, 2037, 2150; Public Law 103–394, Title III, § 312(b), Oct. 22, 1994, 108 Stat. 4140; Public Law 104–132, Title IV, § 433, Apr. 24, 1996, 110 Stat. 1274; Public Law 104–153, § 3, July 2, 1996, 110 Stat. 1386; Public Law 104–208, Div. C, Title II, § 202, Sept. 30, 1996, 110 Stat. 3009–565; Public Law 104–294, Title VI, § § 601(b)(3), (i)(3), 604(b)(6), Oct. 11, 1996, 110 Stat. 3499, 3501, 3506; Public Law 107–56, Title VIII, § 813, Oct. 26, 2001, 115 Stat. 382; Public Law 107–273, Div. B, Title IV, § 4005(f)(1), Nov. 2, 2002, 116 Stat. 1813; Public Law 108–193, § 5(b), Dec. 19, 2003, 117 Stat. 2879; Public Law 108–458, § 6802(e), Dec. 17, 2004, 118 Stat. 3767.

1465 (relating to obscene matter), section 1503 (relating to obstruction of justice), section 1510 (relating to obstruction of criminal investigations), section 1511 (relating to the obstruction of State or local law enforcement), section 1512 (relating to tampering with a witness, victim, or an informant), section 1513 (relating to retaliating against a witness, victim, or an informant), section 1542 (relating to false statement in application and use of passport), section 1543 (relating to forgery or false use of passport), section 1544 (relating to misuse of passport), section 1546 (relating to fraud and misuse of visas, permits, and other documents), sections 1581–1591 (relating to peonage, slavery, and trafficking in persons), section 1951 (relating to interference with commerce, robbery, or extortion), section 1952 (relating to racketeering), section 1953 (relating to interstate transportation of wagering paraphernalia), section 1954 (relating to unlawful welfare fund payments), section 1955 (relating to the prohibition of illegal gambling businesses), section 1956 (relating to the laundering of monetary instruments), section 1957 (relating to engaging in monetary transactions in property derived from specified unlawful activity), section 1958 (relating to use of interstate commerce facilities in the commission of murder-for-hire), sections 2251, 2251A, 2252, and 2260 (relating to sexual exploitation of children), sections 2312 and 2313 (relating to interstate transportation of stolen motor vehicles), sections 2314 and 2315 (relating to interstate transportation of stolen property), section 2318 (relating to trafficking in counterfeit labels for phonorecords, computer programs or computer program documentation or packaging and copies of motion pictures or other audiovisual works), section 2319 (relating to criminal infringement of a copyright), section 2319A (relating to unauthorized fixation of and trafficking in sound recordings and music videos of live musical performances), section 2320 (relating to trafficking in goods or services bearing counterfeit marks), section 2321 (relating to trafficking in certain motor vehicles or motor vehicle parts), sections 2341–2346 (relating to trafficking in contraband cigarettes), sections 2421–24[2] (relating to white slave traffic), sections 175–178 (relating to biological weapons), sections 229–229F (relating to chemical weapons), section 831 (relating to nuclear materials), (C) any act which is indictable under title 29, United States Code, section 186 (dealing with restrictions on payments and loans to labor organizations) or section 501(c) (relating to embezzlement from union funds), (D) any offense involving fraud connected with a case under title 11 (except a case under section 157 of this title), fraud in the sale of securities, or the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), punishable under any law of the United States, (E) any act which is indictable under the Currency and Foreign Transactions Reporting Act, (F) any act which is indictable under the Immigration and Nationality

[2] So in original. Probably should be "2424".

Act, section 274 (relating to bringing in and harboring certain aliens), section 277 (relating to aiding or assisting certain aliens to enter the United States), or section 278 (relating to importation of alien for immoral purpose) if the act indictable under such section of such Act was committed for the purpose of financial gain, or (G) any act that is indictable under any provision listed in section 2332b(g)(5)(B);

(2) "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, any political subdivision, or any department, agency, or instrumentality thereof;

(3) "person" includes any individual or entity capable of holding a legal or beneficial interest in property;

(4) "enterprise" includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity;

(5) "pattern of racketeering activity" requires at least two acts of racketeering activity, one of which occurred after the effective date of this chapter and the last of which occurred within ten years (excluding any period of imprisonment) after the commission of a prior act of racketeering activity;

(6) "unlawful debt" means a debt (A) incurred or contracted in gambling activity which was in violation of the law of the United States, a State or political subdivision thereof, or which is unenforceable under State or Federal law in whole or in part as to principal or interest because of the laws relating to usury, and (B) which was incurred in connection with the business of gambling in violation of the law of the United States, a State or political subdivision thereof, or the business of lending money or a thing of value at a rate usurious under State or Federal law, where the usurious rate is at least twice the enforceable rate;

(7) "racketeering investigator" means any attorney or investigator so designated by the Attorney General and charged with the duty of enforcing or carrying into effect this chapter;

(8) "racketeering investigation" means any inquiry conducted by any racketeering investigator for the purpose of ascertaining whether any person has been involved in any violation of this chapter or of any final order, judgment, or decree of any court of the United States, duly entered in any case or proceeding arising under this chapter;

(9) "documentary material" includes any book, paper, document, record, recording, or other material; and

(10) "Attorney General" includes the Attorney General of the United States, the Deputy Attorney General of the United States, the Associate Attorney General of the United States, any Assistant Attorney General of the United States, or any employee of the Department of Justice or any employee of any department or agency of the United States so designated by the Attorney General to carry out the powers conferred on the Attorney General by this chapter. Any department or agency so designated may use in investigations authorized by this chapter either the investigative provisions of this chapter or

the investigative power of such department or agency otherwise conferred by law.

§ 1962. Prohibited activities [3]

(a) It shall be unlawful for any person who has received any income derived, directly or indirectly, from a pattern of racketeering activity or through collection of an unlawful debt in which such person has participated as a principal within the meaning of section 2, title 18, United States Code, to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce. A purchase of securities on the open market for purposes of investment, and without the intention of controlling or participating in the control of the issuer, or of assisting another to do so, shall not be unlawful under this subsection if the securities of the issuer held by the purchaser, the members of his immediate family, and his or their accomplices in any pattern or racketeering activity or the collection of an unlawful debt after such purchase do not amount in the aggregate to one percent of the outstanding securities of any one class, and do not confer, either in law or in fact, the power to elect one or more directors of the issuer.

(b) It shall be unlawful for any person through a pattern of racketeering activity or through collection of an unlawful debt to acquire or maintain, directly or indirectly, any interest in or control of any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.

(c) It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

(d) It shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section.

§ 1963. Criminal penalties [4]

(a) Whoever violates any provision of section 1962 of this chapter shall be fined under this title or imprisoned not more than 20 years (or for life if the violation is based on a racketeering activity for which the maximum penalty includes life imprisonment), or both, and shall forfeit to the United States, irrespective of any provision of State law—

(1) any interest the person has acquired or maintained in violation of section 1962;

(2) any—

(A) interest in;

(B) security of;

(C) claim against; or

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[3] Added by Public Law 91–452, Title IX, § 901(a), Oct. 15, 1970, 84 Stat. 942, and amended by Public Law 100–690, Title VII, § 7033, Nov. 18, 1988, 102 Stat. 4398.)

[4] Added by Public Law 91–452, Title IX, § 901(a), Oct. 15, 1970, 84 Stat. 943, and amended by Public Law 98–473, Title II, §§ 302, 2301(a)-(c), Oct. 12, 1984, 98 Stat. 2040, 2192; Public Law 99–570, Title XI, § 1153(a), Oct. 27, 1986, 100 Stat. 3207–13; Public Law 99–646, § 23, Nov. 10, 1986, 100 Stat. 3597; Public Law 100–690, Title VII, §§ 7034, 7058(d), Nov. 18, 1988, 102 Stat. 4398, 4403; Public Law 101–647, Title XXXV, § 3561, Nov. 29, 1990, 104 Stat. 4927.

(D) property or contractual right of any kind affording a source of influence over;

any enterprise which the person has established, operated, controlled, conducted, or participated in the conduct of, in violation of section 1962; and

(3) any property constituting, or derived from, any proceeds which the person obtained, directly or indirectly, from racketeering activity or unlawful debt collection in violation of section 1962.

The court, in imposing sentence on such person shall order, in addition to any other sentence imposed pursuant to this section, that the person forfeit to the United States all property described in this subsection. In lieu of a fine otherwise authorized by this section, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.

(b) Property subject to criminal forfeiture under this section includes—

(1) real property, including things growing on, affixed to, and found in land; and

(2) tangible and intangible personal property, including rights, privileges, interests, claims, and securities.

(c) All right, title, and interest in property described in subsection (a) vests in the United States upon the commission of the act giving rise to forfeiture under this section. Any such property that is subsequently transferred to a person other than the defendant may be the subject of a special verdict of forfeiture and thereafter shall be ordered forfeited to the United States, unless the transferee establishes in a hearing pursuant to subsection (l) that he is a bona fide purchaser for value of such property who at the time of purchase was reasonably without cause to believe that the property was subject to forfeiture under this section.

(d)(1) Upon application of the United States, the court may enter a restraining order or injunction, require the execution of a satisfactory performance bond, or take any other action to preserve the availability of property described in subsection (a) for forfeiture under this section—

(A) upon the filing of an indictment or information charging a violation of section 1962 of this chapter and alleging that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section; or

(B) prior to the filing of such an indictment or information, if, after notice to persons appearing to have an interest in the property and opportunity for a hearing, the court determines that—

(i) there is a substantial probability that the United States will prevail on the issue of forfeiture and that failure to enter the order will result in the property being destroyed, removed from the jurisdiction of the court, or otherwise made unavailable for forfeiture; and

(ii) the need to preserve the availability of the property through the entry of the requested order outweighs the

hardship on any party against whom the order is to be entered:

Provided, however, That an order entered pursuant to subparagraph (B) shall be effective for not more than ninety days, unless extended by the court for good cause shown or unless an indictment or information described in subparagraph (A) has been filed.

(2) A temporary restraining order under this subsection may be entered upon application of the United States without notice or opportunity for a hearing when an information or indictment has not yet been filed with respect to the property, if the United States demonstrates that there is probable cause to believe that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section and that provision of notice will jeopardize the availability of the property for forfeiture. Such a temporary order shall expire not more than ten days after the date on which it is entered, unless extended for good cause shown or unless the party against whom it is entered consents to an extension for a longer period. A hearing requested concerning an order entered under this paragraph shall be held at the earliest possible time, and prior to the expiration of the temporary order.

(3) The court may receive and consider, at a hearing held pursuant to this subsection, evidence and information that would be inadmissible under the Federal Rules of Evidence.

(e) Upon conviction of a person under this section, the court shall enter a judgment of forfeiture of the property to the United States and shall also authorize the Attorney General to seize all property ordered forfeited upon such terms and conditions as the court shall deem proper. Following the entry of an order declaring the property forfeited, the court may, upon application of the United States, enter such appropriate restraining orders or injunctions, require the execution of satisfactory performance bonds, appoint receivers, conservators, appraisers, accountants, or trustees, or take any other action to protect the interest of the United States in the property ordered forfeited. Any income accruing to, or derived from, an enterprise or an interest in an enterprise which has been ordered forfeited under this section may be used to offset ordinary and necessary expenses to the enterprise which are required by law, or which are necessary to protect the interests of the United States or third parties.

(f) Following the seizure of property ordered forfeited under this section, the Attorney General shall direct the disposition of the property by sale or any other commercially feasible means, making due provision for the rights of any innocent persons. Any property right or interest not exercisable by, or transferable for value to, the United States shall expire and shall not revert to the defendant, nor shall the defendant or any person acting in concert with or on behalf of the defendant be eligible to purchase forfeited property at any sale held by the United States. Upon application of a person, other than the defendant or a person acting in concert with or on behalf of the defendant, the court may restrain or stay the sale or disposition of the property pending the conclusion of any appeal of

the criminal case giving rise to the forfeiture, if the applicant demonstrates that proceeding with the sale or disposition of the property will result in irreparable injury, harm or loss to him. Notwithstanding 31 U.S.C. 3302(b), the proceeds of any sale or other disposition of property forfeited under this section and any moneys forfeited shall be used to pay all proper expenses for the forfeiture and the sale, including expenses of seizure, maintenance and custody of the property pending its disposition, advertising and court costs. The Attorney General shall deposit in the Treasury any amounts of such proceeds or moneys remaining after the payment of such expenses.

(g) With respect to property ordered forfeited under this section, the Attorney General is authorized to—

(1) grant petitions for mitigation or remission of forfeiture, restore forfeited property to victims of a violation of this chapter, or take any other action to protect the rights of innocent persons which is in the interest of justice and which is not inconsistent with the provisions of this chapter;

(2) compromise claims arising under this section;

(3) award compensation to persons providing information resulting in a forfeiture under this section;

(4) direct the disposition by the United States of all property ordered forfeited under this section by public sale or any other commercially feasible means, making due provision for the rights of innocent persons; and

(5) take appropriate measures necessary to safeguard and maintain property ordered forfeited under this section pending its disposition.

(h) The Attorney General may promulgate regulations with respect to—

(1) making reasonable efforts to provide notice to persons who may have an interest in property ordered forfeited under this section;

(2) granting petitions for remission or mitigation of forfeiture;

(3) the restitution of property to victims of an offense petitioning for remission or mitigation of forfeiture under this chapter;

(4) the disposition by the United States of forfeited property by public sale or other commercially feasible means;

(5) the maintenance and safekeeping of any property forfeited under this section pending its disposition; and

(6) the compromise of claims arising under this chapter.

Pending the promulgation of such regulations, all provisions of law relating to the disposition of property, or the proceeds from the sale thereof, or the remission or mitigation of forfeitures for violation of the customs laws, and the compromise of claims and the award of compensation to informers in respect of such forfeitures shall apply to forfeitures incurred, or alleged to have been incurred, under the provisions of this section, insofar as applicable and not inconsistent with the provisions hereof. Such duties as are imposed upon the Customs Service or any person with respect to the disposition of property under the customs law shall be performed under this chapter by the Attorney General.

(i) Except as provided in subsection (l), no party claiming an interest in property subject to forfeiture under this section may—

(1) intervene in a trial or appeal of a criminal case involving the forfeiture of such property under this section; or

(2) commence an action at law or equity against the United States concerning the validity of his alleged interest in the property subsequent to the filing of an indictment or information alleging that the property is subject to forfeiture under this section.

(j) The district courts of the United States shall have jurisdiction to enter orders as provided in this section without regard to the location of any property which may be subject to forfeiture under this section or which has been ordered forfeited under this section.

(k) In order to facilitate the identification or location of property declared forfeited and to facilitate the disposition of petitions for remission or mitigation of forfeiture, after the entry of an order declaring property forfeited to the United States the court may, upon application of the United States, order that the testimony of any witness relating to the property forfeited be taken by deposition and that any designated book, paper, document, record, recording, or other material not privileged be produced at the same time and place, in the same manner as provided for the taking of depositions under Rule 15 of the Federal Rules of Criminal Procedure.

(l)(1) Following the entry of an order of forfeiture under this section, the United States shall publish notice of the order and of its intent to dispose of the property in such manner as the Attorney General may direct. The Government may also, to the extent practicable, provide direct written notice to any person known to have alleged an interest in the property that is the subject of the order of forfeiture as a substitute for published notice as to those persons so notified.

(2) Any person, other than the defendant, asserting a legal interest in property which has been ordered forfeited to the United States pursuant to this section may, within thirty days of the final publication of notice or his receipt of notice under paragraph (1), whichever is earlier, petition the court for a hearing to adjudicate the validity of his alleged interest in the property. The hearing shall be held before the court alone, without a jury.

(3) The petition shall be signed by the petitioner under penalty of perjury and shall set forth the nature and extent of the petitioner's right, title, or interest in the property, the time and circumstances of the petitioner's acquisition of the right, title, or interest in the property, any additional facts supporting the petitioner's claim, and the relief sought.

(4) The hearing on the petition shall, to the extent practicable and consistent with the interests of justice, be held within thirty days of the filing of the petition. The court may consolidate the hearing on the petition with a hearing on any other petition filed by a person other than the defendant under this subsection.

(5) At the hearing, the petitioner may testify and present evidence and witnesses on his own behalf, and cross-examine witnesses who appear at the hearing. The United States may present evidence and witnesses in rebuttal and in defense of its claim to

the property and cross-examine witnesses who appear at the hearing. In addition to testimony and evidence presented at the hearing, the court shall consider the relevant portions of the record of the criminal case which resulted in the order of forfeiture.

(6) If, after the hearing, the court determines that the petitioner has established by a preponderance of the evidence that—

(A) the petitioner has a legal right, title, or interest in the property, and such right, title, or interest renders the order of forfeiture invalid in whole or in part because the right, title, or interest was vested in the petitioner rather than the defendant or was superior to any right, title, or interest of the defendant at the time of the commission of the acts which gave rise to the forfeiture of the property under this section; or

(B) the petitioner is a bona fide purchaser for value of the right, title, or interest in the property and was at the time of purchase reasonably without cause to believe that the property was subject to forfeiture under this section;

the court shall amend the order of forfeiture in accordance with its determination.

(7) Following the court's disposition of all petitions filed under this subsection, or if no such petitions are filed following the expiration of the period provided in paragraph (2) for the filing of such petitions, the United States shall have clear title to property that is the subject of the order of forfeiture and may warrant good title to any subsequent purchaser or transferee.

(m) If any of the property described in subsection (a), as a result of any act or omission of the defendant—

(1) cannot be located upon the exercise of due diligence;

(2) has been transferred or sold to, or deposited with, a third party;

(3) has been placed beyond the jurisdiction of the court;

(4) has been substantially diminished in value; or

(5) has been commingled with other property which cannot be divided without difficulty;

the court shall order the forfeiture of any other property of the defendant up to the value of any property described in paragraphs (1) through (5).

§ 1964. Civil remedies[5]

(a) The district courts of the United States shall have jurisdiction to prevent and restrain violations of section 1962 of this chapter by issuing appropriate orders, including, but not limited to: ordering any person to divest himself of any interest, direct or indirect, in any enterprise; imposing reasonable restrictions on the future activities or investments of any person, including, but not limited to, prohibiting any person from engaging in the same type of endeavor as the enterprise engaged in, the activities of which affect interstate or foreign commerce; or ordering dissolution or reorganization of any enterprise, making due provision for the rights of innocent persons.

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[5] Added by Public Law 91–452, Title IX, § 901(a), Oct. 15, 1970, 84 Stat. 943, and amended by Public Law 98–620, Title IV, § 402(24)(A), Nov. 8, 1984, 98 Stat. 3359; Public Law 104–67, Title I, § 107, Dec. 22, 1995, 109 Stat. 758.

(b) The Attorney General may institute proceedings under this section. Pending final determination thereof, the court may at any time enter such restraining orders or prohibitions, or take such other actions, including the acceptance of satisfactory performance bonds, as it shall deem proper.

(c) Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee, except that no person may rely upon any conduct that would have been actionable as fraud in the purchase or sale of securities to establish a violation of section 1962. The exception contained in the preceding sentence does not apply to an action against any person that is criminally convicted in connection with the fraud, in which case the statute of limitations shall start to run on the date on which the conviction becomes final.

(d) A final judgment or decree rendered in favor of the United States in any criminal proceeding brought by the United States under this chapter shall estop the defendant from denying the essential allegations of the criminal offense in any subsequent civil proceeding brought by the United States.

§ 1965. Venue and process[6]

(a) Any civil action or proceeding under this chapter against any person may be instituted in the district court of the United States for any district in which such person resides, is found, has an agent, or transacts his affairs.

(b) In any action under section 1964 of this chapter in any district court of the United States in which it is shown that the ends of justice require that other parties residing in any other district be brought before the court, the court may cause such parties to be summoned, and process for that purpose may be served in any judicial district of the United States by the marshal thereof.

(c) In any civil or criminal action or proceeding instituted by the United States under this chapter in the district court of the United States for any judicial district, subpenas issued by such court to compel the attendance of witnesses may be served in any other judicial district, except that in any civil action or proceeding no such subpena shall be issued for service upon any individual who resides in another district at a place more than one hundred miles from the place at which such court is held without approval given by a judge of such court upon a showing of good cause.

(d) All other process in any action or proceeding under this chapter may be served on any person in any judicial district in which such person resides, is found, has an agent, or transacts his affairs.

§ 1966. Expedition of actions[7]

In any civil action instituted under this chapter by the United States in any district court of the United States, the Attorney General may file with the clerk of such court a certificate stating that in his opinion the case is of general public importance. A copy of that certificate shall be furnished immediately by such clerk to the

[6] Added by Public Law 91–452, Title IX, § 901(a), Oct. 15, 1970, 84 Stat. 944.

[7] Added by Public Law 91–452, Title IX, § 901(a), Oct. 15, 1970, 84 Stat. 944, and amended by Public Law 98–620, Title IV, § 402(24)(B), Nov. 8, 1984, 98 Stat. 3359.

chief judge or in his absence to the presiding district judge of the district in which such action is pending. Upon receipt of such copy, such judge shall designate immediately a judge of that district to hear and determine action.

§ 1967. Evidence[8]

In any proceeding ancillary to or in any civil action instituted by the United States under this chapter the proceedings may be open or closed to the public at the discretion of the court after consideration of the rights of affected persons.

§ 1968. Civil investigative demand[9]

(a) Whenever the Attorney General has reason to believe that any person or enterprise may be in possession, custody, or control of any documentary materials relevant to a racketeering investigation, he may, prior to the institution of a civil or criminal proceeding thereon, issue in writing, and cause to be served upon such person, a civil investigative demand requiring such person to produce such material for examination.

(b) Each such demand shall—

(1) state the nature of the conduct constituting the alleged racketeering violation which is under investigation and the provision of law applicable thereto;

(2) describe the class or classes of documentary material produced thereunder with such definiteness and certainty as to permit such material to be fairly identified;

(3) state that the demand is returnable forthwith or prescribe a return date which will provide a reasonable period of time within which the material so demanded may be assembled and made available for inspection and copying or reproduction; and

(4) identify the custodian to whom such material shall be made available.

(c) No such demand shall—

(1) contain any requirement which would be held to be unreasonable if contained in a subpena duces tecum issued by a court of the United States in aid of a grand jury investigation of such alleged racketeering violation; or

(2) require the production of any documentary evidence which would be privileged from disclosure if demanded by a subpena duces tecum issued by a court of the United States in aid of a grand jury investigation of such alleged racketeering violation.

(d) Service of any such demand or any petition filed under this section may be made upon a person by—

(1) delivering a duly executed copy thereof to any partner, executive officer, managing agent, or general agent thereof, or to any agent thereof authorized by appointment or by law to receive service of process on behalf of such person, or upon any individual person;

(2) delivering a duly executed copy thereof to the principal office or place of business of the person to be served; or

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[8] Added by Public Law 91–452, Title IX, § 901(a), Oct. 15, 1970, 84 Stat. 944.
[9] Added by Public Law 91–452, Title IX, § 901(a), Oct. 15, 1970, 84 Stat. 944.

(3) depositing such copy in the United States mail, by registered or certified mail duly addressed to such person at its principal office or place of business.

(e) A verified return by the individual serving any such demand or petition setting forth the manner of such service shall be prima facie proof of such service. In the case of service by registered or certified mail, such return shall be accompanied by the return post office receipt of delivery of such demand.

(f)(1) The Attorney General shall designate a racketeering investigator to serve as racketeer document custodian, and such additional racketeering investigators as he shall determine from time to time to be necessary to serve as deputies to such officer.

(2) Any person upon whom any demand issued under this section has been duly served shall make such material available for inspection and copying or reproduction to the custodian designated therein at the principal place of business of such person, or at such other place as such custodian and such person thereafter may agree and prescribe in writing or as the court may direct, pursuant to this section on the return date specified in such demand, or on such later date as such custodian may prescribe in writing. Such person may upon written agreement between such person and the custodian substitute for copies of all or any part of such material originals thereof.

(3) The custodian to whom any documentary material is so delivered shall take physical possession thereof, and shall be responsible for the use made thereof and for the return thereof pursuant to this chapter. The custodian may cause the preparation of such copies of such documentary material as may be required for official use under regulations which shall be promulgated by the Attorney General. While in the possession of the custodian, no material so produced shall be available for examination, without the consent of the person who produced such material, by any individual other than the Attorney General. Under such reasonable terms and conditions as the Attorney General shall prescribe, documentary material while in the possession of the custodian shall be available for examination by the person who produced such material or any duly authorized representatives of such person.

(4) Whenever any attorney has been designated to appear on behalf of the United States before any court or grand jury in any case or proceeding involving any alleged violation of this chapter, the custodian may deliver to such attorney such documentary material in the possession of the custodian as such attorney determines to be required for use in the presentation of such case or proceeding on behalf of the United States. Upon the conclusion of any such case or proceeding, such attorney shall return to the custodian any documentary material so withdrawn which has not passed into the control of such court or grand jury through the introduction thereof into the record of such case or proceeding.

(5) Upon the completion of—

(i) the racketeering investigation for which any documentary material was produced under this chapter, and

(ii) any case or proceeding arising from such investigation,

the custodian shall return to the person who produced such material all such material other than copies thereof made by the Attorney General pursuant to this subsection which has not passed into the control of any court or grand jury through the introduction thereof into the record of such case or proceeding.

(6) When any documentary material has been produced by any person under this section for use in any racketeering investigation, and no such case or proceeding arising therefrom has been instituted within a reasonable time after completion of the examination and analysis of all evidence assembled in the course of such investigation, such person shall be entitled, upon written demand made upon the Attorney General, to the return of all documentary material other than copies thereof made pursuant to this subsection so produced by such person.

(7) In the event of the death, disability, or separation from service of the custodian of any documentary material produced under any demand issued under this section or the official relief of such custodian from responsibility for the custody and control of such material, the Attorney General shall promptly—

(i) designate another racketeering investigator to serve as custodian thereof, and

(ii) transmit notice in writing to the person who produced such material as to the identity and address of the successor so designated.

Any successor so designated shall have with regard to such materials all duties and responsibilities imposed by this section upon his predecessor in office with regard thereto, except that he shall not be held responsible for any default or dereliction which occurred before his designation as custodian.

(g) Whenever any person fails to comply with any civil investigative demand duly served upon him under this section or whenever satisfactory copying or reproduction of any such material cannot be done and such person refuses to surrender such material, the Attorney General may file, in the district court of the United States for any judicial district in which such person resides, is found, or transacts business, and serve upon such person a petition for an order of such court for the enforcement of this section, except that if such person transacts business in more than one such district such petition shall be filed in the district in which such person maintains his principal place of business, or in such other district in which such person transacts business as may be agreed upon by the parties to such petition.

(h) Within twenty days after the service of any such demand upon any person, or at any time before the return date specified in the demand, whichever period is shorter, such person may file, in the district court of the United States for the judicial district within which such person resides, is found, or transacts business, and serve upon such custodian a petition for an order of such court modifying or setting aside such demand. The time allowed for compliance with the demand in whole or in part as deemed proper and ordered by the court shall not run during the pendency of such petition in the court. Such petition shall specify each ground upon which the petitioner relies in seeking such relief, and may be based upon any failure of such demand to comply with the provisions of

this section or upon any constitutional or other legal right or privilege of such person.

(i) At any time during which any custodian is in custody or control of any documentary material delivered by any person in compliance with any such demand, such person may file, in the district court of the United States for the judicial district within which the office of such custodian is situated, and serve upon such custodian a petition for an order of such court requiring the performance by such custodian of any duty imposed upon him by this section.

(j) Whenever any petition is filed in any district court of the United States under this section, such court shall have jurisdiction to hear and determine the matter so presented, and to enter such order or orders as may be required to carry into effect the provisions of this section.

18 U.S.C. § 2118
Robbery or burglary of controlled substance registrants

Chapter 103. Robbery and Burglary

§ 2118. Robberies and burglaries involving controlled substances [1]

(a) Whoever takes or attempts to take from the person or presence of another by force or violence or by intimidation any material or compound containing any quantity of a controlled substance belonging to or in the care, custody, control, or possession of a person registered with the Drug Enforcement Administration under section 302 of the Controlled Substances Act (21 U.S.C. 822) shall, except as provided in subsection (c), be fined under this title or imprisoned not more than twenty years, or both, if (1) the replacement cost of the material or compound to the registrant was not less than $500, (2) the person who engaged in such taking or attempted such taking traveled in interstate or foreign commerce or used any facility in interstate or foreign commerce to facilitate such taking or attempt, or (3) another person was killed or suffered significant bodily injury as a result of such taking or attempt.

(b) Whoever, without authority, enters or attempts to enter, or remains in, the business premises or property of a person registered with the Drug Enforcement Administration under section 302 of the Controlled Substances Act (21 U.S.C. 822) with the intent to steal any material or compound containing any quantity of a controlled substance shall, except as provided in subsection (c), be fined under this title or imprisoned not more than twenty years, or both, if (1) the replacement cost of the controlled substance to the registrant was not less than $500, (2) the person who engaged in such entry or attempted such entry or who remained in such premises or property traveled in interstate or foreign commerce or used any facility in interstate or foreign commerce to facilitate such entry or attempt or to facilitate remaining in such premises or property, or (3) another person was killed or suffered significant bodily injury as a result of such entry or attempt.

(c)(1) Whoever in committing any offense under subsection (a) or (b) assaults any person, or puts in jeopardy the life of any person, by the use of a dangerous weapon or device shall be fined under this title and imprisoned for not more than twenty-five years.

(2) Whoever in committing any offense under subsection (a) or (b) kills any person shall be fined under this title or imprisoned for any term of years or life, or both.

(d) If two or more persons conspire to violate subsection (a) or (b) of this section and one or more of such persons do any overt act

[1] Added by Public Law 98–305, § 2, May 31, 1984, 98 Stat. 221, and amended by Public Law 103–322, Title XXXIII, § § 330016(1)(O)–(Q), Sept. 13, 1994, 108 Stat. 2148.

to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than ten years or both.

(e) For purposes of this section—

(1) the term "controlled substance" has the meaning prescribed for that term by section 102 of the Controlled Substances Act;

(2) the term "business premises or property" includes conveyances and storage facilities; and

(3) the term "significant bodily injury" means bodily injury which involves a risk of death, significant physical pain, protracted and obvious disfigurement, or a protracted loss or impairment of the function of a bodily member, organ, or mental or sensory faculty.

18 U.S.C. §§ 2510–2520
Electronic surveillance in the case of offenses involving narcotics, marijuana or other dangerous drugs

Chapter 119. Wire and Electronic Communications Interception and Interception of Oral Communications

§ 2510. Definitions[1]

As used in this chapter—

(1) "wire communication" means any aural transfer made in whole or in part through the use of facilities for the transmission of communications by the aid of wire, cable, or other like connection between the point of origin and the point of reception (including the use of such connection in a switching station) furnished or operated by any person engaged in providing or operating such facilities for the transmission of interstate or foreign communications or communications affecting interstate or foreign commerce;

(2) "oral communication" means any oral communication uttered by a person exhibiting an expectation that such communication is not subject to interception under circumstances justifying such expectation, but such term does not include any electronic communication;

(3) "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any territory or possession of the United States;

(4) "intercept" means the aural or other acquisition of the contents of any wire, electronic, or oral communication through the use of any electronic, mechanical, or other device.[2]

(5) "electronic, mechanical, or other device" means any device or apparatus which can be used to intercept a wire, oral, or electronic communication other than—

(a) any telephone or telegraph instrument, equipment or facility, or any component thereof, (i) furnished to the subscriber or user by a provider of wire or electronic communication service in the ordinary course of its business and being used by the subscriber or user in the ordinary course of its business or furnished by such subscriber or user for connection to the facilities of such service and used in the

[1] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 212, and amended by Public Law 99–508, Title I, § 101(a), (c)(1)(A), (4), Oct. 21, 1986, 100 Stat. 1848, 1851; Public Law 103–414, Title II, §§ 202(a), 203, Oct. 25, 1994, 108 Stat. 4290, 4291; Public Law 104–132, Title VII, § 731, Apr. 24, 1996, 110 Stat. 1303; Public Law 107–56, Title II, §§ 203(b)(2), 209(1), 217(1), Oct. 26, 2001, 115 Stat. 280, 283, 291; Public Law 107–108, Title III, § 314(b), Dec. 28, 2001, 115 Stat. 1402; Public Law 107–273, Div. B, Title IV, § 4002(e)(10), Nov. 2, 2002, 116 Stat. 1810.

[2] So in original. The period probably should be a semicolon.

ordinary course of its business; or (ii) being used by a provider of wire or electronic communication service in the ordinary course of its business, or by an investigative or law enforcement officer in the ordinary course of his duties;

(b) a hearing aid or similar device being used to correct subnormal hearing to not better than normal;

(6) "person" means any employee, or agent of the United States or any State or political subdivision thereof, and any individual, partnership, association, joint stock company, trust, or corporation;

(7) "Investigative or law enforcement officer" means any officer of the United States or of a State or political subdivision thereof, who is empowered by law to conduct investigations of or to make arrests for offenses enumerated in this chapter, and any attorney authorized by law to prosecute or participate in the prosecution of such offenses;

(8) "contents", when used with respect to any wire, oral, or electronic communication, includes any information concerning the substance, purport, or meaning of that communication;

(9) "Judge of competent jurisdiction" means—

(a) a judge of a United States district court or a United States court of appeals; and

(b) a judge of any court of general criminal jurisdiction of a State who is authorized by a statute of that State to enter orders authorizing interceptions of wire, oral, or electronic communications;

(10) "communication common carrier" has the meaning given that term in section 3 of the Communications Act of 1934;

(11) "aggrieved person" means a person who was a party to any intercepted wire, oral, or electronic communication or a person against whom the interception was directed;

(12) "electronic communication" means any transfer of signs, signals, writing, images, sounds, data, or intelligence of any nature transmitted in whole or in part by a wire, radio, electromagnetic, photoelectronic or photooptical system that affects interstate or foreign commerce, but does not include—

(A) any wire or oral communication;

(B) any communication made through a tone-only paging device;

(C) any communication from a tracking device (as defined in section 3117 of this title); or

(D) electronic funds transfer information stored by a financial institution in a communications system used for the electronic storage and transfer of funds;

(13) "user" means any person or entity who—

(A) uses an electronic communication service; and

(B) is duly authorized by the provider of such service to engage in such use;

(14) "electronic communications system" means any wire, radio, electromagnetic, photooptical or photoelectronic facilities for the transmission of wire or electronic communications, and any computer facilities or related electronic equipment for the electronic storage of such communications;

(15) "electronic communication service" means any service which provides to users thereof the ability to send or receive wire or electronic communications;

(16) "readily accessible to the general public" means, with respect to a radio communication, that such communication is not—

(A) scrambled or encrypted;

(B) transmitted using modulation techniques whose essential parameters have been withheld from the public with the intention of preserving the privacy of such communication;

(C) carried on a subcarrier or other signal subsidiary to a radio transmission;

(D) transmitted over a communication system provided by a common carrier, unless the communication is a tone only paging system communication; or

(E) transmitted on frequencies allocated under part 25, subpart D, E, or F of part 74, or part 94 of the Rules of the Federal Communications Commission, unless, in the case of a communication transmitted on a frequency allocated under part 74 that is not exclusively allocated to broadcast auxiliary services, the communication is a two-way voice communication by radio;

(17) "electronic storage" means—

(A) any temporary, intermediate storage of a wire or electronic communication incidental to the electronic transmission thereof; and

(B) any storage of such communication by an electronic communication service for purposes of backup protection of such communication;

(18) "aural transfer" means a transfer containing the human voice at any point between and including the point of origin and the point of reception;

(19) "foreign intelligence information", for purposes of section 2517(6) of this title, means—

(A) information, whether or not concerning a United States person, that relates to the ability of the United States to protect against—

(i) actual or potential attack or other grave hostile acts of a foreign power or an agent of a foreign power;

(ii) sabotage or international terrorism by a foreign power or an agent of a foreign power; or

(iii) clandestine intelligence activities by an intelligence service or network of a foreign power or by an agent of a foreign power; or

(B) information, whether or not concerning a United States person, with respect to a foreign power or foreign territory that relates to—

(i) the national defense or the security of the United States; or

(ii) the conduct of the foreign affairs of the United States;

(20) "protected computer" has the meaning set forth in section 1030; and

(21) "computer trespasser"—

(A) means a person who accesses a protected computer without authorization and thus has no reasonable expectation of privacy in any communication transmitted to, through, or from the protected computer; and

(B) does not include a person known by the owner or operator of the protected computer to have an existing contractual relationship with the owner or operator of the protected computer for access to all or part of the protected computer.

§ 2511. Interception and disclosure of wire, oral, or electronic communications prohibited[3]

(1) Except as otherwise specifically provided in this chapter any person who—

(a) intentionally intercepts, endeavors to intercept, or procures any other person to intercept or endeavor to intercept, any wire, oral, or electronic communication;

(b) intentionally uses, endeavors to use, or procures any other person to use or endeavor to use any electronic, mechanical, or other device to intercept any oral communication when—

(i) such device is affixed to, or otherwise transmits a signal through, a wire, cable, or other like connection used in wire communication; or

(ii) such device transmits communications by radio, or interferes with the transmission of such communication; or

(iii) such person knows, or has reason to know, that such device or any component thereof has been sent through the mail or transported in interstate or foreign commerce; or

(iv) such use or endeavor to use (A) takes place on the premises of any business or other commercial establishment the operations of which affect interstate or foreign commerce; or (B) obtains or is for the purpose of obtaining information relating to the operations of any business or other commercial establishment the operations of which affect interstate or foreign commerce; or

(v) such person acts in the District of Columbia, the Commonwealth of Puerto Rico, or any territory or possession of the United States;

(c) intentionally discloses, or endeavors to disclose, to any other person the contents of any wire, oral, or electronic communication, knowing or having reason to know that the information was obtained through the interception of a wire, oral, or electronic communication in violation of this subsection;

(d) intentionally uses, or endeavors to use, the contents of any wire, oral, or electronic communication, knowing or having

[3] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 213, and amended by Public Law 91–358, Title II, § 211(a), July 29, 1970, 84 Stat. 654; Public Law 95–511, Title II, § 201(a) to (c), Oct. 25, 1978, 92 Stat. 1796, 1797; Public Law 98–549, § 6(b)(2), Oct. 30, 1984, 98 Stat. 2804; Public Law 99–508, Title I, § 101(b), (c)(1), (5), (6), (d), (f), 102, Oct. 21, 1986, 100 Stat. 1849 to 1853; Public Law 103–322, Title XXXII, § 320901, Title XXXIII, § 330016(1)(G), Sept. 13, 1994, 108 Stat. 2123, 2147; Public Law 103–414, Title II, § § 202(b), 204, 205, Oct. 25, 1994, 108 Stat. 4290, 4291; Public Law 104–294, Title VI, § 604(b)(42), Oct. 11, 1996, 110 Stat. 3509; Public Law 107–56, Title II, § § 204, 217(2), Oct. 26, 2001, 115 Stat. 281, 291; Public Law 107–296, Title II, § 225(h)(2), (j)(1), Nov. 25, 2002, 116 Stat. 2158.

reason to know that the information was obtained through the interception of a wire, oral, or electronic communication in violation of this subsection; or

(e) (i) intentionally discloses, or endeavors to disclose, to any other person the contents of any wire, oral, or electronic communication, intercepted by means authorized by sections 2511(2)(a)(ii), 2511(2)(b)–(c), 2511(2)(e), 2516, and 2518 of this chapter, (ii) knowing or having reason to know that the information was obtained through the interception of such a communication in connection with a criminal investigation, (iii) having obtained or received the information in connection with a criminal investigation, and (iv) with intent to improperly obstruct, impede, or interfere with a duly authorized criminal investigation,

shall be punished as provided in subsection (4) or shall be subject to suit as provided in subsection (5).

(2)(a)(i) It shall not be unlawful under this chapter for an operator of a switchboard, or an officer, employee, or agent of a provider of wire or electronic communication service, whose facilities are used in the transmission of a wire or electronic communication, to intercept, disclose, or use that communication in the normal course of his employment while engaged in any activity which is a necessary incident to the rendition of his service or to the protection of the rights or property of the provider of that service, except that a provider of wire communication service to the public shall not utilize service observing or random monitoring except for mechanical or service quality control checks.

(ii) Notwithstanding any other law, providers of wire or electronic communication service, their officers, employees, and agents, landlords, custodians, or other persons, are authorized to provide information, facilities, or technical assistance to persons authorized by law to intercept wire, oral, or electronic communications or to conduct electronic surveillance, as defined in section 101 of the Foreign Intelligence Surveillance Act of 1978, if such provider, its officers, employees, or agents, landlord, custodian, or other specified person, has been provided with—

(A) a court order directing such assistance signed by the authorizing judge, or

(B) a certification in writing by a person specified in section 2518(7) of this title or the Attorney General of the United States that no warrant or court order is required by law, that all statutory requirements have been met, and that the specified assistance is required,

setting forth the period of time during which the provision of the information, facilities, or technical assistance is authorized and specifying the information, facilities, or technical assistance required. No provider of wire or electronic communication service, officer, employee, or agent thereof, or landlord, custodian, or other specified person shall disclose the existence of any interception or surveillance or the device used to accomplish the interception or surveillance with respect to which the person has been furnished

a court order or certification under this chapter, except as may otherwise be required by legal process and then only after prior notification to the Attorney General or to the principal prosecuting attorney of a State or any political subdivision of a State, as may be appropriate. Any such disclosure, shall render such person liable for the civil damages provided for in section 2520. No cause of action shall lie in any court against any provider of wire or electronic communication service, its officers, employees, or agents, landlord, custodian, or other specified person for providing information, facilities, or assistance in accordance with the terms of a court order, statutory authorization, or certification under this chapter.

(b) It shall not be unlawful under this chapter for an officer, employee, or agent of the Federal Communications Commission, in the normal course of his employment and in discharge of the monitoring responsibilities exercised by the Commission in the enforcement of chapter 5 of title 47 of the United States Code, to intercept a wire or electronic communication, or oral communication transmitted by radio, or to disclose or use the information thereby obtained.

(c) It shall not be unlawful under this chapter for a person acting under color of law to intercept a wire, oral, or electronic communication, where such person is a party to the communication or one of the parties to the communication has given prior consent to such interception.

(d) It shall not be unlawful under this chapter for a person not acting under color of law to intercept a wire, oral, or electronic communication where such person is a party to the communication or where one of the parties to the communication has given prior consent to such interception unless such communication is intercepted for the purpose of committing any criminal or tortious act in violation of the Constitution or laws of the United States or of any State.

(e) Notwithstanding any other provision of this title or section 705 or 706 of the Communications Act of 1934, it shall not be unlawful for an officer, employee, or agent of the United States in the normal course of his official duty to conduct electronic surveillance, as defined in section 101 of the Foreign Intelligence Surveillance Act of 1978, as authorized by that Act.

(f) Nothing contained in this chapter or chapter 121 or 206 of this title, or section 705 of the Communications Act of 1934, shall be deemed to affect the acquisition by the United States Government of foreign intelligence information from international or foreign communications, or foreign intelligence activities conducted in accordance with otherwise applicable Federal law involving a foreign electronic communications system, utilizing a means other than electronic surveillance as defined in section 101 of the Foreign Intelligence Surveillance Act of 1978, and procedures in this chapter or chapter 121 and the Foreign Intelligence Surveillance Act of 1978 shall be the exclusive means by which electronic surveillance, as defined in section 101 of such Act, and the interception of domestic wire, oral, and electronic communications may be conducted.

(g) It shall not be unlawful under this chapter or chapter 121 of this title for any person—

(i) to intercept or access an electronic communication made through an electronic communication system that is configured so that such electronic communication is readily accessible to the general public;

(ii) to intercept any radio communication which is transmitted—

(I) by any station for the use of the general public, or that relates to ships, aircraft, vehicles, or persons in distress;

(II) by any governmental, law enforcement, civil defense, private land mobile, or public safety communications system, including police and fire, readily accessible to the general public;

(III) by a station operating on an authorized frequency within the bands allocated to the amateur, citizens band, or general mobile radio services; or

(IV) by any marine or aeronautical communications system;

(iii) to engage in any conduct which—

(I) is prohibited by section 633 of the Communications Act of 1934; or

(II) is excepted from the application of section 705(a) of the Communications Act of 1934 by section 705(b) of that Act;

(iv) to intercept any wire or electronic communication the transmission of which is causing harmful interference to any lawfully operating station or consumer electronic equipment, to the extent necessary to identify the source of such interference; or

(v) for other users of the same frequency to intercept any radio communication made through a system that utilizes frequencies monitored by individuals engaged in the provision or the use of such system, if such communication is not scrambled or encrypted.

(h) It shall not be unlawful under this chapter—

(i) to use a pen register or a trap and trace device (as those terms are defined for the purposes of chapter 206 (relating to pen registers and trap and trace devices) of this title); or

(ii) for a provider of electronic communication service to record the fact that a wire or electronic communication was initiated or completed in order to protect such provider, another provider furnishing service toward the completion of the wire or electronic communication, or a user of that service, from fraudulent, unlawful or abusive use of such service.

(i) It shall not be unlawful under this chapter for a person acting under color of law to intercept the wire or electronic communications of a computer trespasser transmitted to, through, or from the protected computer, if—

(I) the owner or operator of the protected computer authorizes the interception of the computer trespasser's communications on the protected computer;

(II) the person acting under color of law is lawfully engaged in an investigation;

(III) the person acting under color of law has reasonable grounds to believe that the contents of the computer trespasser's communications will be relevant to the investigation; and

(IV) such interception does not acquire communications other than those transmitted to or from the computer trespasser.

(3)(a) Except as provided in paragraph (b) of this subsection, a person or entity providing an electronic communication service to the public shall not intentionally divulge the contents of any communication (other than one to such person or entity, or an agent thereof) while in transmission on that service to any person or entity other than an addressee or intended recipient of such communication or an agent of such addressee or intended recipient.

(b) A person or entity providing electronic communication service to the public may divulge the contents of any such communication—

(i) as otherwise authorized in section 2511(2)(a) or 2517 of this title;

(ii) with the lawful consent of the originator or any addressee or intended recipient of such communication;

(iii) to a person employed or authorized, or whose facilities are used, to forward such communication to its destination; or

(iv) which were inadvertently obtained by the service provider and which appear to pertain to the commission of a crime, if such divulgence is made to a law enforcement agency.

(4)(a) Except as provided in paragraph (b) of this subsection or in subsection (5), whoever violates subsection (1) of this section shall be fined under this title or imprisoned not more than five years, or both.

(b) Conduct otherwise an offense under this subsection that consists of or relates to the interception of a satellite transmission that is not encrypted or scrambled and that is transmitted—

(i) to a broadcasting station for purposes of retransmission to the general public; or

(ii) as an audio subcarrier intended for redistribution to facilities open to the public, but not including data transmissions or telephone calls,

is not an offense under this subsection unless the conduct is for the purposes of direct or indirect commercial advantage or private financial gain.

(5)(a)(i) If the communication is—

(A) a private satellite video communication that is not scrambled or encrypted and the conduct in violation of this chapter is the private viewing of that communication and is not for a tortious or illegal purpose or for purposes of direct or indirect commercial advantage or private commercial gain; or

(B) a radio communication that is transmitted on frequencies allocated under subpart D of part 74 of the rules of the Federal Communications Commission that is not scrambled or encrypted and the conduct in violation of this chapter is not for a tortious or illegal purpose or for purposes of direct or indirect commercial advantage or private commercial gain,

then the person who engages in such conduct shall be subject to suit by the Federal Government in a court of competent jurisdiction.

(ii) In an action under this subsection—

(A) if the violation of this chapter is a first offense for the person under paragraph (a) of subsection (4) and such person has not been found liable in a civil action under section 2520 of this title, the Federal Government shall be entitled to appropriate injunctive relief; and

(B) if the violation of this chapter is a second or subsequent offense under paragraph (a) of subsection (4) or such person has been found liable in any prior civil action under section 2520, the person shall be subject to a mandatory $500 civil fine.

(b) The court may use any means within its authority to enforce an injunction issued under paragraph (ii)(A), and shall impose a civil fine of not less than $500 for each violation of such an injunction.

§ 2512. Manufacture, distribution, possession, and advertising of wire, oral, or electronic communication intercepting devices prohibited[4]

(1) Except as otherwise specifically provided in this chapter, any person who intentionally—

(a) sends through the mail, or sends or carries in interstate or foreign commerce, any electronic, mechanical, or other device, knowing or having reason to know that the design of such device renders it primarily useful for the purpose of the surreptitious interception of wire, oral, or electronic communications;

(b) manufactures, assembles, possesses, or sells any electronic, mechanical, or other device, knowing or having reason to know that the design of such device renders it primarily useful for the purpose of the surreptitious interception of wire, oral, or electronic communications, and that such device or any component thereof has been or will be sent through the mail or transported in interstate or foreign commerce; or

(c) places in any newspaper, magazine, handbill, or other publication or disseminates by electronic means any advertisement of—

(i) any electronic, mechanical, or other device knowing the content of the advertisement and knowing or having reason to know that the design of such device renders it primarily useful for the purpose of the surreptitious interception of wire, oral, or electronic communications; or

(ii) any other electronic, mechanical, or other device, where such advertisement promotes the use of such device for the purpose of the surreptitious interception of wire, oral, or electronic communications,

knowing the content of the advertisement and knowing or having reason to know that such advertisement will be sent

[4] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 214, and amended by Public Law 99–508, Title I, § 101(c)(1)(A), (7), (f)(2), Oct. 21, 1986, 100 Stat. 1851, 1853; Public Law 103–322, Title XXXIII, § § 330016(1)(L), 330022, Sept. 13, 1994, 108 Stat. 2147, 2150; Public Law 104–294, Title VI, § 604(b)(45), Oct. 11, 1996, 110 Stat. 3509; Public Law 105–112, § 2, Nov. 21, 1997, 111 Stat. 2273; Public Law 107–296, Title II, § 225(f), Nov. 25, 2002, 116 Stat. 2158.

through the mail or transported in interstate or foreign commerce,

shall be fined under this title or imprisoned not more than five years, or both.

(2) It shall not be unlawful under this section for—

(a) a provider of wire or electronic communication service or an officer, agent, or employee of, or a person under contract with, such a provider, in the normal course of the business of providing that wire or electronic communication service, or

(b) an officer, agent, or employee of, or a person under contract with, the United States, a State, or a political subdivision thereof, in the normal course of the activities of the United States, a State, or a political subdivision thereof,

to send through the mail, send or carry in interstate or foreign commerce, or manufacture, assemble, possess, or sell any electronic, mechanical, or other device knowing or having reason to know that the design of such device renders it primarily useful for the purpose of the surreptitious interception of wire, oral, or electronic communications.

(3) It shall not be unlawful under this section to advertise for sale a device described in subsection (1) of this section if the advertisement is mailed, sent, or carried in interstate or foreign commerce solely to a domestic provider of wire or electronic communication service or to an agency of the United States, a State, or a political subdivision thereof which is duly authorized to use such device.

§ 2513. Confiscation of wire, oral, or electronic communication intercepting devices[5]

Any electronic, mechanical, or other device used, sent, carried, manufactured, assembled, possessed, sold, or advertised in violation of section 2511 or section 2512 of this chapter may be seized and forfeited to the United States. All provisions of law relating to (1) the seizure, summary and judicial forfeiture, and condemnation of vessels, vehicles, merchandise, and baggage for violations of the customs laws contained in title 19 of the United States Code, (2) the disposition of such vessels, vehicles, merchandise, and baggage or the proceeds from the sale thereof, (3) the remission or mitigation of such forfeiture, (4) the compromise of claims, and (5) the award of compensation to informers in respect of such forfeitures, shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under the provisions of this section, insofar as applicable and not inconsistent with the provisions of this section; except that such duties as are imposed upon the collector of customs or any other person with respect to the seizure and forfeiture of vessels, vehicles, merchandise, and baggage under the provisions of the customs laws contained in title 19 of the United States Code shall be performed with respect to seizure and forfeiture of electronic, mechanical, or other intercepting devices under this section by such officers, agents, or other persons as may be authorized or designated for that purpose by the Attorney General.

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[5] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 215, and amended by Public Law 99–508, Title I, § 101(c)(1)(A), Oct. 21, 1986, 100 Stat. 1851.

§ 2515. Prohibition of use as evidence of intercepted wire or oral communications [6]

Whenever any wire or oral communication has been intercepted, no part of the contents of such communication and no evidence derived therefrom may be received in evidence in any trial, hearing, or other proceeding in or before any court, grand jury, department, officer, agency, regulatory body, legislative committee, or other authority of the United States, a State, or a political subdivision thereof if the disclosure of that information would be in violation of this chapter.

§ 2516. Authorization for interception of wire, oral, or electronic communications [7]

(1) The Attorney General, Deputy Attorney General, Associate Attorney General, or any Assistant Attorney General, any acting Assistant Attorney General, or any Deputy Assistant Attorney General or acting Deputy Assistant Attorney General in the Criminal Division specially designated by the Attorney General, may authorize an application to a Federal judge of competent jurisdiction for, and such judge may grant in conformity with section 2518 of this chapter an order authorizing or approving the interception of wire or oral communications by the Federal Bureau of Investigation, or a Federal agency having responsibility for the investigation of the offense as to which the application is made, when such interception may provide or has provided evidence of—

(a) any offense punishable by death or by imprisonment for more than one year under sections 2122 and 2274 through 2277 of title 42 of the United States Code (relating to the enforcement of the Atomic Energy Act of 1954), section 2284 of title 42 of the United States Code (relating to sabotage of nuclear facilities or fuel), or under the following chapters of this title: chapter 37 (relating to espionage), chapter 55 (relating to kidnapping), chapter 90 (relating to protection of trade secrets), chapter 105 (relating to sabotage), chapter 115 (relating to treason), chapter 102 (relating to riots), chapter 65 (relating to malicious mischief), chapter 111 (relating to destruction of vessels), or chapter 81 (relating to piracy);

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[6] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 216.

[7] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 216, and amended by Public Law 91–452, Title VIII, § 810, Title IX, § 902(a), Title XI, § 1103, Oct. 15, 1970, 84 Stat. 940, 947, 959; Public Law 91–644, Title IV, § 16, Jan. 2, 1971, 84 Stat. 1891; Public Law 95–598, Title III, § 314(h), Nov. 6, 1978, 92 Stat. 2677; Public Law 97–285, §§ 2(e), 4(e), Oct. 6, 1982, 96 Stat. 1220, 1221; Public Law 98–292, § 8, May 21, 1984, 98 Stat. 206; Public Law 98–473, Title II, § 1203(c), Oct. 12, 1984, 98 Stat. 2152; Public Law 99–508, Title I, §§ 101(c)(1)(A), 104, 105, Oct. 21, 1986, 100 Stat. 1851, 1855; Public Law 99–570, Title I, § 1365(c), Oct. 27, 1986, 100 Stat. 3207–35; Public Law 100–690, Title VI, § 6461, Title VII, §§ 7036, 7053(d), 7525, Nov. 18, 1988, 102 Stat. 4374, 4399, 4402, 4502; Public Law 101–298, § 3(b), May 22, 1990, 104 Stat. 203; Public Law 101–647, Title XXV, § 2531, Title XXXV, § 3568, Nov. 29, 1990, 104 Stat. 4879, 4928; Public Law 103–272, § 5(e)(11), July 5, 1994, 108 Stat. 1374; Public Law 103–322, Title XXXIII, §§ 330011(c)(1), (q)(1), (r), 330021(1), Sept. 13, 1994, 108 Stat. 2144, 2145, 2150; Public Law 103–414, Title II, § 208, Oct. 25, 1994, 108 Stat. 4292; Public Law 103–429, § 7(a)(4)(A), Oct. 31, 1994, 108 Stat. 4389; Public Law 104–132, Title IV, § 434, Apr. 24, 1996, 110 Stat. 1274; Public Law 104–208, Div. C, Title II, § 201, Sept. 30, 1996, 110 Stat. 3009–564; Public Law 104–287, § 6(a)(2), Oct. 11, 1996, 110 Stat. 3398; Public Law 104–294, Title I, § 102, Title VI, § 601(d), Oct. 11, 1996, 110 Stat. 3491, 3499; Public Law 105–318, § 6(b), Oct. 30, 1998, 112 Stat. 3011; Public Law 106–181, Title V, § 506(c)(2)(B), Apr. 5, 2000, 114 Stat. 139; Public Law 107–56, Title II, §§ 201, 202, Oct. 26, 2001, 115 Stat. 278; Public Law 107–197, Title III, § 301(a), June 25, 2002, 116 Stat. 728; Public Law 107–273, Div. B, Title IV, §§ 4002(c)(1), 4005(a)(1), Nov. 2, 2002, 116 Stat. 1808, 1812; Public Law 108–21, Title II, § 201, Apr. 30, 2003, 117 Stat. 659; Public Law 108–458, § 6907, Dec. 17, 2004, 118 Stat. 3774.

(b) a violation of section 186 or section 501(c) of title 29, United States Code (dealing with restrictions on payments and loans to labor organizations), or any offense which involves murder, kidnapping, robbery, or extortion, and which is punishable under this title;

(c) any offense which is punishable under the following sections of this title: section 201 (bribery of public officials and witnesses), section 215 (relating to bribery of bank officials), section 224 (bribery in sporting contests), subsection (d), (e), (f), (g), (h), or (i) of section 844 (unlawful use of explosives), section 1032 (relating to concealment of assets), section 1084 (transmission of wagering information), section 751 (relating to escape), section 1014 (relating to loans and credit applications generally; renewals and discounts), sections 1503, 1512, and 1513 (influencing or injuring an officer, juror, or witness generally), section 1510 (obstruction of criminal investigations), section 1511 (obstruction of State or local law enforcement), section 1591 (sex trafficking of children by force, fraud, or coercion), section 1751 (Presidential and Presidential staff assassination, kidnapping, and assault), section 1951 (interference with commerce by threats or violence), section 1952 (interstate and foreign travel or transportation in aid of racketeering enterprises), section 1958 (relating to use of interstate commerce facilities in the commission of murder for hire), section 1959 (relating to violent crimes in aid of racketeering activity), section 1954 (offer, acceptance, or solicitation to influence operations of employee benefit plan), section 1955 (prohibition of business enterprises of gambling), section 1956 (laundering of monetary instruments), section 1957 (relating to engaging in monetary transactions in property derived from specified unlawful activity), section 659 (theft from interstate shipment), section 664 (embezzlement from pension and welfare funds), section 1343 (fraud by wire, radio, or television), section 1344 (relating to bank fraud), sections 2251 and 2252 (sexual exploitation of children), section 2251A (selling or buying of children), section 2252A (relating to material constituting or containing child pornography), section 1466A (relating to child obscenity), section 2260 (production of sexually explicit depictions of a minor for importation into the United States), sections 2421, 2422, 2423, and 2425 (relating to transportation for illegal sexual activity and related crimes), sections 2312, 2313, 2314, and 2315 (interstate transportation of stolen property), section 2321 (relating to trafficking in certain motor vehicles or motor vehicle parts), section 1203 (relating to hostage taking), section 1029 (relating to fraud and related activity in connection with access devices), section 3146 (relating to penalty for failure to appear), section 3521(b)(3) (relating to witness relocation and assistance), section 32 (relating to destruction of aircraft or aircraft facilities), section 38 (relating to aircraft parts fraud), section 1963 (violations with respect to racketeer influenced and corrupt organizations), section 115 (relating to threatening or retaliating against a Federal official), section 1341 (relating to mail fraud), a felony violation of section 1030 (relating to computer fraud and abuse), section 351 (violations

with respect to congressional, Cabinet, or Supreme Court assassinations, kidnapping, and assault), section 831 (relating to prohibited transactions involving nuclear materials), section 33 (relating to destruction of motor vehicles or motor vehicle facilities), section 175 (relating to biological weapons), section 175c (relating to variola virus), section 1992 (relating to wrecking trains), a felony violation of section 1028 (relating to production of false identification documentation), section 1425 (relating to the procurement of citizenship or nationalization unlawfully), section 1426 (relating to the reproduction of naturalization or citizenship papers), section 1427 (relating to the sale of naturalization or citizenship papers), section 1541 (relating to passport issuance without authority), section 1542 (relating to false statements in passport applications), section 1543 (relating to forgery or false use of passports), section 1544 (relating to misuse of passports), or section 1546 (relating to fraud and misuse of visas, permits, and other documents);

(d) any offense involving counterfeiting punishable under section 471, 472, or 473 of this title;

(e) any offense involving fraud connected with a case under title 11 or the manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in narcotic drugs, marihuana, or other dangerous drugs, punishable under any law of the United States;

(f) any offense including extortionate credit transactions under sections 892, 893, or 894 of this title;

(g) a violation of section 5322 of title 31, United States Code (dealing with the reporting of currency transactions);

(h) any felony violation of sections 2511 and 2512 (relating to interception and disclosure of certain communications and to certain intercepting devices) of this title;

(i) any felony violation of chapter 71 (relating to obscenity) of this title;

(j) any violation of section 60123(b) (relating to destruction of a natural gas pipeline) or section 46502 (relating to aircraft piracy) of title 49;

(k) any criminal violation of section 2778 of title 22 (relating to the Arms Export Control Act);

(l) the location of any fugitive from justice from an offense described in this section;

(m) a violation of section 274, 277, or 278 of the Immigration and Nationality Act (8 U.S.C. 1324, 1327, or 1328) (relating to the smuggling of aliens);

(n) any felony violation of sections 922 and 924 of title 18, United States Code (relating to firearms);

(o) any violation of section 5861 of the Internal Revenue Code of 1986 (relating to firearms);

(p) a felony violation of section 1028 (relating to production of false identification documents), section 1542 (relating to false statements in passport applications), section 1546 (relating to fraud and misuse of visas, permits, and other documents) of this title or a violation of section 274, 277, or 278 of the Immigration and Nationality Act (relating to the smuggling of aliens);

(q) any criminal violation of section 229 (relating to chemical weapons); or sections 2332, 2332a, 2332b, 2332d, 2332f, 2332g, 2332h, 2339A, 2339B, or 2339C of this title (relating to terrorism); or

(r) any conspiracy to commit any offense described in any subparagraph of this paragraph.

(2) The principal prosecuting attorney of any State, or the principal prosecuting attorney of any political subdivision thereof, if such attorney is authorized by a statute of that State to make application to a State court judge of competent jurisdiction for an order authorizing or approving the interception of wire, oral, or electronic communications, may apply to such judge for, and such judge may grant in conformity with section 2518 of this chapter and with the applicable State statute an order authorizing, or approving the interception of wire, oral, or electronic communications by investigative or law enforcement officers having responsibility for the investigation of the offense as to which the application is made, when such interception may provide or has provided evidence of the commission of the offense of murder, kidnapping, gambling, robbery, bribery, extortion, or dealing in narcotic drugs, marihuana or other dangerous drugs, or other crime dangerous to life, limb, or property, and punishable by imprisonment for more than one year, designated in any applicable State statute authorizing such interception, or any conspiracy to commit any of the foregoing offenses.

(3) Any attorney for the Government (as such term is defined for the purposes of the Federal Rules of Criminal Procedure) may authorize an application to a Federal judge of competent jurisdiction for, and such judge may grant, in conformity with section 2518 of this title, an order authorizing or approving the interception of electronic communications by an investigative or law enforcement officer having responsibility for the investigation of the offense as to which the application is made, when such interception may provide or has provided evidence of any Federal felony.

§ 2517. Authorization for disclosure and use of intercepted wire, oral, or electronic communications[8]

(1) Any investigative or law enforcement officer who, by any means authorized by this chapter, has obtained knowledge of the contents of any wire, oral, or electronic communication, or evidence derived therefrom, may disclose such contents to another investigative or law enforcement officer to the extent that such disclosure is appropriate to the proper performance of the official duties of the officer making or receiving the disclosure.

(2) Any investigative or law enforcement officer who, by any means authorized by this chapter, has obtained knowledge of the contents of any wire, oral, or electronic communication or evidence derived therefrom may use such contents to the extent such use is appropriate to the proper performance of his official duties.

(3) Any person who has received, by any means authorized by this chapter, any information concerning a wire, oral, or electronic

[8] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 217, and amended by Public Law 91–452, Title IX, § 902(b), Oct. 15, 1970, 84 Stat. 947; Public Law 99–508, Title I, § 101(c)(1)(A), Oct. 21, 1986, 100 Stat. 1851; Public Law 107–56, Title II, § 203(b)(1), Oct. 26, 2001, 115 Stat. 280; Public Law 107–296, Title VIII, § 896, Nov. 25, 2002, 116 Stat. 2257.

communication, or evidence derived therefrom intercepted in accordance with the provisions of this chapter may disclose the contents of that communication or such derivative evidence while giving testimony under oath or affirmation in any proceeding held under the authority of the United States or of any State or political subdivision thereof.

(4) No otherwise privileged wire, oral, or electronic communication intercepted in accordance with, or in violation of, the provisions of this chapter shall lose its privileged character.

(5) When an investigative or law enforcement officer, while engaged in intercepting wire, oral, or electronic communications in the manner authorized herein, intercepts wire, oral, or electronic communications relating to offenses other than those specified in the order of authorization or approval, the contents thereof, and evidence derived therefrom, may be disclosed or used as provided in subsections (1) and (2) of this section. Such contents and any evidence derived therefrom may be used under subsection (3) of this section when authorized or approved by a judge of competent jurisdiction where such judge finds on subsequent application that the contents were otherwise intercepted in accordance with the provisions of this chapter. Such application shall be made as soon as practicable.

(6) Any investigative or law enforcement officer, or attorney for the Government, who by any means authorized by this chapter, has obtained knowledge of the contents of any wire, oral, or electronic communication, or evidence derived therefrom, may disclose such contents to any other Federal law enforcement, intelligence, protective, immigration, national defense, or national security official to the extent that such contents include foreign intelligence or counterintelligence (as defined in section 3 of the National Security Act of 1947 (50 U.S.C. 401a)), or foreign intelligence information (as defined in subsection (19) of section 2510 of this title), to assist the official who is to receive that information in the performance of his official duties. Any Federal official who receives information pursuant to this provision may use that information only as necessary in the conduct of that person's official duties subject to any limitations on the unauthorized disclosure of such information.

(7) Any investigative or law enforcement officer, or other Federal official in carrying out official duties as such Federal official, who by any means authorized by this chapter, has obtained knowledge of the contents of any wire, oral, or electronic communication, or evidence derived therefrom, may disclose such contents or derivative evidence to a foreign investigative or law enforcement officer to the extent that such disclosure is appropriate to the proper performance of the official duties of the officer making or receiving the disclosure, and foreign investigative or law enforcement officers may use or disclose such contents or derivative evidence to the extent such use or disclosure is appropriate to the proper performance of their official duties.

(8) Any investigative or law enforcement officer, or other Federal official in carrying out official duties as such Federal official, who by any means authorized by this chapter, has obtained knowledge of the contents of any wire, oral, or electronic communication, or

evidence derived therefrom, may disclose such contents or derivative evidence to any appropriate Federal, State, local, or foreign government official to the extent that such contents or derivative evidence reveals a threat of actual or potential attack or other grave hostile acts of a foreign power or an agent of a foreign power, domestic or international sabotage, domestic or international terrorism, or clandestine intelligence gathering activities by an intelligence service or network of a foreign power or by an agent of a foreign power, within the United States or elsewhere, for the purpose of preventing or responding to such a threat. Any official who receives information pursuant to this provision may use that information only as necessary in the conduct of that person's official duties subject to any limitations on the unauthorized disclosure of such information, and any State, local, or foreign official who receives information pursuant to this provision may use that information only consistent with such guidelines as the Attorney General and Director of Central Intelligence shall jointly issue.

§ 2518. Procedure for interception of wire, oral, or electronic communications[9]

(1) Each application for an order authorizing or approving the interception of a wire, oral, or electronic communication under this chapter shall be made in writing upon oath or affirmation to a judge of competent jurisdiction and shall state the applicant's authority to make such application. Each application shall include the following information:

(a) the identity of the investigative or law enforcement officer making the application, and the officer authorizing the application;

(b) a full and complete statement of the facts and circumstances relied upon by the applicant, to justify his belief that an order should be issued, including (i) details as to the particular offense that has been, is being, or is about to be committed, (ii) except as provided in subsection (11), a particular description of the nature and location of the facilities from which or the place where the communication is to be intercepted, (iii) a particular description of the type of communications sought to be intercepted, (iv) the identity of the person, if known, committing the offense and whose communications are to be intercepted;

(c) a full and complete statement as to whether or not other investigative procedures have been tried and failed or why they reasonably appear to be unlikely to succeed if tried or to be too dangerous;

(d) a statement of the period of time for which the interception is required to be maintained. If the nature of the investigation is such that the authorization for interception should not automatically terminate when the described type of communication has been first obtained, a particular description of

[9] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 218, and amended by Public Law 91–358, Title II, § 211(b), July 29, 1970, 84 Stat. 654; Public Law 95–511, Title II, § 201(d) to (g), Oct. 25, 1978, 92 Stat. 1797, 1798; Public Law 98–473, Title II, § 1203(a), (b), Oct. 12, 1984, 98 Stat. 2152; Public Law 99–508, Title I, §§ 101(c)(1)(A), (8), (e), 106(a) to (d)(3), Oct. 21, 1986, 100 Stat. 1851–1853, 1856, 1857; Public Law 103–414, Title II, § 201(b)(1), Oct. 25, 1994, 108 Stat. 4290; Public Law 105–272, Title VI, § 604, Oct. 20, 1998, 112 Stat. 2413.

facts establishing probable cause to believe that additional communications of the same type will occur thereafter;

(e) a full and complete statement of the facts concerning all previous applications known to the individual authorizing and making the application, made to any judge for authorization to intercept, or for approval of interceptions of, wire, oral, or electronic communications involving any of the same persons, facilities or places specified in the application, and the action taken by the judge on each such application; and

(f) where the application is for the extension of an order, a statement setting forth the results thus far obtained from the interception, or a reasonable explanation of the failure to obtain such results.

(2) The judge may require the applicant to furnish additional testimony or documentary evidence in support of the application.

(3) Upon such application the judge may enter an ex parte order, as requested or as modified, authorizing or approving interception of wire, oral, or electronic communications within the territorial jurisdiction of the court in which the judge is sitting (and outside that jurisdiction but within the United States in the case of a mobile interception device authorized by a Federal court within such jurisdiction), if the judge determines on the basis of the facts submitted by the applicant that—

(a) there is probable cause for belief that an individual is committing, has committed, or is about to commit a particular offense enumerated in section 2516 of this chapter;

(b) there is probable cause for belief that particular communications concerning that offense will be obtained through such interception;

(c) normal investigative procedures have been tried and have failed or reasonably appear to be unlikely to succeed if tried or to be too dangerous;

(d) except as provided in subsection (11), there is probable cause for belief that the facilities from which, or the place where, the wire, oral, or electronic communications are to be intercepted are being used, or are about to be used, in connection with the commission of such offense, or are leased to, listed in the name of, or commonly used by such person.

(4) Each order authorizing or approving the interception of any wire, oral, or electronic communication under this chapter shall specify—

(a) the identity of the person, if known, whose communications are to be intercepted;

(b) the nature and location of the communications facilities as to which, or the place where, authority to intercept is granted;

(c) a particular description of the type of communication sought to be intercepted, and a statement of the particular offense to which it relates;

(d) the identity of the agency authorized to intercept the communications, and of the person authorizing the application; and

(e) the period of time during which such interception is authorized, including a statement as to whether or not the interception shall automatically terminate when the described communication has been first obtained.

An order authorizing the interception of a wire, oral, or electronic communication under this chapter shall, upon request of the applicant, direct that a provider of wire or electronic communication service, landlord, custodian or other person shall furnish the applicant forthwith all information, facilities, and technical assistance necessary to accomplish the interception unobtrusively and with a minimum of interference with the services that such service provider, landlord, custodian, or person is according the person whose communications are to be intercepted. Any provider of wire or electronic communication service, landlord, custodian or other person furnishing such facilities or technical assistance shall be compensated therefor by the applicant for reasonable expenses incurred in providing such facilities or assistance. Pursuant to section 2522 of this chapter, an order may also be issued to enforce the assistance capability and capacity requirements under the Communications Assistance for Law Enforcement Act.

(5) No order entered under this section may authorize or approve the interception of any wire, oral, or electronic communication for any period longer than is necessary to achieve the objective of the authorization, nor in any event longer than thirty days. Such thirty-day period begins on the earlier of the day on which the investigative or law enforcement officer first begins to conduct an interception under the order or ten days after the order is entered. Extensions of an order may be granted, but only upon application for an extension made in accordance with subsection (1) of this section and the court making the findings required by subsection (3) of this section. The period of extension shall be no longer than the authorizing judge deems necessary to achieve the purposes for which it was granted and in no event for longer than thirty days. Every order and extension thereof shall contain a provision that the authorization to intercept shall be executed as soon as practicable, shall be conducted in such a way as to minimize the interception of communications not otherwise subject to interception under this chapter, and must terminate upon attainment of the authorized objective, or in any event in thirty days. In the event the intercepted communication is in a code or foreign language, and an expert in that foreign language or code is not reasonably available during the interception period, minimization may be accomplished as soon as practicable after such interception. An interception under this chapter may be conducted in whole or in part by Government personnel, or by an individual operating under a contract with the Government, acting under the supervision of an investigative or law enforcement officer authorized to conduct the interception.

(6) Whenever an order authorizing interception is entered pursuant to this chapter, the order may require reports to be made to the judge who issued the order showing what progress has been made toward achievement of the authorized objective and the need for continued interception. Such reports shall be made at such intervals as the judge may require.

(7) Notwithstanding any other provision of this chapter, any investigative or law enforcement officer, specially designated by the Attorney General, the Deputy Attorney General, the Associate Attorney General, or by the principal prosecuting attorney of any State or subdivision thereof acting pursuant to a statute of that State, who reasonably determines that—

(a) an emergency situation exists that involves—

(i) immediate danger of death or serious physical injury to any person,

(ii) conspiratorial activities threatening the national security interest, or

(iii) conspiratorial activities characteristic of organized crime,

that requires a wire, oral, or electronic communication to be intercepted before an order authorizing such interception can, with due diligence, be obtained, and

(b) there are grounds upon which an order could be entered under this chapter to authorize such interception,

may intercept such wire, oral, or electronic communication if an application for an order approving the interception is made in accordance with this section within forty-eight hours after the interception has occurred, or begins to occur. In the absence of an order, such interception shall immediately terminate when the communication sought is obtained or when the application for the order is denied, whichever is earlier. In the event such application for approval is denied, or in any other case where the interception is terminated without an order having been issued, the contents of any wire, oral, or electronic communication intercepted shall be treated as having been obtained in violation of this chapter, and an inventory shall be served as provided for in subsection (d) of this section on the person named in the application.

(8)(a) The contents of any wire, oral, or electronic communication intercepted by any means authorized by this chapter shall, if possible, be recorded on tape or wire or other comparable device. The recording of the contents of any wire, oral, or electronic communication under this subsection shall be done in such a way as will protect the recording from editing or other alterations. Immediately upon the expiration of the period of the order, or extensions thereof, such recordings shall be made available to the judge issuing such order and sealed under his directions. Custody of the recordings shall be wherever the judge orders. They shall not be destroyed except upon an order of the issuing or denying judge and in any event shall be kept for ten years. Duplicate recordings may be made for use or disclosure pursuant to the provisions of subsections (1) and (2) of section 2517 of this chapter for investigations. The presence of the seal provided for by this subsection, or a satisfactory explanation for the absence thereof, shall be a prerequisite for the use or disclosure of the contents of any wire, oral, or electronic communication or evidence derived therefrom under subsection (3) of section 2517.

(b) Applications made and orders granted under this chapter shall be sealed by the judge. Custody of the applications and orders shall be wherever the judge directs. Such applications and orders shall be disclosed only upon a showing of good cause before a judge

of competent jurisdiction and shall not be destroyed except on order of the issuing or denying judge, and in any event shall be kept for ten years.

(c) Any violation of the provisions of this subsection may be punished as contempt of the issuing or denying judge.

(d) Within a reasonable time but not later than ninety days after the filing of an application for an order of approval under section 2518(7)(b) which is denied or the termination of the period of an order or extensions thereof, the issuing or denying judge shall cause to be served, on the persons named in the order or the application, and such other parties to intercepted communications as the judge may determine in his discretion that is in the interest of justice, an inventory which shall include notice of—

(1) the fact of the entry of the order or the application;

(2) the date of the entry and the period of authorized, approved or disapproved interception, or the denial of the application; and

(3) the fact that during the period wire, oral, or electronic communications were or were not intercepted.

The judge, upon the filing of a motion, may in his discretion make available to such person or his counsel for inspection such portions of the intercepted communications, applications and orders as the judge determines to be in the interest of justice. On an ex parte showing of good cause to a judge of competent jurisdiction the serving of the inventory required by this subsection may be postponed.

(9) The contents of any wire, oral, or electronic communication intercepted pursuant to this chapter or evidence derived therefrom shall not be received in evidence or otherwise disclosed in any trial, hearing, or other proceeding in a Federal or State court unless each party, not less than ten days before the trial, hearing, or proceeding, has been furnished with a copy of the court order, and accompanying application, under which the interception was authorized or approved. This ten-day period may be waived by the judge if he finds that it was not possible to furnish the party with the above information ten days before the trial, hearing, or proceeding and that the party will not be prejudiced by the delay in receiving such information.

(10)(a) Any aggrieved person in any trial, hearing, or proceeding in or before any court, department, officer, agency, regulatory body, or other authority of the United States, a State, or a political subdivision thereof, may move to suppress the contents of any wire or oral communication intercepted pursuant to this chapter, or evidence derived therefrom, on the grounds that—

(i) the communication was unlawfully intercepted;

(ii) the order of authorization or approval under which it was intercepted is insufficient on its face; or

(iii) the interception was not made in conformity with the order of authorization or approval.

Such motion shall be made before the trial, hearing, or proceeding unless there was no opportunity to make such motion or the person was not aware of the grounds of the motion. If the motion is granted, the contents of the intercepted wire or oral communication, or evidence derived therefrom, shall be treated as having been obtained in violation of this chapter. The judge, upon the filing of

such motion by the aggrieved person, may in his discretion make available to the aggrieved person or his counsel for inspection such portions of the intercepted communication or evidence derived therefrom as the judge determines to be in the interests of justice.

(b) In addition to any other right to appeal, the United States shall have the right to appeal from an order granting a motion to suppress made under paragraph (a) of this subsection, or the denial of an application for an order of approval, if the United States attorney shall certify to the judge or other official granting such motion or denying such application that the appeal is not taken for purposes of delay. Such appeal shall be taken within thirty days after the date the order was entered and shall be diligently prosecuted.

(c) The remedies and sanctions described in this chapter with respect to the interception of electronic communications are the only judicial remedies and sanctions for nonconstitutional violations of this chapter involving such communications.

(11) The requirements of subsections (1)(b)(ii) and (3)(d) of this section relating to the specification of the facilities from which, or the place where, the communication is to be intercepted do not apply if—

(a) in the case of an application with respect to the interception of an oral communication—

(i) the application is by a Federal investigative or law enforcement officer and is approved by the Attorney General, the Deputy Attorney General, the Associate Attorney General, an Assistant Attorney General, or an acting Assistant Attorney General;

(ii) the application contains a full and complete statement as to why such specification is not practical and identifies the person committing the offense and whose communications are to be intercepted; and

(iii) the judge finds that such specification is not practical; and

(b) in the case of an application with respect to a wire or electronic communication—

(i) the application is by a Federal investigative or law enforcement officer and is approved by the Attorney General, the Deputy Attorney General, the Associate Attorney General, an Assistant Attorney General, or an acting Assistant Attorney General;

(ii) the application identifies the person believed to be committing the offense and whose communications are to be intercepted and the applicant makes a showing that there is probable cause to believe that the person's actions could have the effect of thwarting interception from a specified facility;

(iii) the judge finds that such showing has been adequately made; and

(iv) the order authorizing or approving the interception is limited to interception only for such time as it is reasonable to presume that the person identified in the application is or was reasonably proximate to the instrument

through which such communication will be or was transmitted.

(12) An interception of a communication under an order with respect to which the requirements of subsections (1)(b)(ii) and (3)(d) of this section do not apply by reason of subsection (11)(a) shall not begin until the place where the communication is to be intercepted is ascertained by the person implementing the interception order. A provider of wire or electronic communications service that has received an order as provided for in subsection (11)(b) may move the court to modify or quash the order on the ground that its assistance with respect to the interception cannot be performed in a timely or reasonable fashion. The court, upon notice to the government, shall decide such a motion expeditiously.

§ 2519. Reports concerning intercepted wire, oral, or electronic communications[10]

(1) Within thirty days after the expiration of an order (or each extension thereof) entered under section 2518, or the denial of an order approving an interception, the issuing or denying judge shall report to the Administrative Office of the United States Courts—

(a) the fact that an order or extension was applied for;

(b) the kind of order or extension applied for (including whether or not the order was an order with respect to which the requirements of sections 2518(1)(b)(ii) and 2518(3)(d) of this title did not apply by reason of section 2518(11) of this title);

(c) the fact that the order or extension was granted as applied for, was modified, or was denied;

(d) the period of interceptions authorized by the order, and the number and duration of any extensions of the order;

(e) the offense specified in the order or application, or extension of an order;

(f) the identity of the applying investigative or law enforcement officer and agency making the application and the person authorizing the application; and

(g) the nature of the facilities from which or the place where communications were to be intercepted.

(2) In January of each year the Attorney General, an Assistant Attorney General specially designated by the Attorney General, or the principal prosecuting attorney of a State, or the principal prosecuting attorney for any political subdivision of a State, shall report to the Administrative Office of the United States Courts—

(a) the information required by paragraphs (a) through (g) of subsection (1) of this section with respect to each application for an order or extension made during the preceding calendar year;

(b) a general description of the interceptions made under such order or extension, including (i) the approximate nature and frequency of incriminating communications intercepted, (ii) the approximate nature and frequency of other communications intercepted, (iii) the approximate number of persons

[10] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 222, and amended by Public Law 95–511, Title II, § 201(h), Oct. 25, 1978, 92 Stat. 1798; Public Law 99–508, Title I, § § 101(c)(1)(A), 106(d)(4), Oct. 21, 1986, 100 Stat. 1851, 1857; Public Law 106–197, § 2(a), May 2, 2000, 114 Stat. 247.

whose communications were intercepted, (iv) the number of orders in which encryption was encountered and whether such encryption prevented law enforcement from obtaining the plain text of communications intercepted pursuant to such order, and (v) the approximate nature, amount, and cost of the manpower and other resources used in the interceptions;

(c) the number of arrests resulting from interceptions made under such order or extension, and the offenses for which arrests were made;

(d) the number of trials resulting from such interceptions;

(e) the number of motions to suppress made with respect to such interceptions, and the number granted or denied;

(f) the number of convictions resulting from such interceptions and the offenses for which the convictions were obtained and a general assessment of the importance of the interceptions; and

(g) the information required by paragraphs (b) through (f) of this subsection with respect to orders or extensions obtained in a preceding calendar year.

(3) In April of each year the Director of the Administrative Office of the United States Courts shall transmit to the Congress a full and complete report concerning the number of applications for orders authorizing or approving the interception of wire, oral, or electronic communications pursuant to this chapter and the number of orders and extensions granted or denied pursuant to this chapter during the preceding calendar year. Such report shall include a summary and analysis of the data required to be filed with the Administrative Office by subsections (1) and (2) of this section. The Director of the Administrative Office of the United States Courts is authorized to issue binding regulations dealing with the content and form of the reports required to be filed by subsections (1) and (2) of this section.

§ 2520. Recovery of civil damages authorized [11]

(a) IN GENERAL.—Except as provided in section 2511(2)(a)(ii), any person whose wire, oral, or electronic communication is intercepted, disclosed, or intentionally used in violation of this chapter may in a civil action recover from the person or entity, other than the United States, which engaged in that violation such relief as may be appropriate.

(b) RELIEF.—In an action under this section, appropriate relief includes—

(1) such preliminary and other equitable or declaratory relief as may be appropriate;

(2) damages under subsection (c) and punitive damages in appropriate cases; and

(3) a reasonable attorney's fee and other litigation costs reasonably incurred.

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[11] Added by Public Law 90–351, Title III, § 802, June 19, 1968, 82 Stat. 223, and amended by Public Law 91–358, Title II, § 211(c), July 29, 1970, 84 Stat. 654; Public Law 99–508, Title I, § 103, Oct. 21, 1986, 100 Stat. 1853; Public Law 107–56, Title II, § 223(a), Oct. 26, 2001, 115 Stat. 293; Public Law 107–296, Title II, § 225(e), Nov. 25, 2002, 116 Stat. 2157.

(c) COMPUTATION OF DAMAGES.—(1) In an action under this section, if the conduct in violation of this chapter is the private viewing of a private satellite video communication that is not scrambled or encrypted or if the communication is a radio communication that is transmitted on frequencies allocated under subpart D of part 74 of the rules of the Federal Communications Commission that is not scrambled or encrypted and the conduct is not for a tortious or illegal purpose or for purposes of direct or indirect commercial advantage or private commercial gain, then the court shall assess damages as follows:

(A) If the person who engaged in that conduct has not previously been enjoined under section 2511(5) and has not been found liable in a prior civil action under this section, the court shall assess the greater of the sum of actual damages suffered by the plaintiff, or statutory damages of not less than $50 and not more than $500.

(B) If, on one prior occasion, the person who engaged in that conduct has been enjoined under section 2511(5) or has been found liable in a civil action under this section, the court shall assess the greater of the sum of actual damages suffered by the plaintiff, or statutory damages of not less than $100 and not more than $1000.

(2) In any other action under this section, the court may assess as damages whichever is the greater of—

(A) the sum of the actual damages suffered by the plaintiff and any profits made by the violator as a result of the violation; or

(B) statutory damages of whichever is the greater of $100 a day for each day of violation or $10,000.

(d) DEFENSE.—A good faith reliance on—

(1) a court warrant or order, a grand jury subpoena, a legislative authorization, or a statutory authorization;

(2) a request of an investigative or law enforcement officer under section 2518(7) of this title; or

(3) a good faith determination that section 2511(3) or 2511(2)(i) of this title permitted the conduct complained of;

is a complete defense against any civil or criminal action brought under this chapter or any other law.

(e) LIMITATION.—A civil action under this section may not be commenced later than two years after the date upon which the claimant first has a reasonable opportunity to discover the violation.

(f) ADMINISTRATIVE DISCIPLINE.—If a court or appropriate department or agency determines that the United States or any of its departments or agencies has violated any provision of this chapter, and the court or appropriate department or agency finds that the circumstances surrounding the violation raise serious questions about whether or not an officer or employee of the United States acted willfully or intentionally with respect to the violation, the department or agency shall, upon receipt of a true and correct copy of the decision and findings of the court or appropriate department or agency promptly initiate a proceeding to determine whether disciplinary action against the officer or employee is warranted. If the

head of the department or agency involved determines that disciplinary action is not warranted, he or she shall notify the Inspector General with jurisdiction over the department or agency concerned and shall provide the Inspector General with the reasons for such determination.

(g) IMPROPER DISCLOSURE IS VIOLATION.—Any willful disclosure or use by an investigative or law enforcement officer or governmental entity of information beyond the extent permitted by section 2517 is a violation of this chapter for purposes of section 2520(a).

Chapter 207. Release and Detention Pending Judicial Proceedings

§ 3142. Release or detention of a defendant pending trial[1]

(a) IN GENERAL.—Upon the appearance before a judicial officer of a person charged with an offense, the judicial officer shall issue an order that, pending trial, the person be—

(1) released on personal recognizance or upon execution of an unsecured appearance bond, under subsection (b) of this section;

(2) released on a condition or combination of conditions under subsection (c) of this section;

(3) temporarily detained to permit revocation of conditional release, deportation, or exclusion under subsection (d) of this section; or

(4) detained under subsection (e) of this section.

(b) RELEASE ON PERSONAL RECOGNIZANCE OR UNSECURED APPEARANCE BOND.—The judicial officer shall order the pretrial release of the person on personal recognizance, or upon execution of an unsecured appearance bond in an amount specified by the court, subject to the condition that the person not commit a Federal, State, or local crime during the period of release, unless the judicial officer determines that such release will not reasonably assure the appearance of the person as required or will endanger the safety of any other person or the community.

(c) RELEASE ON CONDITIONS.—(1) If the judicial officer determines that the release described in subsection (b) of this section will not reasonably assure the appearance of the person as required or will endanger the safety of any other person or the community, such judicial officer shall order the pretrial release of the person—

(A) subject to the condition that the person not commit a Federal, State, or local crime during the period of release; and

(B) subject to the least restrictive further condition, or combination of conditions, that such judicial officer determines will reasonably assure the appearance of the person as required and the safety of any other person and the community, which may include the condition that the person—

(i) remain in the custody of a designated person, who agrees to assume supervision and to report any violation

[1] Added by Public Law 98–473, Title II, § 203(a), Oct. 12, 1984, 98 Stat. 1976, and amended by Public Law 99–646, §§ 55(a), (c), 72, Nov. 10, 1986, 100 Stat. 3607, 3617; Public Law 100–690, Title VII, § 7073, Nov. 18, 1988, 102 Stat. 4405; Public Law 101–647, Title X, § 1001(b), Title XXXVI, §§ 3622–3624, Nov. 29, 1990, 104 Stat. 4827, 4965; Public Law 104–132, Title VII, §§ 702(d), 729, Apr. 24, 1996, 110 Stat. 1294, 1302; Public Law 108–21, Title II, § 203, Apr. 30, 2003, 117 Stat. 660; Public Law 108–458, § 6952, Dec. 17, 2004, 118 Stat. 3775.

of a release condition to the court, if the designated person is able reasonably to assure the judicial officer that the person will appear as required and will not pose a danger to the safety of any other person or the community;

(ii) maintain employment, or, if unemployed, actively seek employment;

(iii) maintain or commence an educational program;

(iv) abide by specified restrictions on personal associations, place of abode, or travel;

(v) avoid all contact with an alleged victim of the crime and with a potential witness who may testify concerning the offense;

(vi) report on a regular basis to a designated law enforcement agency, pretrial services agency, or other agency;

(vii) comply with a specified curfew;

(viii) refrain from possessing a firearm, destructive device, or other dangerous weapon;

(ix) refrain from excessive use of alcohol, or any use of a narcotic drug or other controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802), without a prescription by a licensed medical practitioner;

(x) undergo available medical, psychological, or psychiatric treatment, including treatment for drug or alcohol dependency, and remain in a specified institution if required for that purpose;

(xi) execute an agreement to forfeit upon failing to appear as required, property of a sufficient unencumbered value, including money, as is reasonably necessary to assure the appearance of the person as required, and shall provide the court with proof of ownership and the value of the property along with information regarding existing encumbrances as the judicial office may require;

(xii) execute a bail bond with solvent sureties; who will execute an agreement to forfeit in such amount as is reasonably necessary to assure appearance of the person as required and shall provide the court with information regarding the value of the assets and liabilities of the surety if other than an approved surety and the nature and extent of encumbrances against the surety's property; such surety shall have a net worth which shall have sufficient unencumbered value to pay the amount of the bail bond;

(xiii) return to custody for specified hours following release for employment, schooling, or other limited purposes; and

(xiv) satisfy any other condition that is reasonably necessary to assure the appearance of the person as required and to assure the safety of any other person and the community.

(2) The judicial officer may not impose a financial condition that results in the pretrial detention of the person.

(3) The judicial officer may at any time amend the order to impose additional or different conditions of release.

(d) TEMPORARY DETENTION TO PERMIT REVOCATION OF CONDITIONAL RELEASE, DEPORTATION, OR EXCLUSION.—If the judicial officer determines that—

(1) such person—

(A) is, and was at the time the offense was committed, on—

(i) release pending trial for a felony under Federal, State, or local law;

(ii) release pending imposition or execution of sentence, appeal of sentence or conviction, or completion of sentence, for any offense under Federal, State, or local law; or

(iii) probation or parole for any offense under Federal, State, or local law; or

(B) is not a citizen of the United States or lawfully admitted for permanent residence, as defined in section 101(a)(20) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(20)); and

(2) such person may flee or pose a danger to any other person or the community;

such judicial officer shall order the detention of such person, for a period of not more than ten days, excluding Saturdays, Sundays, and holidays, and direct the attorney for the Government to notify the appropriate court, probation or parole official, or State or local law enforcement official, or the appropriate official of the Immigration and Naturalization Service. If the official fails or declines to take such person into custody during that period, such person shall be treated in accordance with the other provisions of this section, notwithstanding the applicability of other provisions of law governing release pending trial or deportation or exclusion proceedings. If temporary detention is sought under paragraph (1)(B) of this subsection, such person has the burden of proving to the court such person's United States citizenship or lawful admission for permanent residence.

(e) DETENTION.—If, after a hearing pursuant to the provisions of subsection (f) of this section, the judicial officer finds that no condition or combination of conditions will reasonably assure the appearance of the person as required and the safety of any other person and the community, such judicial officer shall order the detention of the person before trial. In a case described in subsection (f)(1) of this section, a rebuttable presumption arises that no condition or combination of conditions will reasonably assure the safety of any other person and the community if such judicial officer finds that—

(1) the person has been convicted of a Federal offense that is described in subsection (f)(1) of this section, or of a State or local offense that would have been an offense described in subsection (f)(1) of this section if a circumstance giving rise to Federal jurisdiction had existed;

(2) the offense described in paragraph (1) of this subsection was committed while the person was on release pending trial for a Federal, State, or local offense; and

(3) a period of not more than five years has elapsed since the date of conviction, or the release of the person from imprisonment, for the offense described in paragraph (1) of this subsection, whichever is later.

Subject to rebuttal by the person, it shall be presumed that no condition or combination of conditions will reasonably assure the appearance of the person as required and the safety of the community if the judicial officer finds that there is probable cause to believe that the person committed an offense for which a maximum term of imprisonment of ten years or more is prescribed in the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), or the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.), an offense under section 924(c), 956(a), or 2332b of this title, or an offense listed in section 2332b(g)(5)(B) of title 18, United States Code, for which a maximum term of imprisonment of 10 years or more is prescribed or an offense involving a minor victim under section 1201, 1591, 2241, 2242, 2244(a)(1), 2245, 2251, 2251A, 2252(a)(1), 2252(a)(2), 2252(a)(3), 2252A(a)(1), 2252A(a)(2), 2252A(a)(3), 2252A(a)(4), 2260, 2421, 2422, 2423, or 2425 of this title.

(f) DETENTION HEARING.—The judicial officer shall hold a hearing to determine whether any condition or combination of conditions set forth in subsection (c) of this section will reasonably assure the appearance of such person as required and the safety of any other person and the community—

(1) upon motion of the attorney for the Government, in a case that involves—

(A) a crime of violence, or an offense listed in section 2332b(g)(5)(B) for which a maximum term of imprisonment of 10 years or more is prescribed;

(B) an offense for which the maximum sentence is life imprisonment or death;

(C) an offense for which a maximum term of imprisonment of ten years or more is prescribed in the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), or the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.); or

(D) any felony if such person has been convicted of two or more offenses described in subparagraphs (A) through (C) of this paragraph, or two or more State or local offenses that would have been offenses described in subparagraphs (A) through (C) of this paragraph if a circumstance giving rise to Federal jurisdiction had existed, or a combination of such offenses; or

(2) Upon motion of the attorney for the Government or upon the judicial officer's own motion, in a case that involves—

(A) a serious risk that such person will flee; or

(B) a serious risk that such person will obstruct or attempt to obstruct justice, or threaten, injure, or intimidate, or attempt to threaten, injure, or intimidate, a prospective witness or juror.

The hearing shall be held immediately upon the person's first appearance before the judicial officer unless that person, or the attorney for the Government, seeks a continuance. Except for good cause, a continuance on motion of such person may not exceed five days (not including any intermediate Saturday, Sunday, or legal holiday), and a continuance on motion of the attorney for the Government may not exceed three days (not including any intermediate Saturday, Sunday, or legal holiday). During a continuance, such person shall be detained, and the judicial officer, on motion of the attorney for the Government or sua sponte, may order that, while in custody, a person who appears to be a narcotics addict receive a medical examination to determine whether such person is an addict. At the hearing, such person has the right to be represented by counsel, and, if financially unable to obtain adequate representation, to have counsel appointed. The person shall be afforded an opportunity to testify, to present witnesses, to cross-examine witnesses who appear at the hearing, and to present information by proffer or otherwise. The rules concerning admissibility of evidence in criminal trials do not apply to the presentation and consideration of information at the hearing. The facts the judicial officer uses to support a finding pursuant to subsection (e) that no condition or combination of conditions will reasonably assure the safety of any other person and the community shall be supported by clear and convincing evidence. The person may be detained pending completion of the hearing. The hearing may be reopened, before or after a determination by the judicial officer, at any time before trial if the judicial officer finds that information exists that was not known to the movant at the time of the hearing and that has a material bearing on the issue whether there are conditions of release that will reasonably assure the appearance of such person as required and the safety of any other person and the community.

(g) FACTORS TO BE CONSIDERED.— The judicial officer shall, in determining whether there are conditions of release that will reasonably assure the appearance of the person as required and the safety of any other person and the community, take into account the available information concerning—

(1) The nature and circumstances of the offense charged, including whether the offense is a crime of violence, or an offense listed in section 2332b(g)(5)(B) for which a maximum term of imprisonment of 10 years or more is prescribed or involves a narcotic drug;

(2) the weight of the evidence against the person;

(3) the history and characteristics of the person, including—

(A) the person's character, physical and mental condition, family ties, employment, financial resources, length of residence in the community, community ties, past conduct, history relating to drug or alcohol abuse, criminal history, and record concerning appearance at court proceedings; and

(B) whether, at the time of the current offense or arrest, the person was on probation, on parole, or on other release

pending trial, sentencing, appeal, or completion of sentence for an offense under Federal, State, or local law; and

(4) the nature and seriousness of the danger to any person or the community that would be posed by the person's release. In considering the conditions of release described in subsection (c)(1)(B)(xi) or (c)(1)(B)(xii) of this section, the judicial officer may upon his own motion, or shall upon the motion of the Government, conduct an inquiry into the source of the property to be designated for potential forfeiture or offered as collateral to secure a bond, and shall decline to accept the designation, or the use as collateral, of property that, because of its source, will not reasonably assure the appearance of the person as required.

(h) CONTENTS OF RELEASE ORDER.—In a release order issued under subsection (b) or (c) of this section, the judicial officer shall—

(1) include a written statement that sets forth all the conditions to which the release is subject, in a manner sufficiently clear and specific to serve as a guide for the person's conduct; and

(2) advise the person of—

(A) the penalties for violating a condition of release, including the penalties for committing an offense while on pretrial release;

(B) the consequences of violating a condition of release, including the immediate issuance of a warrant for the person's arrest; and

(C) sections 1503 of this title (relating to intimidation of witnesses, jurors, and officers of the court), 1510 (relating to obstruction of criminal investigations), 1512 (tampering with a witness, victim, or an informant), and 1513 (retaliating against a witness, victim, or an informant).

(i) CONTENTS OF DETENTION ORDER.—In a detention order issued under subsection (e) of this section, the judicial officer shall—

(1) include written findings of fact and a written statement of the reasons for the detention;

(2) direct that the person be committed to the custody of the Attorney General for confinement in a corrections facility separate, to the extent practicable, from persons awaiting or serving sentences or being held in custody pending appeal;

(3) direct that the person be afforded reasonable opportunity for private consultation with counsel; and

(4) direct that, on order of a court of the United States or on request of an attorney for the Government, the person in charge of the corrections facility in which the person is confined deliver the person to a United States marshal for the purpose of an appearance in connection with a court proceeding.

The judicial officer may, by subsequent order, permit the temporary release of the person, in the custody of a United States marshal or another appropriate person, to the extent that the judicial officer determines such release to be necessary for preparation of the person's defense or for another compelling reason.

(j) PRESUMPTION OF INNOCENCE.—Nothing in this section shall be construed as modifying or limiting the presumption of innocence.

18 U.S.C. § 3553(f)
Safety valve for otherwise applicable mandatory minimums in controlled substance cases

Chapter 227. Sentences

§ 3553. Imposition of a sentence [1]

* * * * * * *

(f) LIMITATION ON APPLICABILITY OF STATUTORY MINIMUMS IN CERTAIN CASES.—Notwithstanding any other provision of law, in the case of an offense under section 401, 404, or 406 of the Controlled Substances Act (21 U.S.C. 841, 844, 846) or section 1010 or 1013 of the Controlled Substances Import and Export Act (21 U.S.C. 960, 963), the court shall impose a sentence pursuant to guidelines promulgated by the United States Sentencing Commission under section 994 of title 28 without regard to any statutory minimum sentence, if the court finds at sentencing, after the Government has been afforded the opportunity to make a recommendation, that—

(1) the defendant does not have more than 1 criminal history point, as determined under the sentencing guidelines;

(2) the defendant did not use violence or credible threats of violence or possess a firearm or other dangerous weapon (or induce another participant to do so) in connection with the offense;

(3) the offense did not result in death or serious bodily injury to any person;

(4) the defendant was not an organizer, leader, manager, or supervisor of others in the offense, as determined under the sentencing guidelines and was not engaged in a continuing criminal enterprise, as defined in section 408 of the Controlled Substances Act; and

(5) not later than the time of the sentencing hearing, the defendant has truthfully provided to the Government all information and evidence the defendant has concerning the offense or offenses that were part of the same course of conduct or of a common scheme or plan, but the fact that the defendant has no relevant or useful other information to provide or that the Government is already aware of the information shall not preclude a determination by the court that the defendant has complied with this requirement.

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[1] Added by Public Law 103–322, Title VIII, § 80001(a), Sept. 13, 1994, 108 Stat. 1985, and amended by Public Law 104–294, Title VI, § 601(b)(5), (6), Oct. 11, 1996, 110 Stat. 3499.

18 U.S.C. § 3559
Three strikes sentencing relating to serious drug offenses

§ 3559. Sentencing classification of offenses [1]

(a) CLASSIFICATION.—An offense that is not specifically classified by a letter grade in the section defining it, is classified if the maximum term of imprisonment authorized is—

(1) life imprisonment, or if the maximum penalty is death, as a Class A felony;

(2) twenty-five years or more, as a Class B felony;

(3) less than twenty-five years but ten or more years, as a Class C felony;

(4) less than ten years but five or more years, as a Class D felony;

(5) less than five years but more than one year, as a Class E felony;

(6) one year or less but more than six months, as a Class A misdemeanor;

(7) six months or less but more than thirty days, as a Class B misdemeanor;

(8) thirty days or less but more than five days, as a Class C misdemeanor; or

(9) five days or less, or if no imprisonment is authorized, as an infraction.

(b) EFFECT OF CLASSIFICATION.—Except as provided in subsection (c), an offense classified under subsection (a) carries all the incidents assigned to the applicable letter designation, except that the maximum term of imprisonment is the term authorized by the law describing the offense.

(c) IMPRISONMENT OF CERTAIN VIOLENT FELONS.—

(1) MANDATORY LIFE IMPRISONMENT.—Notwithstanding any other provision of law, a person who is convicted in a court of the United States of a serious violent felony shall be sentenced to life imprisonment if—

(A) the person has been convicted (and those convictions have become final) on separate prior occasions in a court of the United States or of a State of—

(i) 2 or more serious violent felonies; or

(ii) one or more serious violent felonies and one or more serious drug offenses; and

(B) each serious violent felony or serious drug offense used as a basis for sentencing under this subsection, other

[1] Added by Public Law 98–473, Title II, § 212(a)(2), Oct. 12, 1984, 98 Stat. 1991, and amended by Public Law 100–185, § 5, Dec. 11, 1987, 101 Stat. 1279; Public Law 100–690, Title VII, § 7041, Nov. 18, 1988, 102 Stat. 4399; Public Law 103–322, Title VII, § 70001, Sept. 13, 1994, 108 Stat. 1982; Public Law 105–314, Title V, § 501, Oct. 30, 1998, 112 Stat. 2980; Public Law 105–386, § 1(b), Nov. 13, 1998, 112 Stat. 3470; Public Law 108–21, Title I, § 106(a), Apr. 30, 2003, 117 Stat. 654; Public Law 108–482, § 204(a), Dec. 23, 2004, 118 Stat. 3917.

than the first, was committed after the defendant's conviction of the preceding serious violent felony or serious drug offense.

(2) DEFINITIONS.—For purposes of this subsection—

(A) the term "assault with intent to commit rape" means an offense that has as its elements engaging in physical contact with another person or using or brandishing a weapon against another person with intent to commit aggravated sexual abuse or sexual abuse (as described in sections 2241 and 2242);

(B) the term "arson" means an offense that has as its elements maliciously damaging or destroying any building, inhabited structure, vehicle, vessel, or real property by means of fire or an explosive;

(C) the term "extortion" means an offense that has as its elements the extraction of anything of value from another person by threatening or placing that person in fear of injury to any person or kidnapping of any person;

(D) the term "firearms use" means an offense that has as its elements those described in section 924(c) or 929(a), if the firearm was brandished, discharged, or otherwise used as a weapon and the crime of violence or drug trafficking crime during and relation to which the firearm was used was subject to prosecution in a court of the United States or a court of a State, or both;

(E) the term "kidnapping" means an offense that has as its elements the abduction, restraining, confining, or carrying away of another person by force or threat of force;

(F) the term "serious violent felony" means—

(i) a Federal or State offense, by whatever designation and wherever committed, consisting of murder (as described in section 1111); manslaughter other than involuntary manslaughter (as described in section 1112); assault with intent to commit murder (as described in section 113(a)); assault with intent to commit rape; aggravated sexual abuse and sexual abuse (as described in sections 2241 and 2242); abusive sexual contact (as described in sections 2244 (a)(1) and (a)(2)); kidnapping; aircraft piracy (as described in section 46502 of Title 49); robbery (as described in section 2111, 2113, or 2118); carjacking (as described in section 2119); extortion; arson; firearms use; firearms possession (as described in section 924(c)); or attempt, conspiracy, or solicitation to commit any of the above offenses; and

(ii) any other offense punishable by a maximum term of imprisonment of 10 years or more that has as an element the use, attempted use, or threatened use of physical force against the person of another or that, by its nature, involves a substantial risk that physical force against the person of another may be used in the course of committing the offense;

(G) the term "State" means a State of the United States, the District of Columbia, and a commonwealth, territory, or possession of the United States; and

(H) the term "serious drug offense" means—

(i) an offense that is punishable under section 401(b)(1)(A) or 408 of the Controlled Substances Act (21 U.S.C. 841(b)(1)(A), 848) or section 1010(b)(1)(A) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)(1)(A)); or

(ii) an offense under State law that, had the offense been prosecuted in a court of the United States, would have been punishable under section 401(b)(1)(A) or 408 of the Controlled Substances Act (21 U.S.C. 841(b)(1)(A), 848) or section 1010(b)(1)(A) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)(1)(A)).

(3) NONQUALIFYING FELONIES.—

(A) ROBBERY IN CERTAIN CASES.—Robbery, an attempt, conspiracy, or solicitation to commit robbery; or an offense described in paragraph (2)(F)(ii) shall not serve as a basis for sentencing under this subsection if the defendant establishes by clear and convincing evidence that—

(i) no firearm or other dangerous weapon was used in the offense and no threat of use of a firearm or other dangerous weapon was involved in the offense; and

(ii) the offense did not result in death or serious bodily injury (as defined in section 1365) to any person.

(B) ARSON IN CERTAIN CASES.—Arson shall not serve as a basis for sentencing under this subsection if the defendant establishes by clear and convincing evidence that—

(i) the offense posed no threat to human life; and

(ii) the defendant reasonably believed the offense posed no threat to human life.

(4) INFORMATION FILED BY UNITED STATES ATTORNEY.—The provisions of section 411(a) of the Controlled Substances Act (21 U.S.C. 851(a)) shall apply to the imposition of sentence under this subsection.

(5) RULE OF CONSTRUCTION.—This subsection shall not be construed to preclude imposition of the death penalty.

(6) SPECIAL PROVISION FOR INDIAN COUNTRY.—No person subject to the criminal jurisdiction of an Indian tribal government shall be subject to this subsection for any offense for which Federal jurisdiction is solely predicated on Indian country (as defined in section 1151) and which occurs within the boundaries of such Indian country unless the governing body of the tribe has elected that this subsection have effect over land and persons subject to the criminal jurisdiction of the tribe.

(7) RESENTENCING UPON OVERTURNING OF PRIOR CONVICTION.—If the conviction for a serious violent felony or serious drug offense that was a basis for sentencing under this subsection is found, pursuant to any appropriate State or Federal procedure, to be unconstitutional or is vitiated on the explicit

basis of innocence, or if the convicted person is pardoned on the explicit basis of innocence, the person serving a sentence imposed under this subsection shall be resentenced to any sentence that was available at the time of the original sentencing.

(d) DEATH OR IMPRISONMENT FOR CRIMES AGAINST CHILDREN.—

(1) IN GENERAL.—Subject to paragraph (2) and notwithstanding any other provision of law, a person who is convicted of a Federal offense that is a serious violent felony (as defined in subsection (c)) or a violation of section 2422, 2423, or 2251 shall, unless the sentence of death is imposed, be sentenced to imprisonment for life, if—

(A) the victim of the offense has not attained the age of 14 years;

(B) the victim dies as a result of the offense; and

(C) the defendant, in the course of the offense, engages in conduct described in section 3591(a)(2).

(2) EXCEPTION.—With respect to a person convicted of a Federal offense described in paragraph (1), the court may impose any lesser sentence that is authorized by law to take into account any substantial assistance provided by the defendant in the investigation or prosecution of another person who has committed an offense, in accordance with the Federal Sentencing Guidelines and the policy statements of the Federal Sentencing Commission pursuant to section 994(p) of title 28, or for other good cause.

(e) MANDATORY LIFE IMPRISONMENT FOR REPEATED SEX OFFENSES AGAINST CHILDREN.—

(1) IN GENERAL.—A person who is convicted of a Federal sex offense in which a minor is the victim shall be sentenced to life imprisonment if the person has a prior sex conviction in which a minor was the victim, unless the sentence of death is imposed.

(2) DEFINITIONS.—For the purposes of this subsection—

(A) the term ''Federal sex offense'' means an offense under section 2241 (relating to aggravated sexual abuse), 2242 (relating to sexual abuse), 2244(a)(1) (relating to abusive sexual contact), 2245 (relating to sexual abuse resulting in death), 2251 (relating to sexual exploitation of children), 2251A (relating to selling or buying of children), 2422(b) (relating to coercion and enticement of a minor into prostitution), or 2423(a) (relating to transportation of minors);

(B) the term ''State sex offense'' means an offense under State law that is punishable by more than one year in prison and consists of conduct that would be a Federal sex offense if, to the extent or in the manner specified in the applicable provision of this title—

(i) the offense involved interstate or foreign commerce, or the use of the mails; or

(ii) the conduct occurred in any commonwealth, territory, or possession of the United States, within the special maritime and territorial jurisdiction of the United States, in a Federal prison, on any land or building owned by, leased to, or otherwise used by or

under the control of the Government of the United States, or in the Indian country (as defined in section 1151);

(C) the term "prior sex conviction" means a conviction for which the sentence was imposed before the conduct occurred constituting the subsequent Federal sex offense, and which was for a Federal sex offense or a State sex offense;

(D) the term "minor" means an individual who has not attained the age of 17 years; and

(E) the term "state" has the meaning given that term in subsection (c)(2).

(3) NONQUALIFYING FELONIES.—An offense described in section 2422(b) or 2423(a) shall not serve as a basis for sentencing under this subsection if the defendant establishes by clear and convincing evidence that—

(A) the sexual act or activity was consensual and not for the purpose of commercial or pecuniary gain;

(B) the sexual act or activity would not be punishable by more than one year in prison under the law of the State in which it occurred; or

(C) no sexual act or activity occurred.

(f)(1) If a defendant who is convicted of a felony offense (other than offense of which an element is the false registration of a domain name) knowingly falsely registered a domain name and knowingly used that domain name in the course of that offense, the maximum imprisonment otherwise provided by law for that offense shall be doubled or increased by 7 years, whichever is less.

(2) As used in this section—

(A) the term "falsely registers" means registers in a manner that prevents the effective identification of or contact with the person who registers; and

(B) the term "domain name" has the meaning given that term is[2] section 45 of the Act entitled "An Act to provide for the registration and protection of trademarks used in commerce, to carry out the provisions of certain international conventions, and for other purposes" approved July 5, 1946 (commonly referred to as the "Trademark Act of 1946") (15 U.S.C. 1127).

[2] As in law. Probably should be "in".

18 U.S.C. § 3563
Refrain from use of controlled substances as a condition of probation

§ 3563. Conditions of probation [1]

(a) MANDATORY CONDITIONS.—The court shall provide, as an explicit condition of a sentence of probation—

(1) for a felony, a misdemeanor, or an infraction, that the defendant not commit another Federal, State, or local crime during the term of probation;

(2) for a felony, that the defendant also abide by at least one condition set forth in subsection (b)(2), (b)(3), or (b)(13), unless the court finds on the record that extraordinary circumstances exist that would make such a condition plainly unreasonable, in which event the court shall impose one or more of the other conditions set forth under subsection (b);

(3) for a felony, a misdemeanor, or an infraction, that the defendant not unlawfully possess a controlled substance;

(4) for a domestic violence crime as defined in section 3561(b) by a defendant convicted of such an offense for the first time that the defendant attend a public, private, or private nonprofit offender rehabilitation program that has been approved by the court, in consultation with a State Coalition Against Domestic Violence or other appropriate experts, if an approved program is readily available within a 50-mile radius of the legal residence of the defendant; and

(5) for a felony, a misdemeanor, or an infraction, that the defendant refrain from any unlawful use of a controlled substance and submit to one drug test within 15 days of release on probation and at least 2 periodic drug tests thereafter (as determined by the court) for use of a controlled substance, but the condition stated in this paragraph may be ameliorated or suspended by the court for any individual defendant if the defendant's presentence report or other reliable sentencing information indicates a low risk of future substance abuse by the defendant;

(6) that the defendant—

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[1] Added by Public Law 98–473, Title II, § 212(a)(2), Oct. 12, 1984, 98 Stat. 1993, and amended by Public Law 99–646, §§ 11(a), 12(a), Nov. 10, 1986, 100 Stat. 3594; Public Law 100–182, §§ 10, 18, Dec. 7, 1987, 101 Stat. 1267, 1270; Public Law 100–690, Title VII, §§ 7086, 7110, 7303(a)(1), 7305(a), Nov. 18, 1988, 102 Stat. 4408, 4419, 4464, 4465; Public Law 101–647, Title XXXV, § 3584, Nov. 29, 1990, 104 Stat. 4930; Public Law 102–521, § 3, Oct. 25, 1992, 106 Stat. 3404; Public Law 103–322, Title II, § 20414(b), Title XXVIII, § 280002, Title XXXII, § 320921(b), Sept. 13, 1994, 108 Stat. 1830, 2096, 2130; Public Law 104–132, Title II, § 203, Apr. 24, 1996, 110 Stat. 1227; Public Law 104–208, Div. C, Title III, §§ 308(g)(10)(E), 374(b), Sept. 30, 1996, 110 Stat. 3009–625, 3009–647; Public Law 104–294, Title VI, § 601(k), Oct. 11, 1996, 110 Stat. 3501; Public Law 105–119, Title I, § 115(a)(8)(B)(i) to (iii), Nov. 26, 1997, 111 Stat. 2465; Public Law 106–546, § 7(a), Dec. 19, 2000, 114 Stat. 2734; Public Law 107–273, Div. B, Title IV, § 4002(c)(1), (e)(12), Nov. 2, 2002, 116 Stat. 1808, 1811.

(A) make restitution in accordance with sections 2248, 2259, 2264, 2327, 3663, 3663A, and 3664; and

(B) pay the assessment imposed in accordance with section 3013;

(7) that the defendant will notify the court of any material change in the defendant's economic circumstances that might affect the defendant's ability to pay restitution, fines, or special assessments;

(8) for a person described in section 4042(c)(4), that the person report the address where the person will reside and any subsequent change of residence to the probation officer responsible for supervision, and that the person register in any State where the person resides, is employed, carries on a vocation, or is a student (as such terms are defined under section 170101(a)(3) of the Violent Crime Control and Law Enforcement Act of 1994); and

(9) that the defendant cooperate in the collection of a DNA sample from the defendant if the collection of such a sample is authorized pursuant to section 3 of the DNA Analysis Backlog Elimination Act of 2000.

If the court has imposed and ordered execution of a fine and placed the defendant on probation, payment of the fine or adherence to the court-established installment schedule shall be a condition of the probation.

(b) DISCRETIONARY CONDITIONS.—The court may provide, as further conditions of a sentence of probation, to the extent that such conditions are reasonably related to the factors set forth in section 3553(a)(1) and (a)(2) and to the extent that such conditions involve only such deprivations of liberty or property as are reasonably necessary for the purposes indicated in section 3553(a)(2), that the defendant—

(1) support his dependents and meet other family responsibilities;

(2) make restitution to a victim of the offense under section 3556 (but not subject to the limitation of section 3663(a) or 3663A(c)(1)(A));

(3) give to the victims of the offense the notice ordered pursuant to the provisions of section 3555;

(4) work conscientiously at suitable employment or pursue conscientiously a course of study or vocational training that will equip him for suitable employment;

(5) refrain, in the case of an individual, from engaging in a specified occupation, business, or profession bearing a reasonably direct relationship to the conduct constituting the offense, or engage in such a specified occupation, business, or profession only to a stated degree or under stated circumstances;

(6) refrain from frequenting specified kinds of places or from associating unnecessarily with specified persons;

(7) refrain from excessive use of alcohol, or any use of a narcotic drug or other controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802), without a prescription by a licensed medical practitioner;

(8) refrain from possessing a firearm, destructive device, or other dangerous weapon;

(9) undergo available medical, psychiatric, or psychological treatment, including treatment for drug or alcohol dependency, as specified by the court, and remain in a specified institution if required for that purpose;

(10) remain in the custody of the Bureau of Prisons during nights, weekends, or other intervals of time, totaling no more than the lesser of one year or the term of imprisonment authorized for the offense, during the first year of the term of probation;

(11) reside at, or participate in the program of, a community corrections facility (including a facility maintained or under contract to the Bureau of Prisons) for all or part of the term of probation;

(12) work in community service as directed by the court;

(13) reside in a specified place or area, or refrain from residing in a specified place or area;

(14) remain within the jurisdiction of the court, unless granted permission to leave by the court or a probation officer;

(15) report to a probation officer as directed by the court or the probation officer;

(16) permit a probation officer to visit him at his home or elsewhere as specified by the court;

(17) answer inquiries by a probation officer and notify the probation officer promptly of any change in address or employment;

(18) notify the probation officer promptly if arrested or questioned by a law enforcement officer;

(19) remain at his place of residence during nonworking hours and, if the court finds it appropriate, that compliance with this condition be monitored by telephonic or electronic signaling devices, except that a condition under this paragraph may be imposed only as an alternative to incarceration;

(20) comply with the terms of any court order or order of an administrative process pursuant to the law of a State, the District of Columbia, or any other possession or territory of the United States, requiring payments by the defendant for the support and maintenance of a child or of a child and the parent with whom the child is living;

(21) be ordered deported by a United States district court, or United States magistrate judge, pursuant to a stipulation entered into by the defendant and the United States under section 238(d)(5) of the Immigration and Nationality Act, except that, in the absence of a stipulation, the United States district court or a United States magistrate judge, may order deportation as a condition of probation, if, after notice and hearing pursuant to such section, the Attorney General demonstrates by clear and convincing evidence that the alien is deportable; or

(22) satisfy such other conditions as the court may impose.

(c) MODIFICATIONS OF CONDITIONS.—The court may modify, reduce, or enlarge the conditions of a sentence of probation at any time prior to the expiration or termination of the term of probation,

pursuant to the provisions of the Federal Rules of Criminal Procedure relating to the modification of probation and the provisions applicable to the initial setting of the conditions of probation.

(d) WRITTEN STATEMENT OF CONDITIONS.—The court shall direct that the probation officer provide the defendant with a written statement that sets forth all the conditions to which the sentence is subject, and that is sufficiently clear and specific to serve as a guide for the defendant's conduct and for such supervision as is required.

(e) RESULTS OF DRUG TESTING.—The results of a drug test administered in accordance with subsection (a)(5) shall be subject to confirmation only if the results are positive, the defendant is subject to possible imprisonment for such failure, and either the defendant denies the accuracy of such test or there is some other reason to question the results of the test. A defendant who tests positive may be detained pending verification of a positive drug test result. A drug test confirmation shall be a urine drug test confirmed using gas chromatography/mass spectrometry techniques or such test as the Director of the Administrative Office of the United States Courts after consultation with the Secretary of Health and Human Services may determine to be of equivalent accuracy. The court shall consider whether the availability of appropriate substance abuse treatment programs, or an individual's current or past participation in such programs, warrants an exception in accordance with United States Sentencing Commission guidelines from the rule of section 3565(b), when considering any action against a defendant who fails a drug test administered in accordance with subsection (a)(5).

18 U.S.C. § 3565
Revocation of probation for failing controlled substance testing

§ 3565. Revocation of probation [1]

(a) CONTINUATION OR REVOCATION.—If the defendant violates a condition of probation at any time prior to the expiration or termination of the term of probation, the court may, after a hearing pursuant to Rule 32.1 of the Federal Rules of Criminal Procedure, and after considering the factors set forth in section 3553(a) to the extent that they are applicable—

(1) continue him on probation, with or without extending the term or modifying or enlarging the conditions; or

(2) revoke the sentence of probation and resentence the defendant under subchapter A.

(b) MANDATORY REVOCATION FOR POSSESSION OF CONTROLLED SUBSTANCE OR FIREARM OR REFUSAL TO COMPLY WITH DRUG TESTING.—If the defendant—

(1) possesses a controlled substance in violation of the condition set forth in section 3563(a)(3);

(2) possesses a firearm, as such term is defined in section 921 of this title, in violation of Federal law, or otherwise violates a condition of probation prohibiting the defendant from possessing a firearm;

(3) refuses to comply with drug testing, thereby violating the condition imposed by section 3563(a)(4); or

(4) as a part of drug testing, tests positive for illegal controlled substances more than 3 times over the course of 1 year;

the court shall revoke the sentence of probation and resentence the defendant under subchapter A to a sentence that includes a term of imprisonment.

(c) DELAYED REVOCATION.—The power of the court to revoke a sentence of probation for violation of a condition of probation, and to impose another sentence, extends beyond the expiration of the term of probation for any period reasonably necessary for the adjudication of matters arising before its expiration if, prior to its expiration, a warrant or summons has been issued on the basis of an allegation of such a violation.

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[1] Added by Public Law 98–473, Title II, § 212(a)(2), Oct. 12, 1984, 98 Stat. 1995, and amended by Public Law 100–690, Title VI, § 6214, Title VII, § 7303(a)(2), Nov. 18, 1988, 102 Stat. 4361, 4464; Public Law 101–647, Title XXXV, § 3585, Nov. 29, 1990, 104 Stat. 4930; Public Law 103–322, Title XI, § 110506, Sept. 13, 1994, 108 Stat. 2017; Public Law 107–273, Div. B, Title II, § 2103(a), Nov. 2, 2002, 116 Stat. 1793.

18 U.S.C. § 3582(d)
Limitation on associates of certain convicted controlled substance offenders

§ 3582. Imposition of a sentence of imprisonment[1]

* * * * * * *

(d) INCLUSION OF AN ORDER TO LIMIT CRIMINAL ASSOCIATION OF ORGANIZED CRIME AND DRUG OFFENDERS.—The court, in imposing a sentence to a term of imprisonment upon a defendant convicted of a felony set forth in chapter 95 (racketeering) or 96 (racketeer influenced and corrupt organizations) of this title or in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.), or at any time thereafter upon motion by the Director of the Bureau of Prisons or a United States attorney, may include as a part of the sentence an order that requires that the defendant not associate or communicate with a specified person, other than his attorney, upon a showing of probable cause to believe that association or communication with such person is for the purpose of enabling the defendant to control, manage, direct, finance, or otherwise participate in an illegal enterprise.

[1] Added by Public Law 98–473, Title II, § 212(a)(2), Oct. 12, 1984, 98 Stat. 1999.

18 U.S.C. § 3583

Refrain from use of controlled substance as a condition of supervised release/revocation of failing testing

§ 3583. Inclusion of a term of supervised release after imprisonment[1]

(a) IN GENERAL.—The court, in imposing a sentence to a term of imprisonment for a felony or a misdemeanor, may include as a part of the sentence a requirement that the defendant be placed on a term of supervised release after imprisonment, except that the court shall include as a part of the sentence a requirement that the defendant be placed on a term of supervised release if such a term is required by statute or if the defendant has been convicted for the first time of a domestic violence crime as defined in section 3561(b).

(b) AUTHORIZED TERMS OF SUPERVISED RELEASE.—Except as otherwise provided, the authorized terms of supervised release are—

(1) for a Class A or Class B felony, not more than five years;

(2) for a Class C or Class D felony, not more than three years; and

(3) for a Class E felony, or for a misdemeanor (other than a petty offense), not more than one year.

(c) FACTORS TO BE CONSIDERED IN INCLUDING A TERM OF SUPERVISED RELEASE.—The court, in determining whether to include a term of supervised release, and, if a term of supervised release is to be included, in determining the length of the term and the conditions of supervised release, shall consider the factors set forth in section 3553(a)(1), (a)(2)(B), (a)(2)(C), (a)(2)(D), (a)(4), (a)(5), (a)(6), and (a)(7).

(d) CONDITIONS OF SUPERVISED RELEASE.—The court shall order, as an explicit condition of supervised release, that the defendant not commit another Federal, State, or local crime during the term of supervision and that the defendant not unlawfully possess a controlled substance. The court shall order as an explicit condition of supervised release for a defendant convicted for the first time of a domestic violence crime as defined in section 3561(b) that the defendant attend a public, private, or private nonprofit offender rehabilitation program that has been approved by the court, in consultation with a State Coalition Against Domestic Violence or other appropriate experts, if an approved program is readily available

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[1] Added by Public Law 98–473, Title II, § 212(a)(2), Oct. 12, 1984, 98 Stat. 1999, and amended by Public Law 99–570, Title I, § 1006(a)(1) to (3), Oct. 27, 1986, 100 Stat. 3207–6, 3207–7; Public Law 99–646, § 14(a), Nov. 10, 1986, 100 Stat. 3594; Public Law 100–182, §§ 8, 9, 12, 25, Dec. 7, 1987, 101 Stat. 1267, 1268, 1272; Public Law 100–690, Title VII, §§ 7108, 7303(b), 7305(b), Nov. 18, 1988, 102 Stat. 4418, 4419, 4464 to 4466; Public Law 101–647, Title XXXV, § 3589, Nov. 29, 1990, 104 Stat. 4930; Public Law 103–322, Title II, § 20414(c), Title XI, § 110505, Title XXXII, § 320921(c), Sept. 13, 1994, 108 Stat. 1831, 2016, 2130; Public Law 105–119, Title I, § 115(a)(8)(B)(iv), Nov. 26, 1997, 111 Stat. 2465; Public Law 106–546, § 7(b), Dec. 19, 2000, 114 Stat. 2734; Public Law 107–56, Title VIII, § 812, Oct. 26, 2001, 115 Stat. 382; Public Law 107–273, Div. B, Title II, § 2103(b), Title III, § 3007, Nov. 2, 2002, 116 Stat. 1793, 1806; Public Law 108–21, Title I, § 101, Apr. 30, 2003, 117 Stat. 651.

within a 50-mile radius of the legal residence of the defendant. The court shall order, as an explicit condition of supervised release for a person described in section 4042(c)(4), that the person report the address where the person will reside and any subsequent change of residence to the probation officer responsible for supervision, and that the person register in any State where the person resides, is employed, carries on a vocation, or is a student (as such terms are defined under section 170101(a)(3) of the Violent Crime Control and Law Enforcement Act of 1994). The court shall order, as an explicit condition of supervised release, that the defendant cooperate in the collection of a DNA sample from the defendant, if the collection of such a sample is authorized pursuant to section 3 of the DNA Analysis Backlog Elimination Act of 2000. The court shall also order, as an explicit condition of supervised release, that the defendant refrain from any unlawful use of a controlled substance and submit to a drug test within 15 days of release on supervised release and at least 2 periodic drug tests thereafter (as determined by the court) for use of a controlled substance. The condition stated in the preceding sentence may be ameliorated or suspended by the court as provided in section 3563(a)(4). The results of a drug test administered in accordance with the preceding subsection shall be subject to confirmation only if the results are positive, the defendant is subject to possible imprisonment for such failure, and either the defendant denies the accuracy of such test or there is some other reason to question the results of the test. A drug test confirmation shall be a urine drug test confirmed using gas chromatography/mass spectrometry techniques or such test as the Director of the Administrative Office of the United States Courts after consultation with the Secretary of Health and Human Services may determine to be of equivalent accuracy. The court shall consider whether the availability of appropriate substance abuse treatment programs, or an individual's current or past participation in such programs, warrants an exception in accordance with United States Sentencing Commission guidelines from the rule of section 3583(g) when considering any action against a defendant who fails a drug test. The court may order, as a further condition of supervised release, to the extent that such condition—

(1) is reasonably related to the factors set forth in section 3553(a)(1), (a)(2)(B), (a)(2)(C), and (a)(2)(D);

(2) involves no greater deprivation of liberty than is reasonably necessary for the purposes set forth in section 3553(a)(2)(B), (a)(2)(C), and (a)(2)(D); and

(3) is consistent with any pertinent policy statements issued by the Sentencing Commission pursuant to 28 U.S.C. 994(a);

any condition set forth as a discretionary condition of probation in section 3563(b)(1) through (b)(10) and (b)(12) through (b)(20), and any other condition it considers to be appropriate. If an alien defendant is subject to deportation, the court may provide, as a condition of supervised release, that he be deported and remain outside the United States, and may order that he be delivered to a duly authorized immigration official for such deportation.

(e) MODIFICATION OF CONDITIONS OR REVOCATION.—The court may, after considering the factors set forth in section 3553(a)(1), (a)(2)(B), (a)(2)(C), (a)(2)(D), (a)(4), (a)(5), (a)(6), and (a)(7)—

(1) terminate a term of supervised release and discharge the defendant released at any time after the expiration of one year of supervised release, pursuant to the provisions of the Federal Rules of Criminal Procedure relating to the modification of probation, if it is satisfied that such action is warranted by the conduct of the defendant released and the interest of justice;

(2) extend a term of supervised release if less than the maximum authorized term was previously imposed, and may modify, reduce, or enlarge the conditions of supervised release, at any time prior to the expiration or termination of the term of supervised release, pursuant to the provisions of the Federal Rules of Criminal Procedure relating to the modification of probation and the provisions applicable to the initial setting of the terms and conditions of post-release supervision;

(3) revoke a term of supervised release, and require the defendant to serve in prison all or part of the term of supervised release authorized by statute for the offense that resulted in such term of supervised release without credit for time previously served on postrelease supervision, if the court, pursuant to the Federal Rules of Criminal Procedure applicable to revocation of probation or supervised release, finds by a preponderance of the evidence that the defendant violated a condition of supervised release, except that a defendant whose term is revoked under this paragraph may not be required to serve on any such revocation more than 5 years in prison if the offense that resulted in the term of supervised release is a class A felony, more than 3 years in prison if such offense is a class B felony, more than 2 years in prison if such offense is a class C or D felony, or more than one year in any other case; or

(4) order the defendant to remain at his place of residence during nonworking hours and, if the court so directs, to have compliance monitored by telephone or electronic signaling devices, except that an order under this paragraph may be imposed only as an alternative to incarceration.

(f) WRITTEN STATEMENT OF CONDITIONS.—The court shall direct that the probation officer provide the defendant with a written statement that sets forth all the conditions to which the term of supervised release is subject, and that is sufficiently clear and specific to serve as a guide for the defendant's conduct and for such supervision as is required.

(g) MANDATORY REVOCATION FOR POSSESSION OF CONTROLLED SUBSTANCE OR FIREARM OR FOR REFUSAL TO COMPLY WITH DRUG TESTING.—If the defendant—

(1) possesses a controlled substance in violation of the condition set forth in subsection (d);

(2) possesses a firearm, as such term is defined in section 921 of this title, in violation of Federal law, or otherwise violates a condition of supervised release prohibiting the defendant from possessing a firearm;

(3) refuses to comply with drug testing imposed as a condition of supervised release; or

(4) as a part of drug testing, tests positive for illegal controlled substances more than 3 times over the course of 1 year;

the court shall revoke the term of supervised release and require the defendant to serve a term of imprisonment not to exceed the maximum term of imprisonment authorized under subsection (e)(3).

(h) SUPERVISED RELEASE FOLLOWING REVOCATION.—When a term of supervised release is revoked and the defendant is required to serve a term of imprisonment, the court may include a requirement that the defendant be placed on a term of supervised release after imprisonment. The length of such a term of supervised release shall not exceed the term of supervised release authorized by statute for the offense that resulted in the original term of supervised release, less any term of imprisonment that was imposed upon revocation of supervised release.

(i) DELAYED REVOCATION.—The power of the court to revoke a term of supervised release for violation of a condition of supervised release, and to order the defendant to serve a term of imprisonment and, subject to the limitations in subsection (h), a further term of supervised release, extends beyond the expiration of the term of supervised release for any period reasonably necessary for the adjudication of matters arising before its expiration if, before its expiration, a warrant or summons has been issued on the basis of an allegation of such a violation.

(j) SUPERVISED RELEASE TERMS FOR TERRORISM PREDICATES.—Notwithstanding subsection (b), the authorized term of supervised release for any offense listed in section 2332b(g)(5)(B), the commission of which resulted in, or created a foreseeable risk of, death or serious bodily injury to another person, is any term of years or life.

(k) Notwithstanding subsection (b), the authorized term of supervised release for any offense under section 1201 involving a minor victim, and for any offense under section 1591, 2241, 2242, 2244(a)(1), 2244(a)(2), 2251, 2251A, 2252, 2252A, 2260, 2421, 2422, 2423, or 2425, is any term of years or life.

Chapter 228. Death Sentence

§ 3591. Sentence of death [1]

(a) A defendant who has been found guilty of—

(1) an offense described in section 794 or section 2381; or

(2) any other offense for which a sentence of death is provided, if the defendant, as determined beyond a reasonable doubt at the hearing under section 3593—

(A) intentionally killed the victim;

(B) intentionally inflicted serious bodily injury that resulted in the death of the victim;

(C) intentionally participated in an act, contemplating that the life of a person would be taken or intending that lethal force would be used in connection with a person, other than one of the participants in the offense, and the victim died as a direct result of the act; or

(D) intentionally and specifically engaged in an act of violence, knowing that the act created a grave risk of death to a person, other than one of the participants in the offense, such that participation in the act constituted a reckless disregard for human life and the victim died as a direct result of the act,

shall be sentenced to death if, after consideration of the factors set forth in section 3592 in the course of a hearing held pursuant to section 3593, it is determined that imposition of a sentence of death is justified, except that no person may be sentenced to death who was less than 18 years of age at the time of the offense.

(b) A defendant who has been found guilty of—

(1) an offense referred to in section 408(c)(1) of the Controlled Substances Act (21 U.S.C. 848(c)(1)), committed as part of a continuing criminal enterprise offense under the conditions described in subsection (b) of that section which involved not less than twice the quantity of controlled substance described in subsection (b)(2)(A) or twice the gross receipts described in subsection (b)(2)(B); or

(2) an offense referred to in section 408(c)(1) of the Controlled Substances Act (21 U.S.C. 848(c)(1)), committed as part of a continuing criminal enterprise offense under that section, where the defendant is a principal administrator, organizer, or leader of such an enterprise, and the defendant, in order to obstruct the investigation or prosecution of the enterprise or an

[1] Added by Public Law 103–322, Title VI, § 60002(a), Sept. 13, 1994, 108 Stat. 1959.

offense involved in the enterprise, attempts to kill or knowingly directs, advises, authorizes, or assists another to attempt to kill any public officer, juror, witness, or members of the family or household of such a person,

shall be sentenced to death if, after consideration of the factors set forth in section 3592 in the course of a hearing held pursuant to section 3593, it is determined that imposition of a sentence of death is justified, except that no person may be sentenced to death who was less than 18 years of age at the time of the offense.

§ 3592. Mitigating and aggravating factors to be considered in determining whether a sentence of death is justified[1]

(a) MITIGATING FACTORS.—In determining whether a sentence of death is to be imposed on a defendant, the finder of fact shall consider any mitigating factor, including the following:

(1) IMPAIRED CAPACITY.—The defendant's capacity to appreciate the wrongfulness of the defendant's conduct or to conform conduct to the requirements of law was significantly impaired, regardless of whether the capacity was so impaired as to constitute a defense to the charge.

(2) DURESS.—The defendant was under unusual and substantial duress, regardless of whether the duress was of such a degree as to constitute a defense to the charge.

(3) MINOR PARTICIPATION.—The defendant is punishable as a principal in the offense, which was committed by another, but the defendant's participation was relatively minor, regardless of whether the participation was so minor as to constitute a defense to the charge.

(4) EQUALLY CULPABLE DEFENDANTS.—Another defendant or defendants, equally culpable in the crime, will not be punished by death.

(5) NO PRIOR CRIMINAL RECORD.—The defendant did not have a significant prior history of other criminal conduct.

(6) DISTURBANCE.—The defendant committed the offense under severe mental or emotional disturbance.

(7) VICTIM'S CONSENT.—The victim consented to the criminal conduct that resulted in the victim's death.

(8) OTHER FACTORS.—Other factors in the defendant's background, record, or character or any other circumstance of the offense that mitigate against imposition of the death sentence.

(b) AGGRAVATING FACTORS FOR ESPIONAGE AND TREASON.—In determining whether a sentence of death is justified for an offense described in section 3591(a)(1), the jury, or if there is no jury, the court, shall consider each of the following aggravating factors for which notice has been given and determine which, if any, exist:

(1) PRIOR ESPIONAGE OR TREASON OFFENSE.—The defendant has previously been convicted of another offense involving espionage or treason for which a sentence of either life imprisonment or death was authorized by law.

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[1] Added by Public Law 103–322, Title VI, § 60002(a), Sept. 13, 1994, 108 Stat. 1960, and amended by Public Law 103–322, Title XXXIII, § 330021(1), Sept. 13, 1994, 108 Stat. 1960, 2150; Public Law 104–132, Title VII, § 728, Apr. 24, 1996, 110 Stat. 1302; Public Law 104–294, Title VI, §§ 601(b)(7), 604(b)(35), Oct. 11, 1996, 110 Stat. 3499, 3508; Public Law 107–273, Div. B, Title IV, § 4002(e)(2), Nov. 2, 2002, 116 Stat. 1810.

(2) GRAVE RISK TO NATIONAL SECURITY.—In the commission of the offense the defendant knowingly created a grave risk of substantial danger to the national security.

(3) GRAVE RISK OF DEATH.—In the commission of the offense the defendant knowingly created a grave risk of death to another person.

The jury, or if there is no jury, the court, may consider whether any other aggravating factor for which notice has been given exists.

(c) AGGRAVATING FACTORS FOR HOMICIDE.—In determining whether a sentence of death is justified for an offense described in section 3591(a)(2), the jury, or if there is no jury, the court, shall consider each of the following aggravating factors for which notice has been given and determine which, if any, exist:

(1) DEATH DURING COMMISSION OF ANOTHER CRIME.—The death, or injury resulting in death, occurred during the commission or attempted commission of, or during the immediate flight from the commission of, an offense under section 32 (destruction of aircraft or aircraft facilities), section 33 (destruction of motor vehicles or motor vehicle facilities), section 37 (violence at international airports), section 351 (violence against Members of Congress, Cabinet officers, or Supreme Court Justices), an offense under section 751 (prisoners in custody of institution or officer), section 794 (gathering or delivering defense information to aid foreign government), section 844(d) (transportation of explosives in interstate commerce for certain purposes), section 844(f) (destruction of Government property by explosives), section 1118 (prisoners serving life term), section 1201 (kidnapping), section 844(i) (destruction of property affecting interstate commerce by explosives), section 1116 (killing or attempted killing of diplomats), section 1203 (hostage taking), section 1992 (wrecking trains), section 2280 (maritime violence), section 2281 (maritime platform violence), section 2332 (terrorist acts abroad against United States nationals), section 2332a (use of weapons of mass destruction), or section 2381 (treason) of this title, or section 46502 of title 49, United States Code (aircraft piracy).

(2) PREVIOUS CONVICTION OF VIOLENT FELONY INVOLVING FIREARM.—For any offense, other than an offense for which a sentence of death is sought on the basis of section 924(c), the defendant has previously been convicted of a Federal or State offense punishable by a term of imprisonment of more than 1 year, involving the use or attempted or threatened use of a firearm (as defined in section 921) against another person.

(3) PREVIOUS CONVICTION OF OFFENSE FOR WHICH A SENTENCE OF DEATH OR LIFE IMPRISONMENT WAS AUTHORIZED.—The defendant has previously been convicted of another Federal or State offense resulting in the death of a person, for which a sentence of life imprisonment or a sentence of death was authorized by statute.

(4) PREVIOUS CONVICTION OF OTHER SERIOUS OFFENSES.—The defendant has previously been convicted of 2 or more Federal or State offenses, punishable by a term of imprisonment of more than 1 year, committed on different occasions, involving

the infliction of, or attempted infliction of, serious bodily injury or death upon another person.

(5) GRAVE RISK OF DEATH TO ADDITIONAL PERSONS.—The defendant, in the commission of the offense, or in escaping apprehension for the violation of the offense, knowingly created a grave risk of death to 1 or more persons in addition to the victim of the offense.

(6) HEINOUS, CRUEL, OR DEPRAVED MANNER OF COMMITTING OFFENSE.—The defendant committed the offense in an especially heinous, cruel, or depraved manner in that it involved torture or serious physical abuse to the victim.

(7) PROCUREMENT OF OFFENSE BY PAYMENT.—The defendant procured the commission of the offense by payment, or promise of payment, of anything of pecuniary value.

(8) PECUNIARY GAIN.—The defendant committed the offense as consideration for the receipt, or in the expectation of the receipt, of anything of pecuniary value.

(9) SUBSTANTIAL PLANNING AND PREMEDITATION.—The defendant committed the offense after substantial planning and premeditation to cause the death of a person or commit an act of terrorism.

(10) CONVICTION FOR TWO FELONY DRUG OFFENSES.—The defendant has previously been convicted of 2 or more State or Federal offenses punishable by a term of imprisonment of more than one year, committed on different occasions, involving the distribution of a controlled substance.

(11) VULNERABILITY OF VICTIM.—The victim was particularly vulnerable due to old age, youth, or infirmity.

(12) CONVICTION FOR SERIOUS FEDERAL DRUG OFFENSES.—The defendant had previously been convicted of violating title II or III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 for which a sentence of 5 or more years may be imposed or had previously been convicted of engaging in a continuing criminal enterprise.

(13) CONTINUING CRIMINAL ENTERPRISE INVOLVING DRUG SALES TO MINORS.—The defendant committed the offense in the course of engaging in a continuing criminal enterprise in violation of section 408(c) of the Controlled Substances Act (21 U.S.C. 848(c)), and that violation involved the distribution of drugs to persons under the age of 21 in violation of section 418 of that Act (21 U.S.C. 859).

(14) HIGH PUBLIC OFFICIALS.—The defendant committed the offense against—

(A) the President of the United States, the President-elect, the Vice President, the Vice President-elect, the Vice President-designate, or, if there is no Vice President, the officer next in order of succession to the office of the President of the United States, or any person who is acting as President under the Constitution and laws of the United States;

(B) a chief of state, head of government, or the political equivalent, of a foreign nation;

(C) a foreign official listed in section 1116(b)(3)(A), if the official is in the United States on official business; or

(D) a Federal public servant who is a judge, a law enforcement officer, or an employee of a United States penal or correctional institution—

(i) while he or she is engaged in the performance of his or her official duties;

(ii) because of the performance of his or her official duties; or

(iii) because of his or her status as a public servant.

For purposes of this subparagraph, a "law enforcement officer" is a public servant authorized by law or by a Government agency or Congress to conduct or engage in the prevention, investigation, or prosecution or adjudication of an offense, and includes those engaged in corrections, parole, or probation functions.

(15) PRIOR CONVICTION OF SEXUAL ASSAULT OR CHILD MOLESTATION.—In the case of an offense under chapter 109A (sexual abuse) or chapter 110 (sexual abuse of children), the defendant has previously been convicted of a crime of sexual assault or crime of child molestation.

(16) MULTIPLE KILLINGS OR ATTEMPTED KILLINGS.—The defendant intentionally killed or attempted to kill more than one person in a single criminal episode.

The jury, or if there is no jury, the court, may consider whether any other aggravating factor for which notice has been given exists.

(d) AGGRAVATING FACTORS FOR DRUG OFFENSE DEATH PENALTY.—In determining whether a sentence of death is justified for an offense described in section 3591(b), the jury, or if there is no jury, the court, shall consider each of the following aggravating factors for which notice has been given and determine which, if any, exist:

(1) PREVIOUS CONVICTION OF OFFENSE FOR WHICH A SENTENCE OF DEATH OR LIFE IMPRISONMENT WAS AUTHORIZED.—The defendant has previously been convicted of another Federal or State offense resulting in the death of a person, for which a sentence of life imprisonment or death was authorized by statute.

(2) PREVIOUS CONVICTION OF OTHER SERIOUS OFFENSES.—The defendant has previously been convicted of two or more Federal or State offenses, each punishable by a term of imprisonment of more than one year, committed on different occasions, involving the importation, manufacture, or distribution of a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) or the infliction of, or attempted infliction of, serious bodily injury or death upon another person.

(3) PREVIOUS SERIOUS DRUG FELONY CONVICTION.—The defendant has previously been convicted of another Federal or State offense involving the manufacture, distribution, importation, or possession of a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) for which a sentence of five or more years of imprisonment was authorized by statute.

(4) USE OF FIREARM.—In committing the offense, or in furtherance of a continuing criminal enterprise of which the offense was a part, the defendant used a firearm or knowingly directed, advised, authorized, or assisted another to use a firearm to threaten, intimidate, assault, or injure a person.

(5) DISTRIBUTION TO PERSONS UNDER 21.—The offense, or a continuing criminal enterprise of which the offense was a part, involved conduct proscribed by section 418 of the Controlled Substances Act (21 U.S.C. 859) which was committed directly by the defendant.

(6) DISTRIBUTION NEAR SCHOOLS.—The offense, or a continuing criminal enterprise of which the offense was a part, involved conduct proscribed by section 419 of the Controlled Substances Act (21 U.S.C. 860) which was committed directly by the defendant.

(7) USING MINORS IN TRAFFICKING.—The offense, or a continuing criminal enterprise of which the offense was a part, involved conduct proscribed by section 420 of the Controlled Substances Act (21 U.S.C. 861) which was committed directly by the defendant.

(8) LETHAL ADULTERANT.—The offense involved the importation, manufacture, or distribution of a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)), mixed with a potentially lethal adulterant, and the defendant was aware of the presence of the adulterant.

The jury, or if there is no jury, the court, may consider whether any other aggravating factor for which notice has been given exists.

18 U.S.C. § 3607
Special expungement procedures for simple possession drug offenders

Chapter 229. Postsentence Administration

§ 3607. Special probation and expungement procedures for drug possessors [1]

(a) PRE-JUDGMENT PROBATION.—If a person found guilty of an offense described in section 404 of the Controlled Substances Act (21 U.S.C. 844)—

(1) has not, prior to the commission of such offense, been convicted of violating a Federal or State law relating to controlled substances; and

(2) has not previously been the subject of a disposition under this subsection;

the court may, with the consent of such person, place him on probation for a term of not more than one year without entering a judgment of conviction. At any time before the expiration of the term of probation, if the person has not violated a condition of his probation, the court may, without entering a judgment of conviction, dismiss the proceedings against the person and discharge him from probation. At the expiration of the term of probation, if the person has not violated a condition of his probation, the court shall, without entering a judgment of conviction, dismiss the proceedings against the person and discharge him from probation. If the person violates a condition of his probation, the court shall proceed in accordance with the provisions of section 3565.

(b) RECORD OF DISPOSITION.—A nonpublic record of a disposition under subsection (a), or a conviction that is the subject of an expungement order under subsection (c), shall be retained by the Department of Justice solely for the purpose of use by the courts in determining in any subsequent proceeding whether a person qualifies for the disposition provided in subsection (a) or the expungement provided in subsection (c). A disposition under subsection (a), or a conviction that is the subject of an expungement order under subsection (c), shall not be considered a conviction for the purpose of a disqualification or a disability imposed by law upon conviction of a crime, or for any other purpose.

(c) EXPUNGEMENT OF RECORD OF DISPOSITION.—If the case against a person found guilty of an offense under section 404 of the Controlled Substances Act (21 U.S.C. 844) is the subject of a disposition under subsection (a), and the person was less than twenty-one years old at the time of the offense, the court shall enter an expungement order upon the application of such person. The

[1] Added by Public Law 98–473, Title II, § 212(a)(2), Oct. 12, 1984, 98 Stat. 2003.

expungement order shall direct that there be expunged from all official records, except the nonpublic records referred to in subsection (b), all references to his arrest for the offense, the institution of criminal proceedings against him, and the results thereof. The effect of the order shall be to restore such person, in the contemplation of the law, to the status he occupied before such arrest or institution of criminal proceedings. A person concerning whom such an order has been entered shall not be held thereafter under any provision of law to be guilty of perjury, false swearing, or making a false statement by reason of his failure to recite or acknowledge such arrests or institution of criminal proceedings, or the results thereof, in response to an inquiry made of him for any purpose.

18 U.S.C. § 3608
Drug testing for Federal offenders on post-conviction release

§ 3608. Drug testing of Federal offenders on post-conviction release [1]

The Director of the Administrative Office of the United States Courts, in consultation with the Attorney General and the Secretary of Health and Human Services, shall, subject to the availability of appropriations, establish a program of drug testing of Federal offenders on post-conviction release. The program shall include such standards and guidelines as the Director may determine necessary to ensure the reliability and accuracy of the drug testing programs. In each judicial district the chief probation officer shall arrange for the drug testing of defendants on post-conviction release pursuant to a conviction for a felony or other offense described in section 3563(a)(4).

[1] Added by Public Law 103–322, Title II, § 20414(a)(1), Sept. 13, 1994, 108 Stat. 1830.

§ 3621. Imprisonment of a convicted person [1]

(a) COMMITMENT TO CUSTODY OF BUREAU OF PRISONS.—A person who has been sentenced to a term of imprisonment pursuant to the provisions of subchapter D of chapter 227 shall be committed to the custody of the Bureau of Prisons until the expiration of the term imposed, or until earlier released for satisfactory behavior pursuant to the provisions of section 3624.

(b) PLACE OF IMPRISONMENT.—The Bureau of Prisons shall designate the place of the prisoner's imprisonment. The Bureau may designate any available penal or correctional facility that meets minimum standards of health and habitability established by the Bureau, whether maintained by the Federal Government or otherwise and whether within or without the judicial district in which the person was convicted, that the Bureau determines to be appropriate and suitable, considering—

(1) the resources of the facility contemplated;
(2) the nature and circumstances of the offense;
(3) the history and characteristics of the prisoner;
(4) any statement by the court that imposed the sentence—
(A) concerning the purposes for which the sentence to imprisonment was determined to be warranted; or
(B) recommending a type of penal or correctional facility as appropriate; and
(5) any pertinent policy statement issued by the Sentencing Commission pursuant to section 994(a)(2) of title 28.

In designating the place of imprisonment or making transfers under this subsection, there shall be no favoritism given to prisoners of high social or economic status. The Bureau may at any time, having regard for the same matters, direct the transfer of a prisoner from one penal or correctional facility to another. The Bureau shall make available appropriate substance abuse treatment for each prisoner the Bureau determines has a treatable condition of substance addiction or abuse.

(c) DELIVERY OF ORDER OF COMMITMENT.—When a prisoner, pursuant to a court order, is placed in the custody of a person in charge of a penal or correctional facility, a copy of the order shall be delivered to such person as evidence of this authority to hold the prisoner, and the original order, with the return endorsed thereon, shall be returned to the court that issued it.

(d) DELIVERY OF PRISONER FOR COURT APPEARANCES.—The United States marshal shall, without charge, bring a prisoner into

[1] Added by Public Law 98–473, Title II, § 212(a)(2), Oct. 12, 1984, 98 Stat. 2007, and amended by Public Law 101–647, Title XXIX, § 2903, Nov. 29, 1990, 104 Stat. 4913; Public Law 103–322, Title II, § 20401, Title III, § 32001, Sept. 13, 1994, 108 Stat. 1824, 1896.

court or return him to a prison facility on order of a court of the United States or on written request of an attorney for the Government.

(e) SUBSTANCE ABUSE TREATMENT.—

(1) PHASE-IN.—In order to carry out the requirement of the last sentence of subsection (b) of this section, that every prisoner with a substance abuse problem have the opportunity to participate in appropriate substance abuse treatment, the Bureau of Prisons shall, subject to the availability of appropriations, provide residential substance abuse treatment (and make arrangements for appropriate aftercare)—

(A) for not less than 50 percent of eligible prisoners by the end of fiscal year 1995, with priority for such treatment accorded based on an eligible prisoner's proximity to release date;

(B) for not less than 75 percent of eligible prisoners by the end of fiscal year 1996, with priority for such treatment accorded based on an eligible prisoner's proximity to release date; and

(C) for all eligible prisoners by the end of fiscal year 1997 and thereafter, with priority for such treatment accorded based on an eligible prisoner's proximity to release date.

(2) INCENTIVE FOR PRISONERS' SUCCESSFUL COMPLETION OF TREATMENT PROGRAM.—

(A) GENERALLY.—Any prisoner who, in the judgment of the Director of the Bureau of Prisons, has successfully completed a program of residential substance abuse treatment provided under paragraph (1) of this subsection, shall remain in the custody of the Bureau under such conditions as the Bureau deems appropriate. If the conditions of confinement are different from those the prisoner would have experienced absent the successful completion of the treatment, the Bureau shall periodically test the prisoner for substance abuse and discontinue such conditions on determining that substance abuse has recurred.

(B) PERIOD OF CUSTODY.—The period a prisoner convicted of a nonviolent offense remains in custody after successfully completing a treatment program may be reduced by the Bureau of Prisons, but such reduction may not be more than one year from the term the prisoner must otherwise serve.

(3) REPORT.—The Bureau of Prisons shall transmit to the Committees on the Judiciary of the Senate and the House of Representatives on January 1, 1995, and on January 1 of each year thereafter, a report. Such report shall contain—

(A) a detailed quantitative and qualitative description of each substance abuse treatment program, residential or not, operated by the Bureau;

(B) a full explanation of how eligibility for such programs is determined, with complete information on what proportion of prisoners with substance abuse problems are eligible; and

(C) a complete statement of to what extent the Bureau has achieved compliance with the requirements of this title.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection—

(A) $13,500,000 for fiscal year 1996;
(B) $18,900,000 for fiscal year 1997;
(C) $25,200,000 for fiscal year 1998;
(D) $27,000,000 for fiscal year 1999; and
(E) $27,900,000 for fiscal year 2000.

(5) DEFINITIONS.—As used in this subsection—

(A) the term ''residential substance abuse treatment'' means a course of individual and group activities, lasting between 6 and 12 months, in residential treatment facilities set apart from the general prison population—

(i) directed at the substance abuse problems of the prisoner; and

(ii) intended to develop the prisoner's cognitive, behavioral, social, vocational, and other skills so as to solve the prisoner's substance abuse and related problems;

(B) the term ''eligible prisoner'' means a prisoner who is—

(i) determined by the Bureau of Prisons to have a substance abuse problem; and

(ii) willing to participate in a residential substance abuse treatment program; and

(C) the term ''aftercare'' means placement, case management and monitoring of the participant in a community-based substance abuse treatment program when the participant leaves the custody of the Bureau of Prisons.

(6) COORDINATION OF FEDERAL ASSISTANCE.—The Bureau of Prisons shall consult with the Department of Health and Human Services concerning substance abuse treatment and related services and the incorporation of applicable components of existing comprehensive approaches including relapse prevention and aftercare services.

Chapter 232. Miscellaneous Sentencing Provisions

§ 3663. Order of restitution [1]

(a)(1)(A) The court, when sentencing a defendant convicted of an offense under this title, section 401, 408(a), 409, 416, 420, or 422(a) of the Controlled Substances Act (21 U.S.C. 841, 848(a), 849, 856, 861, 863) (but in no case shall a participant in an offense under such sections be considered a victim of such offense under this section), or section 46312, 46502, or 46504 of title 49, other than an offense described in section 3663A(c), may order, in addition to or, in the case of a misdemeanor, in lieu of any other penalty authorized by law, that the defendant make restitution to any victim of such offense, or if the victim is deceased, to the victim's estate. The court may also order, if agreed to by the parties in a plea agreement, restitution to persons other than the victim of the offense.

(B)(i) The court, in determining whether to order restitution under this section, shall consider—

(I) the amount of the loss sustained by each victim as a result of the offense; and

(II) the financial resources of the defendant, the financial needs and earning ability of the defendant and the defendant's dependents, and such other factors as the court deems appropriate.

(ii) To the extent that the court determines that the complication and prolongation of the sentencing process resulting from the fashioning of an order of restitution under this section outweighs the need to provide restitution to any victims, the court may decline to make such an order.

(2) For the purposes of this section, the term "victim" means a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered including, in the case of an offense that involves as an element a scheme, conspiracy, or pattern of criminal activity, any person directly harmed by the defendant's criminal conduct in the course of the scheme, conspiracy, or pattern. In the case of a victim who is under 18

[1] June 25, 1948, c. 645, § 1, 62 Stat. 683, § 3579 as added Public Law 97–291, § 5(a), Oct. 12, 1982, 96 Stat. 1253; renumbered and amended Public Law 98–473, Title II, § 212(a)(1), (3), Oct. 12, 1984, 98 Stat. 1987, 2010; Public Law 98–596, § 9, Oct. 30, 1984, 98 Stat. 3138; Nov. 10, 1986, Public Law 99–646, §§ 8(b), 20(a), 77(a), 78(a), 79(a), 100 Stat. 3593, 3596, 3618, 3619; Dec. 7, 1987, Public Law 100–182, § 13, 101 Stat. 1268; Dec. 11, 1987, Public Law 100–185, § 12, 101 Stat. 1285; Nov. 18, 1988, Public Law 100–690, Title VII, § 7042, 102 Stat. 4399; Nov. 29, 1990, Public Law 101–647, Title XXV, § 2509, Title XXXV, § 3595, 104 Stat. 4863, 4931; July 5, 1994, Public Law 103–272, § 5(e)(12), 108 Stat. 1374; Sept. 13, 1994, Public Law 103–322, Title IV, §§ 40504, 40505, 108 Stat. 1947; Apr. 24, 1996, Public Law 104–132, Title II, § 205(a), 110 Stat. 1229; Oct. 11, 1996, Public Law 104–294, Title VI, §§ 601(r)(1),(2), 605(l), 110 Stat. 3502, 3510; Oct. 17, 2000, Public Law 106–310, Div. B, Title XXXVI, § 3613(c), 114 Stat. 1230.

years of age, incompetent, incapacitated, or deceased, the legal guardian of the victim or representative of the victim's estate, another family member, or any other person appointed as suitable by the court, may assume the victim's rights under this section, but in no event shall the defendant be named as such representative or guardian.

(3) The court may also order restitution in any criminal case to the extent agreed to by the parties in a plea agreement.

(b) The order may require that such defendant—

(1) in the case of an offense resulting in damage to or loss or destruction of property of a victim of the offense—

(A) return the property to the owner of the property or someone designated by the owner; or

(B) if return of the property under subparagraph (A) is impossible, impractical, or inadequate, pay an amount equal to the greater of—

(i) the value of the property on the date of the damage, loss, or destruction, or

(ii) the value of the property on the date of sentencing,

less the value (as of the date the property is returned) of any part of the property that is returned;

(2) in the case of an offense resulting in bodily injury to a victim including an offense under chapter 109A or chapter 110—

(A) pay an amount equal to the cost of necessary medical and related professional services and devices relating to physical, psychiatric, and psychological care, including nonmedical care and treatment rendered in accordance with a method of healing recognized by the law of the place of treatment;

(B) pay an amount equal to the cost of necessary physical and occupational therapy and rehabilitation; and

(C) reimburse the victim for income lost by such victim as a result of such offense;

(3) in the case of an offense resulting in bodily injury also results in the death of a victim, pay an amount equal to the cost of necessary funeral and related services;

(4) in any case, reimburse the victim for lost income and necessary child care, transportation, and other expenses related to participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense; and

(5) in any case, if the victim (or if the victim is deceased, the victim's estate) consents, make restitution in services in lieu of money, or make restitution to a person or organization designated by the victim or the estate.

(c)(1) Notwithstanding any other provision of law (but subject to the provisions of subsections (a)(1)(B)(i)(II) and (ii),[2] when sentencing a defendant convicted of an offense described in section 401, 408(a), 409, 416, 420, or 422(a) of the Controlled Substances Act (21 U.S.C. 841, 848(a), 849, 856, 861, 863), in which there is

[2] So in original. Probably should be "(ii))".

no identifiable victim, the court may order that the defendant make restitution in accordance with this subsection.

(2)(A) An order of restitution under this subsection shall be based on the amount of public harm caused by the offense, as determined by the court in accordance with guidelines promulgated by the United States Sentencing Commission.

(B) In no case shall the amount of restitution ordered under this subsection exceed the amount of the fine which may be ordered for the offense charged in the case.

(3) Restitution under this subsection shall be distributed as follows:

(A) 65 percent of the total amount of restitution shall be paid to the State entity designated to administer crime victim assistance in the State in which the crime occurred.

(B) 35 percent of the total amount of restitution shall be paid to the State entity designated to receive Federal substance abuse block grant funds.

(4) The court shall not make an award under this subsection if it appears likely that such award would interfere with a forfeiture under chapter 46 or chapter 96 of this title or under the Controlled Substances Act (21 U.S.C. 801 et seq.).

(5) Notwithstanding section 3612(c) or any other provision of law, a penalty assessment under section 3013 or a fine under subchapter C of chapter 227 shall take precedence over an order of restitution under this subsection.

(6) Requests for community restitution under this subsection may be considered in all plea agreements negotiated by the United States.

(7)(A) The United States Sentencing Commission shall promulgate guidelines to assist courts in determining the amount of restitution that may be ordered under this subsection.

(B) No restitution shall be ordered under this subsection until such time as the Sentencing Commission promulgates guidelines pursuant to this paragraph.

(d) An order of restitution made pursuant to this section shall be issued and enforced in accordance with section 3664.

18 U.S.C. § 3663A
Mandatory restitution relating to controlled substances

§ 3663A. Mandatory restitution to victims of certain crimes[1]

(a)(1) Notwithstanding any other provision of law, when sentencing a defendant convicted of an offense described in subsection (c), the court shall order, in addition to, or in the case of a misdemeanor, in addition to or in lieu of, any other penalty authorized by law, that the defendant make restitution to the victim of the offense or, if the victim is deceased, to the victim's estate.

(2) For the purposes of this section, the term "victim" means a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered including, in the case of an offense that involves as an element a scheme, conspiracy, or pattern of criminal activity, any person directly harmed by the defendant's criminal conduct in the course of the scheme, conspiracy, or pattern. In the case of a victim who is under 18 years of age, incompetent, incapacitated, or deceased, the legal guardian of the victim or representative of the victim's estate, another family member, or any other person appointed as suitable by the court, may assume the victim's rights under this section, but in no event shall the defendant be named as such representative or guardian.

(3) The court shall also order, if agreed to by the parties in a plea agreement, restitution to persons other than the victim of the offense.

(b) The order of restitution shall require that such defendant—

(1) in the case of an offense resulting in damage to or loss or destruction of property of a victim of the offense—

(A) return the property to the owner of the property or someone designated by the owner; or

(B) if return of the property under subparagraph (A) is impossible, impracticable, or inadequate, pay an amount equal to—

(i) the greater of—

(I) the value of the property on the date of the damage, loss, or destruction; or

(II) the value of the property on the date of sentencing, less

(ii) the value (as of the date the property is returned) of any part of the property that is returned;

(2) in the case of an offense resulting in bodily injury to a victim—

(A) pay an amount equal to the cost of necessary medical and related professional services and devices relating to

[1] Added by Public Law 104–132, Title II, § 204(a), Apr. 24, 1996, 110 Stat. 1227, and amended by Public Law 106–310, Div. B, Title XXXVI, § 3613(d), Oct. 17, 2000, 114 Stat. 1230.

physical, psychiatric, and psychological care, including nonmedical care and treatment rendered in accordance with a method of healing recognized by the law of the place of treatment;

(B) pay an amount equal to the cost of necessary physical and occupational therapy and rehabilitation; and

(C) reimburse the victim for income lost by such victim as a result of such offense;

(3) in the case of an offense resulting in bodily injury that results in the death of the victim, pay an amount equal to the cost of necessary funeral and related services; and

(4) in any case, reimburse the victim for lost income and necessary child care, transportation, and other expenses incurred during participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense.

(c)(1) This section shall apply in all sentencing proceedings for convictions of, or plea agreements relating to charges for, any offense—

(A) that is—

(i) a crime of violence, as defined in section 16;

(ii) an offense against property under this title, or under section 416(a) of the Controlled Substances Act (21 U.S.C. 856(a)), including any offense committed by fraud or deceit; or

(iii) an offense described in section 1365 (relating to tampering with consumer products); and

(B) in which an identifiable victim or victims has suffered a physical injury or pecuniary loss.

(2) In the case of a plea agreement that does not result in a conviction for an offense described in paragraph (1), this section shall apply only if the plea specifically states that an offense listed under such paragraph gave rise to the plea agreement.

(3) This section shall not apply in the case of an offense described in paragraph (1)(A)(ii) if the court finds, from facts on the record, that—

(A) the number of identifiable victims is so large as to make restitution impracticable; or

(B) determining complex issues of fact related to the cause or amount of the victim's losses would complicate or prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process.

(d) An order of restitution under this section shall be issued and enforced in accordance with section 3664.

18 U.S.C. § 4042
Bureau of Prisons notification of the release of drug traffickers

Chapter 303. Bureau of Prisons

§ 4042. Duties of Bureau of Prisons [1]

(a) IN GENERAL.—The Bureau of Prisons, under the direction of the Attorney General, shall—

(1) have charge of the management and regulation of all Federal penal and correctional institutions;

(2) provide suitable quarters and provide for the safekeeping, care, and subsistence of all persons charged with or convicted of offenses against the United States, or held as witnesses or otherwise;

(3) provide for the protection, instruction, and discipline of all persons charged with or convicted of offenses against the United States;

(4) provide technical assistance to State and local governments in the improvement of their correctional systems; and

(5) provide notice of release of prisoners in accordance with subsections (b) and (c).

(b) NOTICE OF RELEASE OF PRISONERS.—(1) At least 5 days prior to the date on which a prisoner described in paragraph (3) is to be released on supervised release, or, in the case of a prisoner on supervised release, at least 5 days prior to the date on which the prisoner changes residence to a new jurisdiction, written notice of the release or change of residence shall be provided to the chief law enforcement officer of the State and of the local jurisdiction in which the prisoner will reside. Notice prior to release shall be provided by the Director of the Bureau of Prisons. Notice concerning a change of residence following release shall be provided by the probation officer responsible for the supervision of the released prisoner, or in a manner specified by the Director of the Administrative Office of the United States Courts. The notice requirements under this subsection do not apply in relation to a prisoner being protected under chapter 224.

(2) A notice under paragraph (1) shall disclose—

(A) the prisoner's name;

(B) the prisoner's criminal history, including a description of the offense of which the prisoner was convicted; and

(C) any restrictions on conduct or other conditions to the release of the prisoner that are imposed by law, the sentencing court, or the Bureau of Prisons or any other Federal agency.

[1] June 25, 1948, c. 645, 62 Stat. 849; July 1, 1968, Public Law 90–371, 82 Stat. 280; Sept. 13, 1994, Public Law 103–322, Title II, § 20417, 108 Stat. 1834; Nov. 26, 1997, Public Law 105–119, Title I, § 115(a)(8)(A), 111 Stat. 2464.

(3) A prisoner is described in this paragraph if the prisoner was convicted of—

(A) a drug trafficking crime, as that term is defined in section 924(c)(2); or

(B) a crime of violence (as defined in section 924(c)(3)).

(c) NOTICE OF SEX OFFENDER RELEASE.—(1) In the case of a person described in paragraph (4) who is released from prison or sentenced to probation, notice shall be provided to—

(A) the chief law enforcement officer of the State and of the local jurisdiction in which the person will reside; and

(B) a State or local agency responsible for the receipt or maintenance of sex offender registration information in the State or local jurisdiction in which the person will reside.

The notice requirements under this subsection do not apply in relation to a person being protected under chapter 224.

(2) Notice provided under paragraph (1) shall include the information described in subsection (b)(2), the place where the person will reside, and the information that the person shall be subject to a registration requirement as a sex offender. For a person who is released from the custody of the Bureau of Prisons whose expected place of residence following release is known to the Bureau of Prisons, notice shall be provided at least 5 days prior to release by the Director of the Bureau of Prisons. For a person who is sentenced to probation, notice shall be provided promptly by the probation officer responsible for the supervision of the person, or in a manner specified by the Director of the Administrative Office of the United States Courts. Notice concerning a subsequent change of residence by a person described in paragraph (4) during any period of probation, supervised release, or parole shall also be provided to the agencies and officers specified in paragraph (1) by the probation officer responsible for the supervision of the person, or in a manner specified by the Director of the Administrative Office of the United States Courts.

(3) The Director of the Bureau of Prisons shall inform a person described in paragraph (4) who is released from prison that the person shall be subject to a registration requirement as a sex offender in any State in which the person resides, is employed, carries on a vocation, or is a student (as such terms are defined for purposes of section 170101(a)(3) of the Violent Crime Control and Law Enforcement Act of 1994), and the same information shall be provided to a person described in paragraph (4) who is sentenced to probation by the probation officer responsible for supervision of the person or in a manner specified by the Director of the Administrative Office of the United States Courts.

(4) A person is described in this paragraph if the person was convicted of any of the following offenses (including such an offense prosecuted pursuant to section 1152 or 1153):

(A) An offense under section 1201 involving a minor victim.

(B) An offense under chapter 109A.

(C) An offense under chapter 110.

(D) An offense under chapter 117.

(E) Any other offense designated by the Attorney General as a sexual offense for purposes of this subsection.

(5) The United States and its agencies, officers, and employees shall be immune from liability based on good faith conduct in carrying out this subsection and subsection (b).

(d) APPLICATION OF SECTION.—This section shall not apply to military or naval penal or correctional institutions or the persons confined therein.

18 U.S.C. § 5032
Delinquency proceedings in Federal courts relating to controlled substances

Chapter 403. Juvenile Delinquency

§ 5032. Delinquency proceedings in district courts; transfer for criminal prosecution [1]

A juvenile alleged to have committed an act of juvenile delinquency, other than a violation of law committed within the special maritime and territorial jurisdiction of the United States for which the maximum authorized term of imprisonment does not exceed six months, shall not be proceeded against in any court of the United States unless the Attorney General, after investigation, certifies to the appropriate district court of the United States that (1) the juvenile court or other appropriate court of a State does not have jurisdiction or refuses to assume jurisdiction over said juvenile with respect to such alleged act of juvenile delinquency, (2) the State does not have available programs and services adequate for the needs of juveniles, or (3) the offense charged is a crime of violence that is a felony or an offense described in section 401 of the Controlled Substances Act (21 U.S.C. 841), or section 1002(a), 1003, 1005, 1009, or 1010(b)(1), (2), or (3) of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 953, 955, 959, 960(b)(1), (2), (3)), section 922(x) or section 924(b), (g), or (h) of this title, and that there is a substantial Federal interest in the case or the offense to warrant the exercise of Federal jurisdiction.

If the Attorney General does not so certify, such juvenile shall be surrendered to the appropriate legal authorities of such State. For purposes of this section, the term "State" includes a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

If an alleged juvenile delinquent is not surrendered to the authorities of a State pursuant to this section, any proceedings against him shall be in an appropriate district court of the United States. For such purposes, the court may be convened at any time and place within the district, in chambers or otherwise. The Attorney General shall proceed by information or as authorized under section 3401(g) of this title, and no criminal prosecution shall be instituted for the alleged act of juvenile delinquency except as provided below.

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[1] June 25, 1948, c. 645, 62 Stat. 857; Sept. 7, 1974, Public Law 93–415, Title V, § 502, 88 Stat. 1134; Oct. 12, 1984, Public Law 98–473, Title II, § 1201, 98 Stat. 2149; Nov. 18, 1988, Public Law 100–690, Title VI, § 6467(a), 102 Stat. 4375; Nov. 29, 1990, Public Law 101–647, Title XII, § 1205(n), Title XXXV, § 3599G, 104 Stat. 4831, 4932; Sept. 13, 1994, Public Law 103–322, Title XI, § 110201(c)(2), Title XIV, §§ 140001, 140002, Title XV, § 150002, 108 Stat. 2012, 2031, 2035; Oct. 11, 1996, Public Law 104–294, Title VI, § 601(c)(1), (g)(1), 110 Stat. 3499, 3500.

A juvenile who is alleged to have committed an act of juvenile delinquency and who is not surrendered to State authorities shall be proceeded against under this chapter unless he has requested in writing upon advice of counsel to be proceeded against as an adult, except that, with respect to a juvenile fifteen years and older alleged to have committed an act after his fifteenth birthday which if committed by an adult would be a felony that is a crime of violence or an offense described in section 401 of the Controlled Substances Act (21 U.S.C. 841), or section 1002(a), 1005, or 1009 of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 955, 959), or section 922(x) of this title, or in section 924(b), (g), or (h) of this title, criminal prosecution on the basis of the alleged act may be begun by motion to transfer of the Attorney General in the appropriate district court of the United States, if such court finds, after hearing, such transfer would be in the interest of justice. In the application of the preceding sentence, if the crime of violence is an offense under section 113(a), 113(b), 113(c), 1111, 1113, or, if the juvenile possessed a firearm during the offense, section 2111, 2113, 2241(a), or 2241(c), ''thirteen'' shall be substituted for ''fifteen'' and ''thirteenth'' shall be substituted for ''fifteenth''. Notwithstanding sections 1152 and 1153, no person subject to the criminal jurisdiction of an Indian tribal government shall be subject to the preceding sentence for any offense the Federal jurisdiction for which is predicated solely on Indian country (as defined in section 1151), and which has occurred within the boundaries of such Indian country, unless the governing body of the tribe has elected that the preceding sentence have effect over land and persons subject to its criminal jurisdiction. However, a juvenile who is alleged to have committed an act after his sixteenth birthday which if committed by an adult would be a felony offense that has as an element thereof the use, attempted use, or threatened use of physical force against the person of another, or that, by its very nature, involves a substantial risk that physical force against the person of another may be used in committing the offense, or would be an offense described in section 32, 81, 844(d), (e), (f), (h), (i) or 2275 of this title, subsection (b)(1) (A), (B), or (C), (d), or (e) of section 401 of the Controlled Substances Act, or section 1002(a), 1003, 1009, or 1010(b) (1), (2), or (3) of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 953, 959, 960(b) (1), (2), (3)), and who has previously been found guilty of an act which if committed by an adult would have been one of the offenses set forth in this paragraph or an offense in violation of a State felony statute that would have been such an offense if a circumstance giving rise to Federal jurisdiction had existed, shall be transferred to the appropriate district court of the United States for criminal prosecution.

Evidence of the following factors shall be considered, and findings with regard to each factor shall be made in the record, in assessing whether a transfer would be in the interest of justice: the age and social background of the juvenile; the nature of the alleged offense; the extent and nature of the juvenile's prior delinquency record; the juvenile's present intellectual development and psychological maturity; the nature of past treatment efforts and the juvenile's response to such efforts; the availability of programs designed

to treat the juvenile's behavioral problems. In considering the nature of the offense, as required by this paragraph, the court shall consider the extent to which the juvenile played a leadership role in an organization, or otherwise influenced other persons to take part in criminal activities, involving the use or distribution of controlled substances or firearms. Such a factor, if found to exist, shall weigh in favor of a transfer to adult status, but the absence of this factor shall not preclude such a transfer.

Reasonable notice of the transfer hearing shall be given to the juvenile, his parents, guardian, or custodian and to his counsel. The juvenile shall be assisted by counsel during the transfer hearing, and at every other critical stage of the proceedings.

Once a juvenile has entered a plea of guilty or the proceeding has reached the stage that evidence has begun to be taken with respect to a crime or an alleged act of juvenile delinquency subsequent criminal prosecution or juvenile proceedings based upon such alleged act of delinquency shall be barred.

Statements made by a juvenile prior to or during a transfer hearing under this section shall not be admissible at subsequent criminal prosecutions.

Whenever a juvenile transferred to district court under this section is not convicted of the crime upon which the transfer was based or another crime which would have warranted transfer had the juvenile been initially charged with that crime, further proceedings concerning the juvenile shall be conducted pursuant to the provisions of this chapter.

A juvenile shall not be transferred to adult prosecution nor shall a hearing be held under section 5037 (disposition after a finding of juvenile delinquency) until any prior juvenile court records of such juvenile have been received by the court, or the clerk of the juvenile court has certified in writing that the juvenile has no prior record, or that the juvenile's record is unavailable and why it is unavailable.

Whenever a juvenile is adjudged delinquent pursuant to the provisions of this chapter, the specific acts which the juvenile has been found to have committed shall be described as part of the official record of the proceedings and part of the juvenile's official record.

18 U.S.C. § 5038
Federal juvenile court records relating to controlled substances

§ 5038. Use of juvenile records[1]

(a) Throughout and upon the completion of the juvenile delinquency proceeding, the records shall be safeguarded from disclosure to unauthorized persons. The records shall be released to the extent necessary to meet the following circumstances:

(1) inquiries received from another court of law;

(2) inquiries from an agency preparing a presentence report for another court;

(3) inquiries from law enforcement agencies where the request for information is related to the investigation of a crime or a position within that agency;

(4) inquiries, in writing, from the director of a treatment agency or the director of a facility to which the juvenile has been committed by the court;

(5) inquiries from an agency considering the person for a position immediately and directly affecting the national security; and

(6) inquiries from any victim of such juvenile delinquency, or if the victim is deceased from the immediate family of such victim, related to the final disposition of such juvenile by the court in accordance with section 5037.

Unless otherwise authorized by this section, information about the juvenile record may not be released when the request for information is related to an application for employment, license, bonding, or any civil right or privilege. Responses to such inquiries shall not be different from responses made about persons who have never been involved in a delinquency proceeding.

(b) District courts exercising jurisdiction over any juvenile shall inform the juvenile, and his parent or guardian, in writing in clear and nontechnical language, of rights relating to his juvenile record.

(c) During the course of any juvenile delinquency proceeding, all information and records relating to the proceeding, which are obtained or prepared in the discharge of an official duty by an employee of the court or an employee of any other governmental agency, shall not be disclosed directly or indirectly to anyone other than the judge, counsel for the juvenile and the Government, or others entitled under this section to receive juvenile records.

(d) Whenever a juvenile is found guilty of committing an act which if committed by an adult would be a felony that is a crime of violence or an offense described in section 401 of the Controlled

[1] Added by Public Law 93–415, Title V, § 508, Sept. 7, 1974, 88 Stat. 1137, and amended by Public Law 95–115, § 8(b), Oct. 3, 1977, 91 Stat. 1060; Public Law 98–473, Title II, § 1202, Oct. 12, 1984, 98 Stat. 2150; Public Law 103–322, Title XIV, § 140005, Sept. 13, 1994, 108 Stat. 2032; Public Law 104–294, Title VI, § 601(f)(16), (o), Oct. 11, 1996, 110 Stat. 3500, 3502.

Substances Act or section 1001(a), 1005, or 1009 of the Controlled Substances Import and Export Act, such juvenile shall be fingerprinted and photographed. Except a juvenile described in subsection (f), fingerprints and photographs of a juvenile who is not prosecuted as an adult shall be made available only in accordance with the provisions of subsection (a) of this section. Fingerprints and photographs of a juvenile who is prosecuted as an adult shall be made available in the manner applicable to adult defendants.

(e) Unless a juvenile who is taken into custody is prosecuted as an adult neither the name nor picture of any juvenile shall be made public in connection with a juvenile delinquency proceeding.

(f) Whenever a juvenile has on two separate occasions been found guilty of committing an act which if committed by an adult would be a felony crime of violence or an offense described in section 401 of the Controlled Substances Act or section 1001(a), 1005, or 1009 of the Controlled Substances Import and Export Act, or whenever a juvenile has been found guilty of committing an act after his 13th birthday which if committed by an adult would be an offense described in the second sentence of the fourth paragraph of section 5032 of this title, the court shall transmit to the Federal Bureau of Investigation the information concerning the adjudications, including name, date of adjudication, court, offenses, and sentence, along with the notation that the matters were juvenile adjudications.

19 U.S.C. § 1436
Tariff Act of 1930, Public Law 71–361 (Act of June 17, 1930), sec. 436
Penalty for failure to report on entry or arrival

Title 19. Customs Duties

Chapter 4. Tariff Act of 1930

§ 1436. Penalties for violations of arrival, reporting, entry, and clearance requirements [1]

(a) Unlawful acts

It is unlawful—

(1) to fail to comply with section 1431, 1433, or 1434 of this title or section 91 of the Appendix to Title 46;

(2) to present or transmit, electronically or otherwise, any forged, altered, or false document, paper, information, data or manifest to the Customs Service under section 1431, 1433(d), or 1434 of this title or section 91 of the Appendix to Title 46 without revealing the facts;

(3) to fail to make entry or to obtain clearance as required by section 1434 or 1644 of this title, section 91 of the Appendix to Title 46, or section 1509 of the Appendix to Title 49; or

(4) to fail to comply with, or violate, any regulation prescribed under any section referred to in any of paragraphs (1) through (3).

(b) Civil penalty

Any master, person in charge of a vehicle, or aircraft pilot who commits any violation listed in subsection (a) of this section is liable for a civil penalty of $5,000 for the first violation, and $10,000 for each subsequent violation, and any conveyance used in connection with any such violation is subject to seizure and forfeiture.

(c) Criminal penalty

In addition to being liable for a civil penalty under subsection (b) of this section, any master, person in charge of a vehicle, or aircraft pilot who intentionally commits any violation listed in subsection (a) of this section is, upon conviction, liable for a fine of not more than $2,000 or imprisonment for 1 year, or both; except that if the conveyance has, or is discovered to have had, on board any merchandise (other than sea stores or the equivalent for conveyances other than vessels) the importation of which into the United States

[1] June 17, 1930, c. 497, Title IV, § 436, 46 Stat. 711; Aug. 5, 1935, c. 438, Title II, § 202, 49 Stat. 521; Oct. 27, 1986, Public Law 99–570, Title III, § 3113(a), 100 Stat. 3207–81; Dec. 8, 1993, Public Law 103–182, Title VI, § 611, 107 Stat. 2170; Oct. 11, 1996, Public Law 104–295, § 21(e)(3), 110 Stat. 3530.

is prohibited, such individual is liable for an additional fine of not more than $10,000 or imprisonment for not more than 5 years, or both.

(d) Additional civil penalty

If any merchandise (other than sea stores or the equivalent for conveyances other than a vessel) is imported or brought into the United States in or aboard a conveyance which was not properly reported or entered, the master, person in charge of a vehicle, or aircraft pilot shall be liable for a civil penalty equal to the value of the merchandise and the merchandise may be seized and forfeited unless properly entered by the importer or consignee. If the merchandise consists of any controlled substance listed in section 1584 of this title, the master, individual in charge of a vehicle, or pilot shall be liable to the penalties prescribed in that section.

19 U.S.C. § 1497

Tariff Act of 1930, Public Law 71–361 (Act of June 17, 1930), sec. 497

Penalty for failure to declare, for customs purposes, value of controlled substances

§ 1497. Penalties for failure to declare [1]

(a) In general

(1) Any article which—

(A) is not included in the declaration and entry as made or transmitted; and

(B) is not mentioned before examination of the baggage begins—

(i) in writing by such person, if written declaration and entry was required, or

(ii) orally, if written declaration and entry was not required;

shall be subject to forfeiture and such person shall be liable for a penalty determined under paragraph (2) with respect to such article.

(2) The amount of the penalty imposed under paragraph (1) with respect to any article is equal to—

(A) if the article is a controlled substance, either $500 or an amount equal to 1,000 percent of the value of the article, whichever amount is greater; and

(B) if the article is not a controlled substance, the value of the article.

(b) Value of controlled substances

(1) Notwithstanding any other provision of this chapter, the value of any controlled substance shall, for purposes of this section, be equal to the amount determined by the Secretary in consultation with the Attorney General of the United States, to be equal to the price at which such controlled substance is likely to be illegally sold to the consumer of such controlled substance.

(2) The Secretary and the Attorney General of the United States shall establish a method of determining the price at which each controlled substance is likely to be illegally sold to the consumer of such controlled substance.

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[1] June 17, 1930, c. 497, Title IV, § 497, 46 Stat. 728; Oct. 27, 1986, Public Law 99–570, Title III, § 3116, 100 Stat. 3207–83; Nov. 18, 1988, Public Law 100–690, Title VII, § 7367(a), 102 Stat. 4479; Dec. 8, 1993, Public Law 103–182, Title VI, § 612, 107 Stat. 2170.

19 U.S.C. § 1583

Tariff Act of 1930, Public Law 71–361 (Act of June 17, 1930), sec. 583

Customs inspection of mail leaving the United States relating to the exportation of controlled substances

§ 1583. Examination of outbound mail[1]

(a) Examination

(1) In general

For purposes of ensuring compliance with the Customs laws of the United States and other laws enforced by the Customs Service, including the provisions of law described in paragraph (2), a Customs officer may, subject to the provisions of this section, stop and search at the border, without a search warrant, mail of domestic origin transmitted for export by the United States Postal Service and foreign mail transiting the United States that is being imported or exported by the United States Postal Service.

(2) Provisions of law described

The provisions of law described in this paragraph are the following:

(A) Section 5316 of Title 31 (relating to reports on exporting and importing monetary instruments).

(B) Sections 1461, 1463, 1465, and 1466, and chapter 110 of Title 18 (relating to obscenity and child pornography).

(C) Section 953 of Title 21 (relating to exportation of controlled substances).

(D) The Export Administration Act of 1979 (50 U.S.C. App. 2401 et seq.).

(E) Section 2778 of Title 22.

(F) The International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

(b) Search of mail not sealed against inspection and other mail

Mail not sealed against inspection under the postal laws and regulations of the United States, mail which bears a Customs declaration, and mail with respect to which the sender or addressee has consented in writing to search, may be searched by a Customs officer.

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[1] June 17, 1930, c. 497, Title IV, § 583, as added Aug. 6, 2002, Public Law 107–210, Div. A, Title III, § 344(a), 116 Stat. 986; Dec. 3, 2004, Public Law 108–429, § 2004(a)(12), 118 Stat. 2590.

(c) Search of mail sealed against inspection weighing in excess of 16 ounces

(1) In general

Mail weighing in excess of 16 ounces sealed against inspection under the postal laws and regulations of the United States may be searched by a Customs officer, subject to paragraph (2), if there is reasonable cause to suspect that such mail contains one or more of the following:

(A) Monetary instruments, as defined in section 1956 of Title 18.

(B) A weapon of mass destruction, as defined in section 2332a(b) of Title 18.

(C) A drug or other substance listed in schedule I, II, III, or IV in section 812 of Title 21.

(D) National defense and related information transmitted in violation of any of sections 793 through 798 of Title 18.

(E) Merchandise mailed in violation of section 1715 or 1716 of Title 18.

(F) Merchandise mailed in violation of any provision of chapter 71 (relating to obscenity) or chapter 110 (relating to sexual exploitation and other abuse of children) of Title 18.

(G) Merchandise mailed in violation of the Export Administration Act of 1979 (50 U.S.C. App. 2401 et seq.).

(H) Merchandise mailed in violation of section 2778 of Title 22.

(I) Merchandise mailed in violation of the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

(J) Merchandise mailed in violation of the Trading with the Enemy Act (50 U.S.C. App. 1 et seq.).

(K) Merchandise subject to any other law enforced by the Customs Service.

(2) Limitation

No person acting under the authority of paragraph (1) shall read, or authorize any other person to read, any correspondence contained in mail sealed against inspection unless prior to so reading—

(A) a search warrant has been issued pursuant to rule 41 of the Federal Rules of Criminal Procedure; or

(B) the sender or addressee has given written authorization for such reading.

(d) Search of mail sealed against inspection weighing 16 ounces or less

Notwithstanding any other provision of this section, subsection (a)(1) of this section shall not apply to mail weighing 16 ounces or less sealed against inspection under the postal laws and regulations of the United States.

19 U.S.C. § 1584

Tariff Act of 1930, Public Law 71–361 (Act of June 17, 1930), sec. 584

Penalties for false or incomplete manifests relating to certain controlled substances

§ 1584. Falsity or lack of manifest; penalties [1]

(a) General rule

(1) Any master of any vessel and any person in charge of any vehicle bound to the United States who does not produce the manifest to the officer (whether of the Customs Service or the Coast Guard) demanding the same shall be liable to a penalty of $1,000, and if any merchandise, including sea stores, is found on board of or after having been unladen from such vessel or vehicle which is not included or described in said manifest or does not agree therewith, the master of such vessel or the person in charge of such vehicle or the owner of such vessel or vehicle or any person directly or indirectly responsible for any discrepancy between the merchandise and said manifest shall be liable to a penalty equal to the lesser of $10,000 or the domestic value of the merchandise so found or unladen, and any such merchandise belonging or consigned to the master or other officer or to any of the crew of such vessel, or to the owner or person in charge of such vehicle, shall be subject to forfeiture, and if any merchandise described in such manifest is not found on board the vessel or vehicle the master or other person in charge or the owner of such vessel or vehicle or any person directly or indirectly responsible for any discrepancy between the merchandise and said manifest shall be subject to a penalty of $1,000: *Provided*, That if the Customs Service shall be satisfied that the manifest was lost or mislaid without intentional fraud, or was defaced by accident, or is incorrect by reason of clerical error or other mistake and that no part of the merchandise not found on board was unshipped or discharged except as specified in the report of the master, said penalties shall not be incurred. For purposes of this subsection, the term "clerical error" means a nonnegligent, inadvertent, or typographical mistake in the preparation, assembly, or submission (electronically or otherwise) of the manifest.

(2) If any of such merchandise so found consists of heroin, morphine, cocaine, isonipecaine, or opiate, the master of such vessel or

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[1] June 17, 1930, c. 497, Title IV, § 584, 46 Stat. 748; Aug. 5, 1935, c. 438, Title II, § 204, 49 Stat. 523; July 1, 1944, c. 377, § 10, 58 Stat. 722; Mar. 8, 1946, c. 81, § 9, 60 Stat. 39; June 2, 1970, Public Law 91–271, Title III, § 301(b), 84 Stat. 287; Oct. 27, 1970, Public Law 91–513, Title III, § 1102(m), 84 Stat. 1293; Oct. 3, 1978, Public Law 95–410, Title I, § 109, 92 Stat. 892; Oct. 27, 1986, Public Law 99–570, Title III, § 3118, 100 Stat. 3207–84; Dec. 8, 1993, Public Law 103–182, Title VI, § 619, 107 Stat. 2180; Public Law 106–36, Title I, § 1001(b)(7), June 25, 1999, 113 Stat. 132.

person in charge of such vehicle or the owner of such vessel or vehicle or any person directly or indirectly responsible for heroin, morphine, cocaine, isonipecaine, or opiate being in such merchandise shall be liable to a penalty of $1,000 for each ounce thereof so found. If any of such merchandise so found consists of smoking opium, opium prepared for smoking, or marihuana, the master of such vessel or person in charge of such vehicle or the owner of such vessel or vehicle or any person directly or indirectly responsible for smoking opium, opium prepared for smoking, or marihuana being in such merchandise shall be liable to a penalty of $500 for each ounce thereof so found. If any of such merchandise so found consists of crude opium, the master of such vessel or person in charge of such vehicle or the owner of such vessel or vehicle or any person directly or indirectly responsible for crude opium being in such merchandise shall be liable to a penalty of $200 for each ounce thereof so found. Such penalties shall, notwithstanding the proviso in section 1594 of this title (relating to the immunity of vessels or vehicles used as common carriers), constitute a lien upon such vessel which may be enforced by a libel in rem; except that the master or owner of a vessel used by any person as a common carrier in the transaction of business as such common carrier shall not be liable to such penalties and the vessel shall not be held subject to the lien, if it appears to the satisfaction of the court that neither the master nor any of the officers (including licensed and unlicensed officers and petty officers) nor the owner of the vessel knew, and could not, by the exercise of the highest degree of care and diligence, have known, that such narcotic drugs were on board. Clearance of any such vessel may be withheld until such penalties are paid or until a bond, satisfactory to the Customs Service, is given for the payment thereof. The provisions of this paragraph shall not prevent the forfeiture of any such vessel or vehicle under any other provision of law. As used in this paragraph, the terms "opiate" and "marihuana" shall have the same meaning given those terms by sections 802(18) and 802(16), respectively, of Title 21.

(3) If any of such merchandise (sea stores excepted), the importation of which into the United States is prohibited, be so found upon any vessel not exceeding five hundred net tons, the vessel shall, in addition to any other penalties herein or by law provided, be seized and forfeited.

(b) Procedures

(1) If the Customs Service has reasonable cause to believe that there has been a violation of subsection (a)(1) of this section and determines that further proceedings are warranted, the Customs Service shall issue or electronically transmit to the person concerned a notice of intent to issue or electronically transmit a claim for a monetary penalty. Such notice shall—

(A) describe the merchandise;

(B) set forth the details of the error in the manifest;

(C) specify all laws and regulations allegedly violated;

(D) disclose all the material facts which establish the alleged violation;

(E) state the estimated loss of lawful duties, if any, and, taking into account all of the circumstances, the amount of the proposed monetary penalty; and

(F) inform such person that he will have a reasonable opportunity to make representations, both oral and written, as to why such penalty claim should not be issued.

No notice is required under this subsection for any violation of subsection (a)(1) of this section for which the proposed penalty is $1,000 or less.

(2) After considering representations, if any, made by the person concerned pursuant to the notice issued under paragraph (1), the Customs Service shall determine whether any violation of subsection (a)(1) of this section, as alleged in the notice, has occurred. If the Customs Service determines that there was no violation, the Customs Service shall promptly issue or electronically transmit a statement of the determination to the person to whom the notice was sent. If the Customs Service determines that there was a violation, the Customs Service shall issue or electronically transmit a penalty claim to such person. The penalty claim shall specify all changes in the information provided under subparagraphs (A) through (E) of paragraph (1).

19 U.S.C. § 1590
Tariff Act of 1930, Public Law 71–361 (Act of June 17, 1930), sec. 590
Aviation smuggling of controlled substances

§ 1590. Aviation smuggling [1]

(a) In general

It is unlawful for the pilot of any aircraft to transport, or for any individual on board any aircraft to possess, merchandise knowing, or intending, that the merchandise will be introduced into the United States contrary to law.

(b) Sea transfers

It is unlawful for any person to transfer merchandise between an aircraft and a vessel on the high seas or in the customs waters of the United States if such person has not been authorized by the Secretary to make such transfer and—

(1) either—

(A) the aircraft is owned by a citizen of the United States or is registered in the United States, or

(B) the vessel is a vessel of the United States (within the meaning of section 1703(b) of this title), or

(2) regardless of the nationality of the vessel or aircraft, such transfer is made under circumstances indicating the intent to make it possible for such merchandise, or any part thereof, to be introduced into the United States unlawfully.

(c) Civil penalties

Any person who violates any provision of this section is liable for a civil penalty equal to twice the value of the merchandise involved in the violation, but not less than $10,000. The value of any controlled substance included in the merchandise shall be determined in accordance with section 1497(b) of this title.

(d) Criminal penalties

In addition to being liable for a civil penalty under subsection (c) of this section, any person who intentionally commits a violation of any provision of this section is, upon conviction—

(1) liable for a fine of not more than $10,000 or imprisonment for not more than 5 years, or both, if none of the merchandise involved was a controlled substance; or

(2) liable for a fine of not more than $250,000 or imprisonment for not more than 20 years, or both, if any of the merchandise involved was a controlled substance.

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[1] June 17, 1930, c. 497, Title IV, § 590, as added Oct. 27, 1986, Public Law 99–570, Title III, § 3120, 100 Stat. 3207–84.

(e) Seizure and forfeiture

(1) Except as provided in paragraph (2), a vessel or aircraft used in connection with, or in aiding or facilitating, any violation of this section, whether or not any person is charged in connection with such violation, may be seized and forfeited in accordance with the customs laws.

(2) Paragraph (1) does not apply to a vessel or aircraft operated as a common carrier.

(f) "Merchandise" defined

As used in this section, the term "merchandise" means only merchandise the importation of which into the United States is prohibited or restricted.

(g) Intent of transfer of merchandise

For purposes of imposing civil penalties under this section, any of the following acts, when performed within 250 miles of the territorial sea of the United States, shall be prima facie evidence that the transportation or possession of merchandise was unlawful and shall be presumed to constitute circumstances indicating that the purpose of the transfer is to make it possible for such merchandise, or any part thereof, to be introduced into the United States unlawfully, and for purposes of subsection (e) of this section or section 1595a of this title, shall be prima facie evidence that an aircraft or vessel was used in connection with, or to aid or facilitate, a violation of this section:

(1) The operation of an aircraft or a vessel without lights during such times as lights are required to be displayed under applicable law.

(2) The presence on an aircraft of an auxiliary fuel tank which is not installed in accordance with applicable law.

(3) The failure to identify correctly—

(A) the vessel by name or country of registration, or

(B) the aircraft by registration number and country of registration,

when requested to do so by a customs officer or other government authority.

(4) The external display of false registration numbers, false country of registration, or, in the case of a vessel, false vessel name.

(5) The presence on board of unmanifested merchandise, the importation of which is prohibited or restricted.

(6) The presence on board of controlled substances which are not manifested or which are not accompanied by the permits or licenses required under Single Convention on Narcotic Drugs or other international treaty.

(7) The presence of any compartment or equipment which is built or fitted out for smuggling.

(8) The failure of a vessel to stop when hailed by a customs officer or other government authority.

19 U.S.C. § 1595a

Tariff Act of 1930, Public Law 71–361 (Act of June 17, 1930), sec. 596

Forfeiture of controlled substances unlawfully introduced into the United States

§ 1595a. Forfeitures and other penalties [1]

(a) Importation, removal, etc. contrary to laws of United States

Except as specified in subsection (b) or (c) of section 1594 of this title, every vessel, vehicle, animal, aircraft, or other thing used in, to aid in, or to facilitate, by obtaining information or in any other way, the importation, bringing in, unlading, landing, removal, concealing, harboring, or subsequent transportation of any article which is being or has been introduced, or attempted to be introduced, into the United States contrary to law, whether upon such vessel, vehicle, animal, aircraft, or other thing or otherwise, may be seized and forfeited together with its tackle, apparel, furniture, harness, or equipment.

(b) Penalty for aiding unlawful importation

Every person who directs, assists financially or otherwise, or is in any way concerned in any unlawful activity mentioned in the preceding subsection shall be liable to a penalty equal to the value of the article or articles introduced or attempted to be introduced.

(c) Merchandise introduced contrary to law

Merchandise which is introduced or attempted to be introduced into the United States contrary to law shall be treated as follows:

(1) The merchandise shall be seized and forfeited if it—

(A) is stolen, smuggled, or clandestinely imported or introduced;

(B) is a controlled substance, as defined in the Controlled Substances Act (21 U.S.C. 801 et seq.), and is not imported in accordance with applicable law;

(C) is a contraband article, as defined in section 80302 of Title 49; or

(D) is a plastic explosive, as defined in section 841(q) of Title 18, which does not contain a detection agent, as defined in section 841(p) of such title.

(2) The merchandise may be seized and forfeited if—

[1] June 17, 1930, c. 497, Title IV, § 596, as added Sept. 1, 1954, c. 1213, Title V, § 502, 68 Stat. 1140, and amended Oct. 27, 1986, Public Law 99–570, Title III, § 3123, 100 Stat. 3207–87; Dec. 8, 1993, Public Law 103–182, Title VI, § 624, 107 Stat. 2187; Apr. 24, 1996, Public Law 104–132, Title VI, § 606, 110 Stat. 1290.

(A) its importation or entry is subject to any restriction or prohibition which is imposed by law relating to health, safety, or conservation and the merchandise is not in compliance with the applicable rule, regulation, or statute;

(B) its importation or entry requires a license, permit or other authorization of an agency of the United States Government and the merchandise is not accompanied by such license, permit, or authorization;

(C) it is merchandise or packaging in which copyright, trademark, or trade name protection violations are involved (including, but not limited to, violations of section 1124, 1125, or 1127 of Title 15, section 506 or 509 of Title 17, or section 2318 or 2320 of Title 18);

(D) it is trade dress merchandise involved in the violation of a court order citing section 1125 of Title 15;

(E) it is merchandise which is marked intentionally in violation of section 1304 of this title; or

(F) it is merchandise for which the importer has received written notices that previous importations of identical merchandise from the same supplier were found to have been marked in violation of section 1304 of this title.

(3) If the importation or entry of the merchandise is subject to quantitative restrictions requiring a visa, permit, license, or other similar document, or stamp from the United States Government or from a foreign government or issuing authority pursuant to a bilateral or multilateral agreement, the merchandise shall be subject to detention in accordance with section 1499 of this title unless the appropriate visa, license, permit, or similar document or stamp is presented to the Customs Service; but if the visa, permit, license, or similar document or stamp which is presented in connection with the importation or entry of the merchandise is counterfeit, the merchandise may be seized and forfeited.

(4) If the merchandise is imported or introduced contrary to a provision of law which governs the classification or value of merchandise and there are no issues as to the admissibility of the merchandise into the United States, it shall not be seized except in accordance with section 1592 of this title.

(5) In any case where the seizure and forfeiture of merchandise are required or authorized by this section, the Secretary may—

(A) remit the forfeiture under section 1618 of this title, or

(B) permit the exportation of the merchandise, unless its release would adversely affect health, safety, or conservation or be in contravention of a bilateral or multilateral agreement or treaty.

19 U.S.C. § 1607

Tariff Act of 1930, Public Law 71–361 (Act of June 17, 1930), sec. 607

Confiscation of conveyances used to smuggle controlled substances

§ 1607. Seizure; value $500,000 or less, prohibited articles, transporting conveyances [1]

(a) Notice of seizure

If—

(1) the value of such seized vessel, vehicle, aircraft, merchandise, or baggage does not exceed $500,000;

(2) such seized merchandise is merchandise the importation of which is prohibited;

(3) such seized vessel, vehicle, or aircraft was used to import, export, transport, or store any controlled substance or listed chemical; or

(4) such seized merchandise is any monetary instrument within the meaning of section 5312(a)(3) of Title 31;

the appropriate customs officer shall cause a notice of the seizure of such articles and the intention to forfeit and sell or otherwise dispose of the same according to law to be published for at least three successive weeks in such manner as the Secretary of the Treasury may direct. Written notice of seizure together with information on the applicable procedures shall be sent to each party who appears to have an interest in the seized article.

(b) "Controlled substance" and "listed chemical" defined

As used in this section, the terms "controlled substance" and "listed chemical" have the meaning given such terms in section 802 of Title 21.

(c) Report to Congress

The Commissioner of Customs shall submit to the Congress, by no later than February 1 of each fiscal year, a report on the total dollar value of uncontested seizures of monetary instruments having a value of over $100,000 which, or the proceeds of which, have not been deposited into the Customs Forfeiture Fund under section 1613b of this title within 120 days of seizure, as of the end of the previous fiscal year.

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[1] June 17, 1930, c. 497, Title IV, § 607, 46 Stat. 754; June 25, 1938, c. 679, § 28(a), 52 Stat. 1089; Sept. 1, 1954, c. 1213, Title V, § 506, 68 Stat. 1141; June 2, 1970, Public Law 91–271, Title III, § 301(ee), 84 Stat. 291; Oct. 3, 1978, Public Law 95–410, Title I, § 111(a), 92 Stat. 897; Oct. 12, 1984, Public Law 98–473, Title II, § 311, 98 Stat. 2053; Oct. 30, 1984, Public Law 98–573, Title II, § 213(a)(4), 98 Stat. 2984; Aug. 20, 1990, Public Law 101–382, Title I, § 122, 104 Stat. 642; Oct. 3, 1996, Public Law 104–237, Title II, § 201(c), 110 Stat. 3101.

19 U.S.C. § 1613b

Tariff Act of 1930, Public Law 71–361 (Act of June 17, 1930), sec. 613A

Authority to use Customs Forfeiture Fund to purchase evidence of smuggling controlled substances

§ 1613b. Customs Forfeiture Fund [1]

(a) In general

(1) There is established in the Treasury of the United States a fund to be known as the "Customs Forfeiture Fund" (hereafter in this section referred to as the "Fund"), which shall be available to the United States Customs Service, subject to appropriation, with respect to seizures and forfeitures by the United States Customs Service and the United States Coast Guard under any law enforced or administered by those agencies for payment, or for reimbursement to the appropriation from which payment was made, for—

(A) all proper expenses of the seizure (including investigative costs incurred by the United States Customs Service leading to seizures) or the proceedings of forfeiture and sale, including, but not limited to, the expenses of inventory, security, and maintenance of custody of the property, advertisement and sale of the property, and if condemned by the court and a bond for such costs was not given, the costs as taxed by the court;

(B) awards of compensation to informers under section 1619 of this title;

(C) satisfaction of—

(i) liens for freight, charges, and contributions in general average, notice of which has been filed with the appropriate customs officer according to law, and

(ii) other liens against forfeited property;

(D) amounts authorized by law with respect to remission and mitigation;

(E) claims of parties in interest to property disposed of under section 1612(b) of this title, in the amounts applicable to such claims at the time of seizure; and

(F) equitable sharing payments made to other Federal agencies, State and local law enforcement agencies, and foreign countries under the authority of section 1616a(c) of this title or section 981 of Title 18.

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[1] June 17, 1930, c. 497, Title IV, § 613A, as added Oct. 30, 1984, Public Law 98–573, Title II, § 213(a)(11), 98 Stat. 2986, and amended Oct. 27, 1986, Public Law 99–570, Title I, § 1152(b)(2), Title III, § 3142(a), 100 Stat. 3207–12, 3207–93; July 11, 1987, Public Law 100–71, Title I, § 101, 101 Stat. 438; Dec. 22, 1987, Public Law 100–202, Title I, § 101(m), [Title I, § 106], 101 Stat. 1329–390, 1329–397; Aug. 23, 1988, Public Law 100–418, Title I, § 1912, 102 Stat. 1320; Nov. 18, 1988, Public Law 100–690, Title VII, § 7364, 102 Stat. 4475; Aug. 20, 1990, Public Law 101–382, Title I, § 121, 104 Stat. 640; Nov. 5, 1990, Public Law 101–508, Title X, § 10012(a), 104 Stat. 1388–390; Oct. 19, 1996, Public Law 104–316, Title I, § 110(a), 110 Stat. 3832.

(2)(A) Any payment made under subparagraph (C) or (D) of paragraph (1) with respect to a seizure or a forfeiture of property shall not exceed the value of the property at the time of the seizure.

(B) Any payment made under subparagraph (F) of paragraph (1) with respect to a seizure or forfeiture of property shall not exceed the value of the property at the time of disposition.

(3) In addition to the purposes described in paragraph (1), the Fund shall be available for—

(A) purchases by the United States Customs Service of evidence of—

(i) smuggling of controlled substances, and

(ii) violations of the currency and foreign transaction reporting requirements of chapter 51 of Title 31, if there is a substantial probability that the violations of these requirements are related to the smuggling of controlled substances;

(B) equipment for any vessel, vehicle, or aircraft available for official use by the United States Customs Service to enable the vessel, vehicle, or aircraft to assist in law enforcement functions;

(C) the reimbursement, at the discretion of the Secretary, of private persons for expenses incurred by such persons in cooperating with the United States Customs Service in investigations and undercover law enforcement operations;

(D) publication of the availability of awards under section 1619 of this title;

(E) equipment for any vessel, vehicle, or aircraft available for official use by a State or local law enforcement agency to enable the vessel, vehicle, or aircraft to assist in law enforcement functions if the conveyance will be used in joint law enforcement operations with the United States Customs Service; and

(F) payment of overtime salaries, travel, fuel, training, equipment, and other similar costs of State and local law enforcement officers that are incurred in joint law enforcement operations with the United States Customs Service.

(b) United States Coast Guard

The Commissioner of Customs shall make available to the United States Coast Guard, from funds appropriated under subsection (f)(2) of this section in excess of $10,000,000 for a fiscal year, proceeds in the Fund derived from seizures by the Coast Guard. Funds made available under this subsection may be used for—

(1) equipment for any vessel, vehicle, or aircraft available for official use by the United States Coast Guard to enable the vessel, vehicle, or aircraft to assist in law enforcement functions;

(2) equipment for any vessel, vehicle, equipment, or aircraft available for official use by a State or local law enforcement agency to enable the vessel, vehicle, or aircraft to assist in law enforcement functions if the conveyance will be used in joint law enforcement operations with the United States Coast Guard;

(3) payment of overtime salaries, travel, fuel, training, equipment, and other similar costs of State and local law enforcement officers that are incurred in joint law enforcement operations with the United States Coast Guard; and

(4) expenses incurred in bringing vessels into compliance with applicable environmental laws prior to disposal by sinking.

(c) Deposits

There shall be deposited into the Fund all forfeited currency and proceeds from forfeiture under any law enforced or administered by the United States Customs Service or the United States Coast Guard and all income from investments made under subsection (d) of this section.

(d) Investment

Amounts in the Fund which are not currently needed for the purposes of this section shall be invested in obligations of, or guaranteed by, the United States.

(e) Annual reports; audits

(1) The Commissioner of Customs shall transmit to the Congress, by no later than February 1 of each fiscal year the following detailed reports:

(A) a report on—

(i) the estimated total value of property forfeited under any law enforced or administered by the United States Customs Service or the United States Coast Guard with respect to which funds were not deposited in the Fund during the previous fiscal year, and

(ii) the estimated total value of all such property transferred to any State or local law enforcement agency;

(B) a report on—

(i) the balance of the Fund at the beginning of the preceding fiscal year;

(ii) liens and mortgages paid and amount of money shared with State and local law enforcement agencies during the previous fiscal year;

(iii) the net amount realized from the operations of the Fund during the previous fiscal year, the amount of seized cash being held as evidence, and the amount of money that has been carried over to the current fiscal year;

(iv) any defendant's equity in property valued at $1,000,000 or more;

(v) the balance of the Fund at the end of the previous fiscal year; and

(C) a report containing, for the previous fiscal year—

(i) a complete set of audited financial statements (including a balance sheet, income statement, and cash flow analysis) prepared in a manner consistent with the requirements of the Comptroller General, and

(ii) an analysis of income and expenses showing the revenue received or lost—

(I) by property category (general property, vehicles, vessels, aircraft, cash, and real property) and

(II) by type of disposition (sales, remissions, cancellations, placed into official use, sharing with State and local agencies, and destructions).

(2) The Fund shall be subject to audits conducted by the Comptroller General of the United States, under such conditions as the Comptroller General determines appropriate.

(f) Authorization of appropriations

(1) There are hereby appropriated from the Fund such sums as may be necessary to carry out the purposes set forth in subsection (a)(1) of this section.

(2)(A) Subject to subparagraph (B), there are authorized to be appropriated from the Fund not to exceed $20,000,000 for each fiscal year to carry out the purposes set forth in subsections (a)(3) and (b) for such fiscal year.

(B) Of the amount authorized to be appropriated under subparagraph (A), not to exceed the following, shall be available to carry out the purposes set forth in subsection (a)(3) of this section:

(i) $14,855,000 for fiscal year 1991.

(ii) $15,598,000 for fiscal year 1992.

(3) At the end of each fiscal year, any unobligated amount in excess of $15,000,000 remaining in the Fund shall be deposited into the general fund of the Treasury of the United States.

19 U.S.C. § 2484
Trade Act of 1974, Public Law 93–618, sec. 606
Annual report on countries associated with entry of illicit controlled substances into the United States

Chapter 12. Trade Act of 1974

§ 2484. International drug control[1]

The President shall submit a report to Congress at least once each calendar year listing those foreign countries in which narcotic drugs and other controlled substances (as listed under section 812 of Title 21) are produced, processed, or transported for unlawful entry into the United States. Such report shall include a description of the measures such countries are taking to prevent such production, processing, or transport.

[1] Public Law 93–618, Title VI, § 606, Jan. 3, 1975, 88 Stat. 2073.

19 U.S.C. §§ 2491–2495
Trade Act of 1974, Public Law 93–618, secs. 801–805
Tariff treatment of merchandise from countries associated with entry of illicit controlled substances into the United States

§ 2491. Short title [1]

This subchapter may be cited as the "Narcotics Control Trade Act".

§ 2492. Tariff treatment of products of uncooperative major drug producing or drug-transit countries [2]

(a) Required action by President

Subject to subsection (b) of this section, for every major drug producing country and every major drug-transit country, the President shall, on or after March 1, 1987, and March 1 of each succeeding year, to the extent considered necessary by the President to achieve the purposes of this subchapter—

(1) deny to any or all of the products of that country tariff treatment under the Generalized System of Preferences, the Caribbean Basin Economic Recovery Act, or any other law providing preferential tariff treatment;

(2) apply to any or all of the dutiable products of that country an additional duty at a rate not to exceed 50 percent ad valorem or the specific rate equivalent;

(3) apply to one or more duty-free products of that country a duty at a rate not to exceed 50 percent ad valorem;

(4) take the steps described in subsection (d)(1) or (d)(2) of this section, or both, to curtail air transportation between the United States and that country;

(5) withdraw the personnel and resources of the United States from participation in any arrangement with that country for the pre-clearance of customs by visitors between the United States and that country; or

(6) take any combination of the actions described in paragraphs (1) through (5).

(b) Certifications; Congressional action

(1)(A) Subject to paragraph (3), subsection (a) of this section shall not apply with respect to a country if the President determines and certifies to the Congress, at the time of the submission of the report required by section 2291h of Title 22, that—

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[1] Public Law 93–618, Title VIII, § 801, as added Public Law 99–570, Title IX, § 9001, Oct. 27, 1986, 100 Stat. 3207–164.

[2] Public Law 93–618, Title VIII, § 802, as added Public Law 99–570, Title IX, § 9001, Oct. 27, 1986, 100 Stat. 3207–164, and amended by Public Law 100–204, Title VIII, § 806(a), Dec. 22, 1987, 101 Stat. 1398; Public Law 100–690, Title IV, § 4408, Nov. 18, 1988, 102 Stat. 4281; Public Law 101–231, § 17(h)(1)–(4), Dec. 13, 1989, 103 Stat. 1965; Public Law 106–36, Title I, § 1001(a)(8), June 25, 1999, 113 Stat. 131.

(i) during the previous year the country has cooperated fully with the United States, or has taken adequate steps on its own—

(I) in satisfying the goals agreed to in an applicable bilateral narcotics agreement with the United States (as described in paragraph (B)) or a multilateral agreement which achieves the objectives of paragraph (B),

(II) in preventing narcotic and psychotropic drugs and other controlled substances produced or processed, in whole or in part, in such country or transported through such country, from being sold illegally within the jurisdiction of such country to United States Government personnel or their dependents or from being transported, directly or indirectly, into the United States,

(III) in preventing and punishing the laundering in that country of drug-related profits or drug-related moneys, and

(IV) in preventing and punishing bribery and other forms of public corruption which facilitate the illicit production, processing, or shipment of narcotic and psychotropic drugs and other controlled substances, or which discourage the investigation and prosecution of such acts; or

(ii) for a country that would not otherwise qualify for certification under clause (i), the vital national interests of the United States require that subsection (a) of this section not be applied with respect to that country.

(B) A bilateral narcotics agreement referred to in subparagraph (A)(i)(I) is an agreement between the United States and a foreign country in which the foreign country agrees to take specific activities, including, where applicable, efforts to—

(i) reduce drug production, drug consumption, and drug trafficking within its territory, including activities to address illicit crop eradication and crop substitution;

(ii) increase drug interdiction and enforcement;

(iii) increase drug education and treatment programs;

(iv) increase the identification of and elimination of illicit drug laboratories;

(v) increase the identification and elimination of the trafficking of essential precursor chemicals for the use in production of illegal drugs;

(vi) increase cooperation with United States drug enforcement officials; and

(vii) where applicable, increase participation in extradition treaties, mutual legal assistance provisions directed at money laundering, sharing of evidence, and other initiatives for cooperative drug enforcement.

(C) A country which in the previous year was designated as a major drug producing country or a major drug-transit country may not be determined to be cooperating fully under subparagraph (A)(i) unless it has in place a bilateral narcotics agreement with the United States or a multilateral agreement which achieves the objectives of subparagraph (B).

(D) If the President makes a certification with respect to a country pursuant to subparagraph (A)(ii), he shall include in such certification—

(i) a full and complete description of the vital national interests placed at risk if action is taken pursuant to subsection (a) of this section with respect to that country; and

(ii) a statement weighing the risk described in clause (i) against the risks posed to the vital national interests of the United States by the failure of such country to cooperate fully with the United States in combating narcotics or to take adequate steps to combat narcotics on its own.

(E) The President may make a certification under subparagraph (A)(i) with respect to a major drug producing country or drug-transit country which is also a producer of licit opium only if the President determines that such country has taken steps to prevent significant diversion of its licit cultivation and production into the illicit market, maintains production and stockpiles at levels no higher than those consistent with licit market demand, and prevents illicit cultivation and production.

(2) In determining whether to make the certification required by paragraph (1) with respect to a country, the President shall consider the following:

(A) Have the actions of the government of that country resulted in the maximum reductions in illicit drug production which were determined to be achievable pursuant to section 2291(e)(4) of Title 22? In the case of a major drug producing country, the President shall give foremost consideration, in determining whether to make the certification required by paragraph (1), to whether the government of that country has taken actions which have resulted in such reductions.

(B) Has that government taken the legal and law enforcement measures to enforce in its territory, to the maximum extent possible, the elimination of illicit cultivation and the suppression of illicit manufacturing of and trafficking in narcotic and psychotropic drugs and other controlled substances, as evidenced by seizures of such drugs and substances and of illicit laboratories and the arrest and prosecution of violators involved in the traffic in such drugs and substances significantly affecting the United States?

(C) Has that government taken the legal and law enforcement steps necessary to eliminate, to the maximum extent possible, the laundering in that country of drug-related profits or drug-related moneys, as evidenced by—

(i) the enactment and enforcement by that government of laws prohibiting such conduct,

(ii) that government entering into, and cooperating under the terms of, mutual legal assistance agreements with the United States governing (but not limited to) money laundering, and

(iii) the degree to which that government otherwise cooperates with United States law enforcement authorities on anti-money laundering efforts?

(D) Has that government taken the legal and law enforcement steps necessary to eliminate, to the maximum extent possible, bribery and other forms of public corruption which facilitate the illicit production, processing, or shipment of narcotic and psychotropic drugs and other controlled substances, or

which discourage the investigation and prosecution of such acts, as evidenced by the enactment and enforcement of laws prohibiting such conduct?

(E) Has that government, as a matter of government policy, encouraged or facilitated the production or distribution of illicit narcotic and psychotropic drugs and other controlled substances?

(F) Does any senior official of that government engage in, encourage, or facilitate the production or distribution of illicit narcotic and psychotropic drugs and other controlled substances?

(G) Has that government investigated aggressively all cases in which any member of an agency of the United States Government engaged in drug enforcement activities since January 1, 1985, has been the victim of acts or threats of violence, inflicted by or with the complicity of any law enforcement or other officer of such country or any political subdivision thereof, and has energetically sought to bring the perpetrators of such offense or offenses to justice?

(H) Having been requested to do so by the United States Government, does that government fail to provide reasonable cooperation to lawful activities of United States drug enforcement agents, including the refusal of permission to such agents engaged in interdiction of aerial smuggling into the United States to pursue suspected aerial smugglers a reasonable distance into the airspace of the requested country?

(I) Has that government made necessary changes in legal codes in order to enable law enforcement officials to move more effectively against narcotics traffickers, such as new conspiracy laws and new asset seizure laws?

(J) Has that government expeditiously processed United States extradition requests relating to narcotics trafficking?

(K) Has that government refused to protect or give haven to any known drug traffickers, and has it expeditiously processed extradition requests relating to narcotics trafficking made by other countries?

(3) Subsection (a) of this section shall apply to a country without regard to paragraph (1) of this subsection if the Congress enacts, within 45 days of continuous session after receipt of a certification under paragraph (1), a joint resolution disapproving the determination of the President contained in that certification.

(4) If the President takes action under subsection (a) of this section, that action shall remain in effect until—

(A) the President makes the certification under paragraph (1), a period of 45 days of continuous session of Congress elapses, and during that period the Congress does not enact a joint resolution of disapproval; or

(B) the President submits at any other time a certification of the matters described in paragraph (1) with respect to that country, a period of 45 days of continuous session of Congress elapses, and during that period the Congress does not enact a joint resolution of disapproving the determination contained in that certification.

(5) For the purpose of expediting the consideration and enactment of joint resolutions under paragraphs (3) and (4)—

(A) a motion to proceed to the consideration of any such joint resolution after it has been reported by the Committee on Ways and Means shall be treated as highly privileged in the House of Representatives; and

(B) a motion to proceed to the consideration of any such joint resolution after it has been reported by the Committee on Finance shall be treated as privileged in the Senate.

(c) Duration of action

The action taken by the President under paragraph (1), (2), or (3) of subsection (a) of this section shall apply to the products of a foreign country that are entered, or withdrawn from warehouse for consumption, during the period that such action is in effect.

(d) Presidential action regarding aviation

(1)(A) The President is authorized to notify the government of a country against which is imposed the sanction described in subsection (a)(4) of this section of his intention to suspend the authority of foreign air carriers owned or controlled by the government or nationals of that country to engage in foreign air transportation to or from the United States.

(B) Within 10 days after the date of notification of a government under subparagraph (A), the Secretary of Transportation shall take all steps necessary to suspend at the earliest possible date the authority of any foreign air carrier owned or controlled, directly or indirectly, by the government or nationals of that country to engage in foreign air transportation to or from the United States, notwithstanding any agreement relating to air services.

(C) The President may also direct the Secretary of Transportation to take such steps as may be necessary to suspend the authority of any air carrier to engage in foreign air transportation between the United States and that country.

(2)(A) The President may direct the Secretary of State to terminate any air service agreement between the United States and a country against which the sanction described in subsection (a)(4) of this section is imposed in accordance with the provisions of that agreement.

(B) Upon termination of an agreement under this paragraph, the Secretary of Transportation shall take such steps as may be necessary to revoke at the earliest possible date the right of any foreign air carrier owned, or controlled, directly or indirectly, by the government or nationals of that country to engage in foreign air transportation to or from the United States.

(C) Upon termination of an agreement under this paragraph, the Secretary of Transportation may also revoke the authority of any air carrier to engage in foreign air transportation between the United States and that country.

(3) The Secretary of Transportation may provide for such exceptions from paragraphs (1) and (2) as the Secretary considers necessary to provide for emergencies in which the safety of an aircraft or its crew or passengers is threatened.

(4) For purposes of this subsection, the terms "air transportation", "air carrier", "foreign air carrier" and "foreign air transportation" have the meanings such terms have under section 40102(a) of Title 49.

(e) Standards and guidelines for determining major drug-transit countries

For each calendar year, the Secretary of State, after consultation with the appropriate committees of the Congress, shall establish numerical standards and other guidelines for determining which countries will be considered to be major drug-transit countries under section 2495(3)(A) and (B) of this title.

§ 2493. Sugar quota [3]

Notwithstanding any other provision of law, the President may not allocate any limitation imposed on the quantity of sugar to any country which has a Government involved in the trade of illicit narcotics or is failing to cooperate with the United States in narcotics enforcement activities as defined in section 2492(b) of this title as determined by the President.

§ 2494. Progress reports [4]

The President shall include as a part of the annual report required under section 2291h of Title 22 an evaluation of progress that each major drug producing country and each major drug-transit country has made during the reporting period in achieving the objectives set forth in section 2492(b) of this title.

§ 2495. Definitions [5]

For purposes of this subchapter—

(1) continuity of a session of Congress is broken only by an adjournment of the Congress sine die, and the days on which either House is not in session because of an adjournment of more than three days to a day certain are excluded in the computation of the period indicated;

(2) the term "major drug producing country" means a country that illicitly produces during a fiscal year 5 metric tons or more of opium or opium derivative, 500 metric tons or more of coca, or 500 metric tons or more of marijuana;

(3) the term "major drug-transit country" means a country—

(A) that is a significant direct source of illicit narcotic or psychotropic drugs or other controlled substances significantly affecting the United States;

(B) through which are transported such drugs or substances; or

(C) through which significant sums of drug-related profits or monies are laundered with the knowledge or complicity of the government; and

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[3] Public Law 93–618, Title VIII, § 803, as added Public Law 99–570, Title IX, § 9001, Oct. 27, 1986, 100 Stat. 3207–165.

[4] Public Law 93–618, Title VIII, § 804, as added Public Law 99–570, Title IX, § 9001, Oct. 27, 1986, 100 Stat. 3207–166, and amended by Public Law 106–36, Title I, § 1001(a)(9), June 25, 1999, 113 Stat. 131.

[5] Public Law 93–618, Title VIII, § 805, as added Public Law 99–570, Title IX, § 9001, Oct. 27, 1986, 100 Stat. 3207–166, and amended by Public Law 101–231, § 17(h)(5), Dec. 13, 1989, 103 Stat. 1965; Public Law 106–36, Title I, § 1001(a)(10), June 25, 1999, 113 Stat. 131.

(4) the term "narcotic and psychotropic drugs and other controlled substances" has the same meaning as is given by any applicable international narcotics control agreement or domestic law of the country or countries concerned.

20 U.S.C. § 1011i
Higher Education Act of 1965, Public Law 89–329, sec. 120
Ineligibility for Federal funds for failure to maintain a drug abuse and alcohol abuse program

Title 20. Education

Chapter 28. Higher Education Resources and Student Assistance

§ 1011i. Drug and alcohol abuse prevention [1]

(a) Restriction on eligibility

Notwithstanding any other provision of law, no institution of higher education shall be eligible to receive funds or any other form of financial assistance under any Federal program, including participation in any federally funded or guaranteed student loan program, unless the institution certifies to the Secretary that the institution has adopted and has implemented a program to prevent the use of illicit drugs and the abuse of alcohol by students and employees that, at a minimum, includes—

(1) the annual distribution to each student and employee of—

(A) standards of conduct that clearly prohibit, at a minimum, the unlawful possession, use, or distribution of illicit drugs and alcohol by students and employees on the institution's property or as part of any of the institution's activities;

(B) a description of the applicable legal sanctions under local, State, or Federal law for the unlawful possession or distribution of illicit drugs and alcohol;

(C) a description of the health-risks associated with the use of illicit drugs and the abuse of alcohol;

(D) a description of any drug or alcohol counseling, treatment, or rehabilitation or re-entry programs that are available to employees or students; and

(E) a clear statement that the institution will impose sanctions on students and employees (consistent with local, State, and Federal law), and a description of those sanctions, up to and including expulsion or termination of employment and referral for prosecution, for violations of the standards of conduct required by subparagraph (A); and

(2) a biennial review by the institution of the institution's program to—

[1] Public Law 89–329, Title I, § 120, as added Public Law 105–244, Title I, § 101(a), Oct. 7, 1998, 112 Stat. 1596.

(A) determine the program's effectiveness and implement changes to the program if the changes are needed; and

(B) ensure that the sanctions required by paragraph (1)(E) are consistently enforced.

(b) Information availability

Each institution of higher education that provides the certification required by subsection (a) of this section shall, upon request, make available to the Secretary and to the public a copy of each item required by subsection (a)(1) as well as the results of the biennial review required by subsection (a)(2) of this section.

(c) Regulations

(1) In general

The Secretary shall publish regulations to implement and enforce the provisions of this section, including regulations that provide for—

(A) the periodic review of a representative sample of programs required by subsection (a) of this section; and

(B) a range of responses and sanctions for institutions of higher education that fail to implement their programs or to consistently enforce their sanctions, including information and technical assistance, the development of a compliance agreement, and the termination of any form of Federal financial assistance.

(2) Rehabilitation program

The sanctions required by subsection (a)(1)(E) of this section may include the completion of an appropriate rehabilitation program.

(d) Appeals

Upon determination by the Secretary to terminate financial assistance to any institution of higher education under this section, the institution may file an appeal with an administrative law judge before the expiration of the 30-day period beginning on the date such institution is notified of the decision to terminate financial assistance under this section. Such judge shall hold a hearing with respect to such termination of assistance before the expiration of the 45-day period beginning on the date that such appeal is filed. Such judge may extend such 45-day period upon a motion by the institution concerned. The decision of the judge with respect to such termination shall be considered to be a final agency action.

(e) Alcohol and drug abuse prevention grants

(1) Program authority

The Secretary may make grants to institutions of higher education or consortia of such institutions, and enter into contracts with such institutions, consortia, and other organizations, to develop, implement, operate, improve, and disseminate programs of prevention, and education (including treatment-referral) to reduce and eliminate the illegal use of drugs

and alcohol and the violence associated with such use. Such grants or contracts may also be used for the support of a higher education center for alcohol and drug abuse prevention that will provide training, technical assistance, evaluation, dissemination, and associated services and assistance to the higher education community as determined by the Secretary and institutions of higher education.

(2) Awards

Grants and contracts shall be awarded under paragraph (1) on a competitive basis.

(3) Applications

An institution of higher education, a consortium of such institutions, or another organization that desires to receive a grant or contract under paragraph (1) shall submit an application to the Secretary at such time, in such manner, and containing or accompanied by such information as the Secretary may reasonably require by regulation.

(4) Additional requirements

(A) Participation

In awarding grants and contracts under this subsection the Secretary shall make every effort to ensure—

(i) the equitable participation of private and public institutions of higher education (including community and junior colleges); and

(ii) the equitable geographic participation of such institutions.

(B) Consideration

In awarding grants and contracts under this subsection the Secretary shall give appropriate consideration to institutions of higher education with limited enrollment.

(5) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection $5, 000,000 for fiscal year 1999 and such sums as may be necessary for each of the 4 succeeding fiscal years.

(f) National recognition awards

(1) Purpose

It is the purpose of this subsection to provide models of innovative and effective alcohol and drug abuse prevention programs in higher education and to focus national attention on exemplary alcohol and drug abuse prevention efforts.

(2) Awards

(A) In general

The Secretary shall make 5 National Recognition Awards for outstanding alcohol prevention programs and 5 National Recognition Awards for outstanding drug abuse

prevention programs, on an annual basis, to institutions of higher education that—

(i) have developed and implemented innovative and effective alcohol prevention programs or drug abuse prevention programs; and

(ii) with respect to an application for an alcohol prevention program award, demonstrate in the application submitted under paragraph (3) that the institution has undertaken efforts designed to change the culture of college drinking consistent with the review criteria described in paragraph (3)(C)(iii).

(B) Ceremony

The awards shall be made at a ceremony in Washington, D.C.

(C) Document

The Secretary shall publish a document describing the alcohol and drug abuse prevention programs of institutions of higher education that receive the awards under this subsection and disseminate the document nationally to all public and private secondary school guidance counselors for use by secondary school juniors and seniors preparing to enter an institution of higher education. The document shall be disseminated not later than January 1 of each academic year.

(D) Amount and use

Each institution of higher education selected to receive an award under this subsection shall receive an award in the amount of $50,000. Such award shall be used for the maintenance and improvement of the institution's outstanding prevention program for the academic year following the academic year for which the award is made.

(3) Application

(A) In general

Each institution of higher education desiring an award under this subsection shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require. Each such application shall contain—

(i) a clear description of the goals and objectives of the prevention program of the institution;

(ii) a description of program activities that focus on alcohol or drug policy issues, policy development, modification, or refinement, policy dissemination and implementation, and policy enforcement;

(iii) a description of activities that encourage student and employee participation and involvement in activity development and implementation;

(iv) the objective criteria used to determine the effectiveness of the methods used in such programs and

the means used to evaluate and improve the programs' efforts;

(v) a description of special initiatives used to reduce high-risk behavior or increase low-risk behavior; and

(vi) a description of coordination and networking efforts that exist in the community in which the institution is located for purposes of such programs.

(B) Application review

The Secretary shall appoint a committee to review applications submitted under this paragraph. The committee may include representatives of Federal departments or agencies the programs of which include alcohol abuse prevention and education efforts and drug abuse prevention and education efforts, directors or heads (or their representatives) of professional associations that focus on alcohol and drug abuse prevention efforts, and non-Federal scientists who have backgrounds in social science evaluation and research methodology and in education. Decisions of the committee shall be made directly to the Secretary without review by any other entity in the Department.

(C) Review criteria

The committee described in subparagraph (B) shall develop specific review criteria for reviewing and evaluating applications submitted under this paragraph. The review criteria shall include—

(i) measures of the effectiveness of the program of the institution, that includes changes in the campus alcohol or other drug environment or the climate and changes in alcohol or other drug use before and after the initiation of the program;

(ii) measures of program institutionalization, including—

(I) an assessment of needs of the institution;

(II) the institution's alcohol and drug policies, staff and faculty development activities, drug prevention criteria, student, faculty, and campus community involvement; and

(III) whether the program will be continued after the cessation of Federal funding; and

(iii) with respect to an application for an alcohol prevention program award, criteria for determining whether the institution has policies in effect that—

(I) prohibit alcoholic beverage sponsorship of athletic events, and prohibit alcoholic beverage advertising inside athletic facilities;

(II) prohibit alcoholic beverage marketing on campus, which may include efforts to ban alcohol advertising in institutional publications or efforts to prohibit alcohol-related advertisements at campus events;

(III) establish or expand upon alcohol-free living arrangements for all college students;

(IV) establish partnerships with community members and organizations to further alcohol prevention efforts on campus and the areas surrounding campus; and

(V) establish innovative communications programs involving students and faculty in an effort to educate students about alcohol-related risks.

(4) Eligibility

In order to be eligible to receive a National Recognition Award an institution of higher education shall—

(A) offer an associate or baccalaureate degree;

(B) have established an alcohol abuse prevention and education program or a drug abuse prevention and education program;

(C) nominate itself or be nominated by others, such as professional associations or student organizations, to receive the award; and

(D) not have received an award under this subsection during the 5 academic years preceding the academic year for which the determination is made.

(5) Authorization of appropriations

(A) In general

There is authorized to be appropriated to carry out this subsection $750, 000 for fiscal year 1999.

(B) Availability

Funds appropriated under subparagraph (A) shall remain available until expended.

20 U.S.C. § 1091
Higher Education Act of 1965, Public Law 89–329, sec. 484
Suspension of student eligibility for drug-related offenses

§ 1091. Student eligibility [1]

(a) In general

In order to receive any grant, loan, or work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42, a student must—

(1) be enrolled or accepted for enrollment in a degree, certificate, or other program (including a program of study abroad approved for credit by the eligible institution at which such student is enrolled) leading to a recognized educational credential at an institution of higher education that is an eligible institution in accordance with the provisions of section 1094 of this title, except as provided in subsections (b)(3) and (b)(4) of this section, and not be enrolled in an elementary or secondary school;

(2) if the student is presently enrolled at an institution, be maintaining satisfactory progress in the course of study the student is pursuing in accordance with the provisions of subsection (c) of this section;

(3) not owe a refund on grants previously received at any institution under this subchapter and part C of subchapter I of chapter 34 of Title 42, or be in default on any loan from a student loan fund at any institution provided for in part D of this subchapter, or a loan made, insured, or guaranteed by the Secretary under this subchapter and part C of subchapter I of chapter 34 of Title 42 for attendance at any institution;

(4) file with the Secretary, as part of the original financial aid application process, a certification,,[2] which need not be notarized, but which shall include—

(A) a statement of educational purpose stating that the money attributable to such grant, loan, or loan guarantee will be used solely for expenses related to attendance or continued attendance at such institution; and

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[1] Public Law 89–329, Title IV, § 484, as added Public Law 99–498, Title IV, § 407(a), Oct. 17, 1986, 100 Stat. 1479, and amended by Public Law 99–603, Title I, § 121(a)(3), Nov. 6, 1986, 100 Stat. 3388; Public Law 100–50, § 15(7) to (9), June 3, 1987, 101 Stat. 356, 357; Public Law 100–369, §§ 1, 2, 6, July 18, 1988, 102 Stat. 835, 836; Public Law 100–525, § 2(g), Oct. 24, 1988, 102 Stat. 2611; Public Law 101–508, Title III, § 3005(a), Nov. 5, 1990, 104 Stat. 1388–27; Public Law 102–26, § 2(b), (c)(2), (d)(2)(A), Apr. 9, 1991, 105 Stat. 123, 124; Public Law 102–73, Title VIII, § 801(a), July 25, 1991, 105 Stat. 359; Public Law 102–325, Title IV, § 484(a), (b)(1), (c) to (h), July 23, 1992, 106 Stat. 615 to 619; Public Law 103–208, § 2(h)(13) to (25), Dec. 20, 1993, 107 Stat. 2476, 2477; Public Law 103–382, Title III, § 360A, Oct. 20, 1994, 108 Stat. 3969; Public Law 104–208, Div. C, Title V, § 507(b), Sept. 30, 1996, 110 Stat. 3009–673; Public Law 105–244, Title IV, § 483(a) to (f)(1), Oct. 7, 1998, 112 Stat. 1735, 1736.

[2] So in original. The second comma probably should not appear.

(B) such student's social security number, except that the provisions of this subparagraph shall not apply to a student from the Republic of the Marshall Islands, the Federated States of Micronesia, or the Republic of Palau; [3]

(5) be a citizen or national of the United States, a permanent resident of the United States, able to provide evidence from the Immigration and Naturalization Service that he or she is in the United States for other than a temporary purpose with the intention of becoming a citizen or permanent resident,[4] a citizen of any one of the Freely Associated States.

(b) Eligibility for student loans

(1) In order to be eligible to receive any loan under this subchapter and part C of subchapter I of chapter 34 of Title 42 (other than a loan under section 1078–2 or 1078–3 of this title) for any period of enrollment, a student who is not a graduate or professional student (as defined in regulations of the Secretary), and who is enrolled in a program at an institution which has a participation agreement with the Secretary to make awards under subpart 1 of part A of this subchapter, shall—

(A) (i) have received a determination of eligibility or ineligibility for a Pell Grant under such subpart 1 for such period of enrollment; and (ii) if determined to be eligible, have filed an application for a Pell Grant for such enrollment period; or

(B) have (A) filed an application with the Pell Grant processor for such institution for such enrollment period, and (B) received from the financial aid administrator of the institution a preliminary determination of the student's eligibility or ineligibility for a grant under such subpart 1.

(2) In order to be eligible to receive any loan under section 1078–1 of this title for any period of enrollment, a student shall—

(A) have received a determination of need for a loan under section 1078(a)(2)(B) of this title;

(B) if determined to have need for a loan under section 1078 of this title, have applied for such a loan; and

(C) has applied for a loan under section 1078–8 of this title, if such student is eligible to apply for such a loan.

(3) A student who—

(A) is carrying at least one-half the normal full-time work load for the course of study that the student is pursuing, as determined by an eligible institution, and

(B) is enrolled in a course of study necessary for enrollment in a program leading to a degree or certificate,

shall be, notwithstanding paragraph (1) of subsection (a) of this section, eligible to apply for loans under part B or C of this subchapter. The eligibility described in this paragraph shall be restricted to one 12-month period.

(4) A student who—

(A) is carrying at least one-half the normal full-time work load for the course of study the student is pursuing, as determined by the institution, and

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[3] So in original. Probably should be followed by "and".
[4] So in original. Probably should be followed by "or".

(B) is enrolled or accepted for enrollment in a program at an eligible institution necessary for a professional credential or certification from a State that is required for employment as a teacher in an elementary or secondary school in that State,

shall be, notwithstanding paragraph (1) of subsection (a) of this section, eligible to apply for loans under part B, C, or D of this subchapter or work-study assistance under part C of subchapter I of chapter 34 of Title 42.

(5) Notwithstanding any other provision of this subsection, no incarcerated student is eligible to receive a loan under this subchapter and part C of subchapter I of chapter 34 of Title 42.

(c) Satisfactory progress

(1) For the purpose of subsection (a)(2) of this section, a student is maintaining satisfactory progress if—

(A) the institution at which the student is in attendance, reviews the progress of the student at the end of each academic year, or its equivalent, as determined by the institution, and

(B) the student has a cumulative C average, or its equivalent or academic standing consistent with the requirements for graduation, as determined by the institution, at the end of the second such academic year.

(2) Whenever a student fails to meet the eligibility requirements of subsection (a)(2) of this section as a result of the application of this subsection and subsequent to that failure the student has academic standing consistent with the requirements for graduation, as determined by the institution, for any grading period, the student may, subject to this subsection, again be eligible under subsection (a)(2) of this section for a grant, loan, or work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42.

(3) Any institution of higher education at which the student is in attendance may waive the provisions of paragraph (1) or paragraph (2) of this subsection for undue hardship based on—

(A) the death of a relative of the student,

(B) the personal injury or illness of the student, or

(C) special circumstances as determined by the institution.

(d) Students who are not high school graduates

In order for a student who does not have a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate, to be eligible for any assistance under subparts 1, 3, and 4 of part A and parts B, C, and D of this subchapter and part C of subchapter I of chapter 34 of Title 42, the student shall meet one of the following standards:

(1) The student shall take an independently administered examination and shall achieve a score, specified by the Secretary, demonstrating that such student can benefit from the education or training being offered. Such examination shall be approved by the Secretary on the basis of compliance with such standards for development, administration, and scoring as the Secretary may prescribe in regulations.

(2) The student shall be determined as having the ability to benefit from the education or training in accordance with such

process as the State shall prescribe. Any such process described or approved by a State for the purposes of this section shall be effective 6 months after the date of submission to the Secretary unless the Secretary disapproves such process. In determining whether to approve or disapprove such process, the Secretary shall take into account the effectiveness of such process in enabling students without high school diplomas or the equivalent thereof to benefit from the instruction offered by institutions utilizing such process, and shall also take into account the cultural diversity, economic circumstances, and educational preparation of the populations served by the institutions.

(3) The student has completed a secondary school education in a home school setting that is treated as a home school or private school under State law.

(e) Certification for GSL eligibility

Each eligible institution may certify student eligibility for a loan by an eligible lender under part B of this subchapter prior to completing the review for accuracy of the information submitted by the applicant required by regulations issued under this subchapter and part C of subchapter I of chapter 34 of Title 42, if—

(1) checks for the loans are mailed to the eligible institution prior to disbursements;

(2) the disbursement is not made until the review is complete; and

(3) the eligible institution has no evidence or documentation on which the institution may base a determination that the information submitted by the applicant is incorrect.

(f) Loss of eligibility for violation of loan limits

(1) No student shall be eligible to receive any grant, loan, or work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42 if the eligible institution determines that the student fraudulently borrowed in violation of the annual loan limits under part B, part C, or part D of this subchapter in the same academic year, or if the student fraudulently borrowed in excess of the aggregate maximum loan limits under such part B, part C, or part D.

(2) If the institution determines that the student inadvertently borrowed amounts in excess of such annual or aggregate maximum loan limits, such institution shall allow the student to repay any amount borrowed in excess of such limits prior to certifying the student's eligibility for further assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42.

(g) Verification of immigration status

(1) In general

The Secretary shall implement a system under which the statements and supporting documentation, if required, of an individual declaring that such individual is in compliance with the requirements of subsection (a)(5) of this section shall be verified prior to the individual's receipt of a grant, loan, or

work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42.

(2) Special rule

The documents collected and maintained by an eligible institution in the admission of a student to the institution may be used by the student in lieu of the documents used to establish both employment authorization and identity under section 1324a(b)(1)(B) of Title 8 to verify eligibility to participate in work-study programs under part C of subchapter I of chapter 34 of Title 42.

(3) Verification mechanisms

The Secretary is authorized to verify such statements and supporting documentation through a data match, using an automated or other system, with other Federal agencies that may be in possession of information relevant to such statements and supporting documentation.

(4) Review

In the case of such an individual who is not a citizen or national of the United States, if the statement described in paragraph (1) is submitted but the documentation required under paragraph (2) is not presented or if the documentation required under paragraph (2)(A) is presented but such documentation is not verified under paragraph (3)—

(A) the institution—

(i) shall provide a reasonable opportunity to submit to the institution evidence indicating a satisfactory immigration status, and

(ii) may not delay, deny, reduce, or terminate the individual's eligibility for the grant, loan, or work assistance on the basis of the individual's immigration status until such a reasonable opportunity has been provided; and

(B) if there are submitted documents which the institution determines constitute reasonable evidence indicating such status—

(i) the State shall transmit to the Immigration and Naturalization Service either photostatic or other similar copies of such documents, or information from such documents, as specified by the Immigration and Naturalization Service, for official verification,

(ii) pending such verification, the institution may not delay, deny, reduce, or terminate the individual's eligibility for the grant, loan, or work assistance on the basis of the individual's immigration status, and

(iii) the institution shall not be liable for the consequences of any action, delay, or failure of the Service to conduct such verification.

(h) Limitations of enforcement actions against institutions

The Secretary shall not take any compliance, disallowance, penalty, or other regulatory action against an institution of higher education with respect to any error in the institution's determination to make a student eligible for a grant, loan, or work assistance based on citizenship or immigration status—

(1) if the institution has provided such eligibility based on a verification of satisfactory immigration status by the Immigration and Naturalization Service,

(2) because the institution, under subsection (h)(4)(A)(i) of this section, was required to provide a reasonable opportunity to submit documentation, or

(3) because the institution, under subsection (h)(4)(B)(i) of this section, was required to wait for the response of the Immigration and Naturalization Service to the institution's request for official verification of the immigration status of the student.

(i) Validity of loan guarantees for loan payments made before immigration status verification completed

Notwithstanding subsection (h) of this section, if—

(1) a guaranty is made under this subchapter and part C of subchapter I of chapter 34 of Title 42 for a loan made with respect to an individual,

(2) at the time the guaranty is entered into, the provisions of subsection (h) of this section had been complied with,

(3) amounts are paid under the loan subject to such guaranty, and

(4) there is a subsequent determination that, because of an unsatisfactory immigration status, the individual is not eligible for the loan,

the official of the institution making the determination shall notify and instruct the entity making the loan to cease further payments under the loan, but such guaranty shall not be voided or otherwise nullified with respect to such payments made before the date the entity receives the notice.

(j) Assistance under subparts 1 and 3 of part A, and part C

Notwithstanding any other provision of law, a student shall be eligible until September 30, 2004, for assistance under subparts 1 and 3 of part A of this subchapter, and part C of subchapter 1 of chapter 34 of Title 42, if the student is otherwise qualified and—

(1) is a citizen of any one of the Freely Associated States and attends an institution of higher education in a State or a public or nonprofit private institution of higher education in the Freely Associated States; or

(2) meets the requirements of subsection (a)(5) of this section and attends a public or nonprofit private institution of higher education in any one of the Freely Associated States.

(k) Special rule for correspondence courses

A student shall not be eligible to receive grant, loan, or work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42 for a correspondence course unless such course

is part of a program leading to an associate, bachelor or graduate degree.

(l) Courses offered through telecommunications

(1) Relation to correspondence courses

(A) In general

A student enrolled in a course of instruction at an institution of higher education that is offered in whole or in part through telecommunications and leads to a recognized certificate for a program of study of 1 year or longer, or a recognized associate, baccalaureate, or graduate degree, conferred by such institution, shall not be considered to be enrolled in correspondence courses unless the total amount of telecommunications and correspondence courses at such institution equals or exceeds 50 percent of the total amount of all courses at the institution.

(B) Requirement

An institution of higher education referred to in subparagraph (A) is an institution of higher education—

(i) that is not an institute or school described in section 2471(4)(C) of this title; and

(ii) for which at least 50 percent of the programs of study offered by the institution lead to the award of a recognized associate, baccalaureate, or graduate degree.

(2) Restriction or reductions of financial aid

A student's eligibility to receive grants, loans, or work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42 shall be reduced if a financial aid officer determines under the discretionary authority provided in section 1087tt of this title that telecommunications instruction results in a substantially reduced cost of attendance to such student.

(3) Special rule

For award years prior to July 23, 1992, the Secretary shall not take any compliance, disallowance, penalty, or other action against a student or an eligible institution when such action arises out of such institution's prior award of student assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42 if the institution demonstrates to the satisfaction of the Secretary that its course of instruction would have been in conformance with the requirements of this subsection.

(4) "Telecommunications", defined

For the purposes of this subsection, the term "telecommunications" means the use of television, audio, or computer transmission, including open broadcast, closed circuit, cable, microwave, or satellite, audio conferencing, computer conferencing,

or video cassettes or discs, except that such term does not include a course that is delivered using video cassette or disc recordings at such institution and that is not delivered in person to other students of that institution.

(m) Students with a first baccalaureate or professional degree

A student shall not be ineligible for assistance under parts B, C, and D of this subchapter and part C of subchapter I of chapter 34 of Title 42 because such student has previously received a baccalaureate or professional degree.

(n) Data base matching

To enforce the Selective Service registration provisions of section 1113 of Public Law 97–252, the Secretary shall conduct data base matches with the Selective Service, using common demographic data elements. Appropriate confirmation, through an application output document or through other means, of any person's registration shall fulfill the requirement to file a separate statement of compliance. In the absence of a confirmation from such data matches, an institution may also use data or documents that support either the student's registration, or the absence of a registration requirement for the student, to fulfill the requirement to file a separate statement of compliance. The mechanism for reporting the resolution of nonconfirmed matches shall be prescribed by the Secretary in regulations.

(o) Study abroad

Nothing in this chapter shall be construed to limit or otherwise prohibit access to study abroad programs approved by the home institution at which a student is enrolled. An otherwise eligible student who is engaged in a program of study abroad approved for academic credit by the home institution at which the student is enrolled shall be eligible to receive grant, loan, or work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42, without regard to whether such study abroad program is required as part of the student's degree program.

(p) Verification of social security number

The Secretary of Education, in cooperation with the Commissioner of the Social Security Administration, shall verify any social security number provided by a student to an eligible institution under subsection (a)(4) of this section and shall enforce the following conditions:

(1) Except as provided in paragraphs (2) and (3), an institution shall not deny, reduce, delay, or terminate a student's eligibility for assistance under this part because social security number verification is pending.

(2) If there is a determination by the Secretary that the social security number provided to an eligible institution by a student is incorrect, the institution shall deny or terminate the student's eligibility for any grant, loan, or work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42 until such time as the student provides documented

evidence of a social security number that is determined by the institution to be correct.

(3) If there is a determination by the Secretary that the social security number provided to an eligible institution by a student is incorrect, and a correct social security number cannot be provided by such student, and a loan has been guaranteed for such student under part B of this subchapter, the institution shall notify and instruct the lender and guaranty agency making and guaranteeing the loan, respectively, to cease further disbursements of the loan, but such guaranty shall not be voided or otherwise nullified with respect to such disbursements made before the date that the lender and the guaranty agency receives such notice.

(4) Nothing in this subsection shall permit the Secretary to take any compliance, disallowance, penalty, or other regulatory action against—

(A) any institution of higher education with respect to any error in a social security number, unless such error was a result of fraud on the part of the institution; or

(B) any student with respect to any error in a social security number, unless such error was a result of fraud on the part of the student.

(q) Verification of income data

(1) Confirmation with IRS

The Secretary of Education, in cooperation with the Secretary of the Treasury, is authorized to confirm with the Internal Revenue Service the adjusted gross income, Federal income taxes paid, filing status, and exemptions reported by applicants (including parents) under this subchapter and part C of subchapter I of chapter 34 of Title 42 on their Federal income tax returns for the purpose of verifying the information reported by applicants on student financial aid applications.

(2) Notification

The Secretary shall establish procedures under which an applicant is notified that the Internal Revenue Service will disclose to the Secretary tax return information as authorized under section 6103(l)(13) of Title 26.

(r) Suspension of eligibility for drug-related offenses

(1) In general

A student who has been convicted of any offense under any Federal or State law involving the possession or sale of a controlled substance shall not be eligible to receive any grant, loan, or work assistance under this subchapter and part C of subchapter I of chapter 34 of Title 42 during the period beginning on the date of such conviction and ending after the interval specified in the following table:

If convicted of an offense involving:	
The possession of a controlled substance:	**Ineligibility period is:**
First offense	1 year
Second offense	2 years
Third offense	Indefinite.
The sale of a controlled substance:	**Ineligibility period is:**
First offense	2 years
Second offense	Indefinite.

(2) Rehabilitation

A student whose eligibility has been suspended under paragraph (1) may resume eligibility before the end of the ineligibility period determined under such paragraph if—

(A) the student satisfactorily completes a drug rehabilitation program that—

(i) complies with such criteria as the Secretary shall prescribe in regulations for purposes of this paragraph; and

(ii) includes two unannounced drug tests; or

(B) the conviction is reversed, set aside, or otherwise rendered nugatory.

(3) Definitions

In this subsection, the term "controlled substance" has the meaning given the term in section 802(6) of Title 21.

20 U.S.C. § 1232g(i)
General Education Act, Public Law 90–247, sec. 444
Family education and privacy rights with respect to education records do not preclude disclosure to parents of minor child's disciplinary violations involving illicit controlled substances

Chapter 31. General Provisions Concerning Education

§ 1232g. Family educational and privacy rights [1]

* * * * * * *

(i) Drug and alcohol violation disclosures

(1) In general

Nothing in this Act or the Higher Education Act of 1965 shall be construed to prohibit an institution of higher education from disclosing, to a parent or legal guardian of a student, information regarding any violation of any Federal, State, or local law, or of any rule or policy of the institution, governing the use or possession of alcohol or a controlled substance, regardless of whether that information is contained in the student's education records, if—

(A) the student is under the age of 21; and

(B) the institution determines that the student has committed a disciplinary violation with respect to such use or possession.

(2) State law regarding disclosure

Nothing in paragraph (1) shall be construed to supersede any provision of State law that prohibits an institution of higher education from making the disclosure described in subsection (a) of this section.

* * * * * * *

[1] Public Law 90–247, Title IV, § 444, formerly § 438, as added Public Law 93–380, Title V, § 513(a), Aug. 21, 1974, 88 Stat. 571, and amended by Public Law 105–244, Title IX, § 952, Oct. 7, 1998, 112 Stat. 1836.

20 U.S.C. §§ 7101–7165
Safe and Drug-Free Schools and Communities Act, Public Law 107–110, secs. 4001–4155

Chapter 70. Strengthening and Improvement of Elementary and Secondary Schools

§ 7101. Short title [1]

This part may be cited as the "Safe and Drug-Free Schools and Communities Act".

§ 7102. Purpose [2]

The purpose of this part is to support programs that prevent violence in and around schools; that prevent the illegal use of alcohol, tobacco, and drugs; that involve parents and communities; and that are coordinated with related Federal, State, school, and community efforts and resources to foster a safe and drug-free learning environment that supports student academic achievement, through the provision of Federal assistance to—

(1) States for grants to local educational agencies and consortia of such agencies to establish, operate, and improve local programs of school drug and violence prevention and early intervention;

(2) States for grants to, and contracts with, community-based organizations and public and private entities for programs of drug and violence prevention and early intervention, including community-wide drug and violence prevention planning and organizing activities;

(3) States for development, training, technical assistance, and coordination activities; and

(4) public and private entities to provide technical assistance; conduct training, demonstrations, and evaluation; and to provide supplementary services and community-wide drug and violence prevention planning and organizing activities for the prevention of drug use and violence among students and youth.

§ 7103. Authorization of appropriations [3]

There are authorized to be appropriated—

(1) $650,000,000 for fiscal year 2002, and such sums as may be necessary for each of the 5 succeeding fiscal years, for State grants under subpart 1; and

(2) such sums for fiscal year 2002, and for each of the 5 succeeding fiscal years, for national programs under subpart 2.

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[1] Public Law 89–10, Title IV, § 4001, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1734.
[2] Public Law 89–10, Title IV, § 4002, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1734.
[3] Public Law 89–10, Title IV, § 4003, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1734.

§ 7111. Reservations and allotments[4]

(a) Reservations

(1) In general

From the amount made available under section 7103(1) of this title to carry out this subpart for each fiscal year, the Secretary—

(A) shall reserve 1 percent or $4,750,000 (whichever is greater) of such amount for grants to Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands, to be allotted in accordance with the Secretary's determination of their respective needs and to carry out programs described in this subpart;

(B) shall reserve 1 percent or $4,750,000 (whichever is greater) of such amount for the Secretary of the Interior to carry out programs described in this subpart for Indian youth; and

(C) shall reserve 0.2 percent of such amount for Native Hawaiians to be used under section 7117 of this title to carry out programs described in this subpart.

(2) Other reservations

From the amount made available under section 7103(2) of this title to carry out subpart 2 for each fiscal year, the Secretary—

(A) may reserve not more than $2,000,000 for the national impact evaluation required by section 7132(a) of this title;

(B) notwithstanding section 3 of the No Child Left Behind Act of 2001,[5] shall reserve an amount necessary to make continuation grants to grantees under the Safe Schools/Healthy Students initiative (under the same terms and conditions as provided for in the grants involved).

(b) State allotments

(1) In general

Except as provided in paragraph (2), the Secretary shall, for each fiscal year, allot among the States—

(A) one-half of the remainder not reserved under subsection (a) of this section according to the ratio between the school-aged population of each State and the school-aged population of all the States; and

(B) one-half of such remainder according to the ratio between the amount each State received under section 6334 of this title for the preceding year and the sum of such amounts received by all the States.

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[4] Public Law 89–10, Title IV, § 4111, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1735.

[5] So in original. Probably should be "section 4 of the No Child Left Behind Act of 2001".

(2) Minimum

For any fiscal year, no State shall be allotted under this subsection an amount that is less than the greater of—

(A) one-half of 1 percent of the total amount allotted to all the States under this subsection; or

(B) the amount such State received for fiscal year 2001 under section 4111 as such section was in effect the day preceding January 8, 2002.

(3) Reallotment

(A) Reallotment for failure to apply

If any State does not apply for an allotment under this subpart for a fiscal year, the Secretary shall reallot the amount of the State's allotment to the remaining States in accordance with this section.

(B) Reallotment of unused funds

The Secretary may reallot any amount of any allotment to a State if the Secretary determines that the State will be unable to use such amount within 2 years of such allotment. Such reallotments shall be made on the same basis as allotments are made under paragraph (1).

(4) Definition

In this section the term "State" means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

(c) Limitation

Amounts appropriated under section 7103(2) of this title for a fiscal year may not be increased above the amounts appropriated under such section for the previous fiscal year unless the amounts appropriated under section 7103(1) of this title for the fiscal year involved are at least 10 percent greater that the amounts appropriated under such section 7103(1) of this title for the previous fiscal year.

§ 7112. Reservation of State funds for safe and drug-free schools [6]

(a) State reservation for the chief executive officer of a State

(1) In general

The chief executive officer of a State may reserve not more than 20 percent of the total amount allocated to a State under section 7111(b) of this title for each fiscal year to award competitive grants and contracts to local educational agencies, community-based organizations (including community antidrug coalitions) other public entities and private organizations, and consortia thereof. Such grants and contracts shall be used to carry out the comprehensive State plan described in section

[6] Public Law 89–10, Title IV, § 4112, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1736.

7113(a) of this title through programs or activities that complement and support activities of local educational agencies described in section 7115(b) of this title. Such officer shall award grants based on—

(A) the quality of the program or activity proposed; and

(B) how the program or activity meets the principles of effectiveness described in section 7115(a) of this title.

(2) Priority

In making such grants and contracts under this section, a chief executive officer shall give priority to programs and activities that prevent illegal drug use and violence for—

(A) children and youth who are not normally served by State educational agencies or local educational agencies; or

(B) populations that need special services or additional resources (such as youth in juvenile detention facilities, runaway or homeless children and youth, pregnant and parenting teenagers, and school dropouts).

(3) Special consideration

In awarding funds under paragraph (1), a chief executive officer shall give special consideration to grantees that pursue a comprehensive approach to drug and violence prevention that includes providing and incorporating mental health services related to drug and violence prevention in their program.

(4) Peer review

Grants or contracts awarded under this section shall be subject to a peer review process.

(5) Use of funds

Grants and contracts under this section shall be used to implement drug and violence prevention activities, including—

(A) activities that complement and support local educational agency activities under section 7115 of this title, including developing and implementing activities to prevent and reduce violence associated with prejudice and intolerance;

(B) dissemination of information about drug and violence prevention; and

(C) development and implementation of community-wide drug and violence prevention planning and organizing.

(6) Administrative costs

The chief executive officer of a State may use not more than 3 percent of the amount described in paragraph (1) for the administrative costs incurred in carrying out the duties of such officer under this section.

(b) In State distribution

(1) In general

A State educational agency shall distribute not less than 93 percent of the amount made available to the State under section 7111(b) of this title, less the amount reserved under subsection (a) of this section, to its local educational agencies.

(2) State administration costs

(A) In general

A State educational agency may use not more than 3 percent of the amount made available to the State under section 7111(b) of this title for each fiscal year less the amount reserved under subsection (a) of this section, for State educational agency administrative costs, including the implementation of the uniform management information and reporting system as provided for under subsection (c)(3) of this section.

(B) Additional amounts for the uniform management information system

In the case of fiscal year 2002, a State educational agency may, in addition to amounts provided for in subparagraph (A), use 1 percent of the amount made available to the State educational agency under section 7111(b) of this title for each fiscal year less the amount reserved under subsection (a) of this section, for implementation of the uniform management information and reporting system as provided for under subsection (c)(3) of this section.

(c) State activities

(1) In general

A State educational agency may use not more than 5 percent of the amount made available to the State under section 7111(b) of this title for each fiscal year less the amount reserved under subsection (a) of this section, for activities described in this subsection.

(2) Activities

A State educational agency shall use the amounts described in paragraph (1), either directly, or through grants and contracts, to plan, develop, and implement capacity building, technical assistance and training, evaluation, program improvement services, and coordination activities for local educational agencies, community-based organizations, and other public and private entities. Such uses—

(A) shall meet the principles of effectiveness described in section 7115(a) of this title;

(B) shall complement and support local uses of funds under section 7115(b) of this title;

(C) shall be in accordance with the purposes of this part; and

(D) may include, among others activities—

(i) identification, development, evaluation, and dissemination of drug and violence prevention strategies, programs, activities, and other information;

(ii) training, technical assistance, and demonstration projects to address violence that is associated with prejudice and intolerance; and

(iii) financial assistance to enhance drug and violence prevention resources available in areas that serve large numbers of low-income children, are sparsely populated, or have other special needs.

(3) Uniform management information and reporting system

(A) Information and statistics

A State shall establish a uniform management information and reporting system.

(B) Uses of funds

A State may use funds described in subparagraphs (A) and (B) of subsection (b)(2) of this section, either directly or through grants and contracts, to implement the uniform management information and reporting system described in subparagraph (A), for the collection of information on—

(i) truancy rates;

(ii) the frequency, seriousness, and incidence of violence and drug-related offenses resulting in suspensions and expulsions in elementary schools and secondary schools in the State;

(iii) the types of curricula, programs, and services provided by the chief executive officer, the State educational agency, local educational agencies, and other recipients of funds under this subpart; and

(iv) the incidence and prevalence, age of onset, perception of health risk, and perception of social disapproval of drug use and violence by youth in schools and communities.

(C) Compilation of statistics

In compiling the statistics required for the uniform management information and reporting system, the offenses described in subparagraph (B)(ii) shall be defined pursuant to the State's criminal code, but shall not identify victims of crimes or persons accused of crimes. The collected data shall include incident reports by school officials, anonymous student surveys, and anonymous teacher surveys.

(D) Reporting

The information described under subparagraph (B) shall be reported to the public and the data referenced in clauses (i) and (ii) of such subparagraph shall be reported to the State on a school-by-school basis.

(E) Limitation

Nothing in this subsection shall be construed to authorize the Secretary to require particular policies, procedures, or practices with respect to crimes committed on school property or school security.

§ 7113. State application [7]

(a) In general

In order to receive an allotment under section 7111(b) of this title for any fiscal year, a State shall submit to the Secretary, at such time as the Secretary may require, an application that—

(1) contains a comprehensive plan for the use of funds by the State educational agency and the chief executive officer of the State to provide safe, orderly, and drug-free schools and communities through programs and activities that complement and support activities of local educational agencies under section 7115(b) of this title, that comply with the principles of effectiveness under section 7115(a) of this title, and that otherwise are in accordance with the purpose of this part;

(2) describes how activities funded under this subpart will foster a safe and drug-free learning environment that supports academic achievement;

(3) provides an assurance that the application was developed in consultation and coordination with appropriate State officials and others, including the chief executive officer, the chief State school officer, the head of the State alcohol and drug abuse agency, the heads of the State health and mental health agencies, the head of the State criminal justice planning agency, the head of the State child welfare agency, the head of the State board of education, or their designees, and representatives of parents, students, and community-based organizations;

(4) describes how the State educational agency will coordinate such agency's activities under this subpart with the chief executive officer's drug and violence prevention programs under this subpart and with the prevention efforts of other State agencies and other programs, as appropriate, in accordance with the provisions in section 7846 of this title;

(5) provides an assurance that funds reserved under section 7112(a) of this title will not duplicate the efforts of the State educational agency and local educational agencies with regard to the provision of school-based drug and violence prevention activities and that those funds will be used to serve populations not normally served by the State educational agencies and local educational agencies and populations that need special services, such as school dropouts, suspended and expelled students, youth in detention centers, runaway or homeless children and youth, and pregnant and parenting youth;

(6) provides an assurance that the State will cooperate with, and assist, the Secretary in conducting data collection as required by section 7132 of this title;

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[7] Public Law 89–10, Title IV, § 4113, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1739.

(7) provides an assurance that the local educational agencies in the State will comply with the provisions of section 7881 of this title pertaining to the participation of private school children and teachers in the programs and activities under this subpart;

(8) provides an assurance that funds under this subpart will be used to increase the level of State, local, and other non-Federal funds that would, in the absence of funds under this subpart, be made available for programs and activities authorized under this subpart, and in no case supplant such State, local, and other non-Federal funds;

(9) contains the results of a needs assessment conducted by the State for drug and violence prevention programs, which shall be based on ongoing State evaluation activities, including data on—

(A) the incidence and prevalence of illegal drug use and violence among youth in schools and communities, including the age of onset, the perception of health risks, and the perception of social disapproval among such youth;

(B) the prevalence of risk factors, including high or increasing rates of reported cases of child abuse or domestic violence;

(C) the prevalence of protective factors, buffers, or assets; and

(D) other variables in the school and community identified through scientifically based research;

(10) provides a statement of the State's performance measures for drug and violence prevention programs and activities to be funded under this subpart that will be focused on student behavior and attitudes, derived from the needs assessment described in paragraph (9), and be developed in consultation between the State and local officials, and that consist of—

(A) performance indicators for drug and violence prevention programs and activities; and

(B) levels of performance for each performance indicator;

(11) describes the procedures the State will use for assessing and publicly reporting progress toward meeting the performance measures described in paragraph (10);

(12) provides an assurance that the State application will be available for public review after submission of the application;

(13) describes the special outreach activities that will be carried out by the State educational agency and the chief executive officer of the State to maximize the participation of community-based organizations of demonstrated effectiveness that provide services such as mentoring programs in low-income communities;

(14) describes how funds will be used by the State educational agency and the chief executive officer of the State to support, develop, and implement community-wide comprehensive drug and violence prevention planning and organizing activities;

(15) describes how input from parents will be sought regarding the use of funds by the State educational agency and the chief executive officer of the State;

(16) describes how the State educational agency will review applications from local educational agencies, including how the agency will receive input from parents in such review;

(17) describes how the State educational agency will monitor the implementation of activities under this subpart, and provide technical assistance for local educational agencies, community-based organizations, other public entities, and private organizations;

(18) describes how the chief executive officer of the State will award funds under section 7112(a) of this title and implement a plan for monitoring the performance of, and providing technical assistance to, recipients of such funds; and

(19) includes any other information the Secretary may require.

(b) Interim application

(1) Authority

Notwithstanding any other provision of this section, a State may submit for fiscal year 2002 a 1-year interim application and plan for the use of funds under this subpart that is consistent with the requirements of this section and contains such information as the Secretary may specify in regulations.

(2) Purpose

The purpose of such interim application and plan shall be to afford the State the opportunity to fully develop and review such State's application and comprehensive plan otherwise required by this section.

(3) Exception

A State may not receive a grant under this subpart for a fiscal year after fiscal year 2002 unless the Secretary has approved such State's application and comprehensive plan as described in subsection (a) of this section.

(c) Approval process

(1) Deemed approval

An application submitted by a State pursuant to this section shall undergo peer review by the Secretary and shall be deemed to be approved by the Secretary unless the Secretary makes a written determination, prior to the expiration of the 120-day period beginning on the date on which the Secretary received the application, that the application is not in compliance with this subpart.

(2) Disapproval

The Secretary shall not finally disapprove the application, except after giving the State educational agency and the chief executive officer of the State notice and an opportunity for a hearing.

(3) Notification

If the Secretary finds that the application is not in compliance, in whole or in part, with this subpart, the Secretary shall—

(A) give the State educational agency and the chief executive officer of the State notice and an opportunity for a hearing; and

(B) notify the State educational agency and the chief executive officer of the State of the finding of noncompliance, and in such notification, shall—

(i) cite the specific provisions in the application that are not in compliance; and

(ii) request additional information, only as to the noncompliant provisions, needed to make the application compliant.

(4) Response

If the State educational agency and the chief executive officer of the State respond to the Secretary's notification described in paragraph (3)(B) during the 45-day period beginning on the date on which the agency received the notification, and resubmit the application with the requested information described in paragraph (3)(B)(ii), the Secretary shall approve or disapprove such application prior to the later of—

(A) the expiration of the 45-day period beginning on the date on which the application is resubmitted; or

(B) the expiration of the 120-day period described in paragraph (1).

(5) Failure to respond

If the State educational agency and the chief executive officer of the State do not respond to the Secretary's notification described in paragraph (3)(B) during the 45-day period beginning on the date on which the agency received the notification, such application shall be deemed to be disapproved.

§ 7114. Local educational agency program[8]

(a) In general

(1) Funds to local educational agencies

A State shall provide the amount made available to the State under this subpart, less the amounts reserved under section 7112 of this title to local educational agencies for drug and violence prevention and education programs and activities as follows:

(A) 60 percent of such amount based on the relative amount such agencies received under part A of subchapter I for the preceding fiscal year.

(B) 40 percent of such amount based on the relative enrollments in public and private nonprofit elementary

[8] Public Law 89–10, Title IV, § 4114, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1742.

schools and secondary schools within the boundaries of such agencies.

(2) Administrative costs

Of the amount received under paragraph (1), a local educational agency may use not more than 2 percent for the administrative costs of carrying out its responsibilities under this subpart.

(3) Return of funds to State; reallocation

(A) Return

Except as provided in subparagraph (B), upon the expiration of the 1-year period beginning on the date on which a local educational agency receives its allocation under this subpart—

(i) such agency shall return to the State educational agency any funds from such allocation that remain unobligated; and

(ii) the State educational agency shall reallocate any such amount to local educational agencies that have submitted plans for using such amount for programs or activities on a timely basis.

(B) Carryover

In any fiscal year, a local educational agency, may retain for obligation in the succeeding fiscal year—

(i) an amount equal to not more than 25 percent of the allocation it received under this subpart for such fiscal year; or

(ii) upon a demonstration of good cause by such agency and approval by the State educational agency, an amount that exceeds 25 percent of such allocation.

(C) Reallocation

If a local educational agency chooses not to apply to receive the amount allocated to such agency under this subsection, or if such agency's application under subsection (d) of this section is disapproved by the State educational agency, the State educational agency shall reallocate such amount to one or more of its other local educational agencies.

(b) Eligibility

To be eligible to receive a subgrant under this subpart, a local educational agency desiring a subgrant shall submit an application to the State educational agency in accordance with subsection (d) of this section. Such an application shall be amended, as necessary, to reflect changes in the activities and programs of the local educational agency.

(c) Development

(1) Consultation

(A) In general

A local educational agency shall develop its application through timely and meaningful consultation with State and local government representatives, representatives of schools to be served (including private schools), teachers and other staff, parents, students, community-based organizations, and others with relevant and demonstrated expertise in drug and violence prevention activities (such as medical, mental health, and law enforcement professionals).

(B) Continued consultation

On an ongoing basis, the local educational agency shall consult with such representatives and organizations in order to seek advice regarding how best to coordinate such agency's activities under this subpart with other related strategies, programs, and activities being conducted in the community.

(2) Design and development

To ensure timely and meaningful consultation under paragraph (1), a local educational agency at the initial stages of design and development of a program or activity shall consult, in accordance with this subsection, with appropriate entities and persons on issues regarding the design and development of the program or activity, including efforts to meet the principles of effectiveness described in section 7115(a) of this title.

(d) Contents of applications

An application submitted by a local educational agency under this section shall contain—

(1) an assurance that the activities or programs to be funded comply with the principles of effectiveness described in section 7115(a) of this title and foster a safe and drug-free learning environment that supports academic achievement;

(2) a detailed explanation of the local educational agency's comprehensive plan for drug and violence prevention, including a description of—

(A) how the plan will be coordinated with programs under this chapter, and other Federal, State, and local programs for drug and violence prevention, in accordance with section 7846 of this title;

(B) the local educational agency's performance measures for drug and violence prevention programs and activities, that shall consist of—

(i) performance indicators for drug and violence prevention programs and activities; including—

(I) specific reductions in the prevalence of identified risk factors; and

(II) specific increases in the prevalence of protective factors, buffers, or assets if any have been identified; and

(ii) levels of performance for each performance indicator;

(C) how such agency will assess and publicly report progress toward attaining its performance measures;

(D) the drug and violence prevention activity or program to be funded, including how the activity or program will meet the principles of effectiveness described in section 7115(a) of this title, and the means of evaluating such activity or program; and

(E) how the services will be targeted to schools and students with the greatest need;

(3) a description for how the results of the evaluations of the effectiveness of the program will be used to refine, improve, and strengthen the program;

(4) an assurance that funds under this subpart will be used to increase the level of State, local, and other non-Federal funds that would, in the absence of funds under this subpart, be made available for programs and activities authorized under this subpart, and in no case supplant such State, local, and other non-Federal funds;

(5) a description of the mechanisms used to provide effective notice to the community of an intention to submit an application under this subpart;

(6) an assurance that drug and violence prevention programs supported under this subpart convey a clear and consistent message that acts of violence and the illegal use of drugs are wrong and harmful;

(7) an assurance that the applicant has, or the schools to be served have, a plan for keeping schools safe and drug-free that includes—

(A) appropriate and effective school discipline policies that prohibit disorderly conduct, the illegal possession of weapons, and the illegal use, possession, distribution, and sale of tobacco, alcohol, and other drugs by students;

(B) security procedures at school and while students are on the way to and from school;

(C) prevention activities that are designed to create and maintain safe, disciplined, and drug-free environments;

(D) a crisis management plan for responding to violent or traumatic incidents on school grounds; and

(E) a code of conduct policy for all students that clearly states the responsibilities of students, teachers, and administrators in maintaining a classroom environment that—

(i) allows a teacher to communicate effectively with all students in the class;

(ii) allows all students in the class to learn;

(iii) has consequences that are fair, and developmentally appropriate;

(iv) considers the student and the circumstances of the situation; and

(v) is enforced accordingly;

(8) an assurance that the application and any waiver request under section 7115(a)(3) of this title will be available for public review after submission of the application; and

(9) such other assurances, goals, and objectives identified through scientifically based research that the State may reasonably require in accordance with the purpose of this part.

(e) Review of application

(1) In general

In reviewing local applications under this section, a State educational agency shall use a peer review process or other methods of assuring the quality of such applications.

(2) Considerations

In determining whether to approve the application of a local educational agency under this section, a State educational agency shall consider the quality of application and the extent to which the application meets the principles of effectiveness described in section 7115(a) of this title.

(f) Approval process

(1) Deemed approval

An application submitted by a local educational agency pursuant to this section shall be deemed to be approved by the State educational agency unless the State educational agency makes a written determination, prior to the expiration of the 120-day period beginning on the date on which the State educational agency received the application, that the application is not in compliance with this subpart.

(2) Disapproval

The State educational agency shall not finally disapprove the application, except after giving the local educational agency notice and opportunity for a hearing.

(3) Notification

If the State educational agency finds that the application is not in compliance, in whole or in part, with this subpart, the State educational agency shall—

(A) give the local educational agency notice and an opportunity for a hearing; and

(B) notify the local educational agency of the finding of noncompliance, and in such notification, shall—

(i) cite the specific provisions in the application that are not in compliance; and

(ii) request additional information, only as to the noncompliant provisions, needed to make the application compliant.

(4) Response

If the local educational agency responds to the State educational agency's notification described in paragraph (3)(B)

during the 45-day period beginning on the date on which the agency received the notification, and resubmits the application with the requested information described in paragraph (3)(B)(ii), the State educational agency shall approve or disapprove such application prior to the later of—

(A) the expiration of the 45-day period beginning on the date on which the application is resubmitted; or

(B) the expiration of the 120-day period described in paragraph (1).

(5) Failure to respond

If the local educational agency does not respond to the State educational agency's notification described in paragraph (3)(B) during the 45-day period beginning on the date on which the agency received the notification, such application shall be deemed to be disapproved.

§ 7115. Authorized activities[9]

(a) Principles of effectiveness

(1) In general

For a program or activity developed pursuant to this subpart to meet the principles of effectiveness, such program or activity shall—

(A) be based on an assessment of objective data regarding the incidence of violence and illegal drug use in the elementary schools and secondary schools and communities to be served, including an objective analysis of the current conditions and consequences regarding violence and illegal drug use, including delinquency and serious discipline problems, among students who attend such schools (including private school students who participate in the drug and violence prevention program) that is based on ongoing local assessment or evaluation activities;

(B) be based on an established set of performance measures aimed at ensuring that the elementary schools and secondary schools and communities to be served by the program have a safe, orderly, and drug-free learning environment;

(C) be based on scientifically based research that provides evidence that the program to be used will reduce violence and illegal drug use;

(D) be based on an analysis of the data reasonably available at the time, of the prevalence of risk factors, including high or increasing rates of reported cases of child abuse and domestic violence; protective factors, buffers, assets; or other variables in schools and communities in the State identified through scientifically based research; and

(E) include meaningful and ongoing consultation with and input from parents in the development of the application and administration of the program or activity.

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[9] Public Law 89–10, Title IV, § 4115, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1745.

(2) Periodic evaluation

(A) Requirement

The program or activity shall undergo a periodic evaluation to assess its progress toward reducing violence and illegal drug use in schools to be served based on performance measures described in section 7114(d)(2)(B) of this title.

(B) Use of results

The results shall be used to refine, improve, and strengthen the program, and to refine the performance measures, and shall also be made available to the public upon request, with public notice of such availability provided.

(3) Waiver

A local educational agency may apply to the State for a waiver of the requirement of subsection (a)(1)(C) of this section to allow innovative activities or programs that demonstrate substantial likelihood of success.

(b) Local educational agency activities

(1) Program requirements

A local educational agency shall use funds made available under section 7114 of this title to develop, implement, and evaluate comprehensive programs and activities, which are coordinated with other school and community-based services and programs, that shall—

(A) foster a safe and drug-free learning environment that supports academic achievement;

(B) be consistent with the principles of effectiveness described in subsection (a)(1) of this section;

(C) be designed to—

(i) prevent or reduce violence; the use, possession and distribution of illegal drugs; and delinquency; and

(ii) create a well disciplined environment conducive to learning, which includes consultation between teachers, principals, and other school personnel to identify early warning signs of drug use and violence and to provide behavioral interventions as part of classroom management efforts; and

(D) include activities to—

(i) promote the involvement of parents in the activity or program;

(ii) promote coordination with community groups and coalitions, and government agencies; and

(iii) distribute information about the local educational agency's needs, goals, and programs under this subpart.

(2) Authorized activities

Each local educational agency, or consortium of such agencies, that receives a subgrant under this subpart may use such funds to carry out activities that comply with the principles of effectiveness described in subsection (a) of this section, such as the following:

(A) Age appropriate and developmentally based activities that—

(i) address the consequences of violence and the illegal use of drugs, as appropriate;

(ii) promote a sense of individual responsibility;

(iii) teach students that most people do not illegally use drugs;

(iv) teach students to recognize social and peer pressure to use drugs illegally and the skills for resisting illegal drug use;

(v) teach students about the dangers of emerging drugs;

(vi) engage students in the learning process; and

(vii) incorporate activities in secondary schools that reinforce prevention activities implemented in elementary schools.

(B) Activities that involve families, community sectors (which may include appropriately trained seniors), and a variety of drug and violence prevention providers in setting clear expectations against violence and illegal use of drugs and appropriate consequences for violence and illegal use of drugs.

(C) Dissemination of drug and violence prevention information to schools and the community.

(D) Professional development and training for, and involvement of, school personnel, pupil services personnel, parents, and interested community members in prevention, education, early identification and intervention, mentoring, or rehabilitation referral, as related to drug and violence prevention.

(E) Drug and violence prevention activities that may include the following:

(i) Community-wide planning and organizing activities to reduce violence and illegal drug use, which may include gang activity prevention.

(ii) Acquiring and installing metal detectors, electronic locks, surveillance cameras, or other related equipment and technologies.

(iii) Reporting criminal offenses committed on school property.

(iv) Developing and implementing comprehensive school security plans or obtaining technical assistance concerning such plans, which may include obtaining a security assessment or assistance from the School Security and Technology Resource Center at the Sandia National Laboratory located in Albuquerque, New Mexico.

(v) Supporting safe zones of passage activities that ensure that students travel safely to and from school, which may include bicycle and pedestrian safety programs.

(vi) The hiring and mandatory training, based on scientific research, of school security personnel (including school resource officers) who interact with students in support of youth drug and violence prevention activities under this part that are implemented in the school.

(vii) Expanded and improved school-based mental health services related to illegal drug use and violence, including early identification of violence and illegal drug use, assessment, and direct or group counseling services provided to students, parents, families, and school personnel by qualified school-based mental health service providers.

(viii) Conflict resolution programs, including peer mediation programs that educate and train peer mediators and a designated faculty supervisor, and youth anti-crime and anti-drug councils and activities.

(ix) Alternative education programs or services for violent or drug abusing students that reduce the need for suspension or expulsion or that serve students who have been suspended or expelled from the regular educational settings, including programs or services to assist students to make continued progress toward meeting the State academic achievement standards and to reenter the regular education setting.

(x) Counseling, mentoring, referral services, and other student assistance practices and programs, including assistance provided by qualified school-based mental health services providers and the training of teachers by school-based mental health services providers in appropriate identification and intervention techniques for students at risk of violent behavior and illegal use of drugs.

(xi) Programs that encourage students to seek advice from, and to confide in, a trusted adult regarding concerns about violence and illegal drug use.

(xii) Drug and violence prevention activities designed to reduce truancy.

(xiii) Age-appropriate, developmentally-based violence prevention and education programs that address victimization associated with prejudice and intolerance, and that include activities designed to help students develop a sense of individual responsibility and respect for the rights of others, and to resolve conflicts without violence.

(xiv) Consistent with the fourth amendment to the Constitution of the United States, the testing of a student for illegal drug use or the inspecting of a student's locker for weapons or illegal drugs or drug paraphernalia, including at the request of or with the consent of a parent or legal guardian of the student, if the local educational agency elects to so test or inspect.

(xv) Emergency intervention services following traumatic crisis events, such as a shooting, major accident, or a drug-related incident that have disrupted the learning environment.

(xvi) Establishing or implementing a system for transferring suspension and expulsion records, consistent with section 1232g of this title, by a local educational agency to any public or private elementary school or secondary school.

(xvii) Developing and implementing character education programs, as a component of drug and violence prevention programs, that take into account the views of parents of the students for whom the program is intended and such students, such as a program described in subpart 3 of part D of subchapter V of this chapter.

(xviii) Establishing and maintaining a school safety hotline.

(xix) Community service, including community service performed by expelled students, and service-learning projects.

(xx) Conducting a nationwide background check of each local educational agency employee, regardless of when hired, and prospective employees for the purpose of determining whether the employee or prospective employee has been convicted of a crime that bears upon the employee's fitness—

(I) to be responsible for the safety or well-being of children;

(II) to serve in the particular capacity in which the employee or prospective employee is or will be employed; or

(III) to otherwise be employed by the local educational agency.

(xxi) Programs to train school personnel to identify warning signs of youth suicide and to create an action plan to help youth at risk of suicide.

(xxii) Programs that respond to the needs of students who are faced with domestic violence or child abuse.

(F) The evaluation of any of the activities authorized under this subsection and the collection of objective data used to assess program needs, program implementation, or program success in achieving program goals and objectives.

(c) Limitation

(1) In general

Except as provided in paragraph (2), not more than 40 percent of the funds available to a local educational agency under this subpart may be used to carry out the activities described in clauses (ii) through (vi) of subsection (b)(2)(E) of this section, of which not more than 50 percent of such amount may be used to carry out the activities described in clauses (ii) through (v) of such subsection.

(2) Exception

A local educational agency may use funds under this subpart for activities described in clauses (ii) through (v) of subsection (b)(2)(E) of this section only if funding for these activities is not received from other Federal agencies.

(d) Rule of construction

Nothing in this section shall be construed to prohibit the use of funds under this subpart by any local educational agency or school for the establishment or implementation of a school uniform policy if such policy is part of the overall comprehensive drug and violence prevention plan of the State involved and is supported by the State's needs assessment and other scientifically based research information.

§ 7116. Reporting [10]

(a) State report

(1) In general

By December 1, 2003, and every 2 years thereafter, the chief executive officer of the State, in cooperation with the State educational agency, shall submit to the Secretary a report—

(A) on the implementation and outcomes of State programs under section 7112(a)(1) of this title and section 7112(c) of this title and local educational agency programs under section 7115(b) of this title, as well as an assessment of their effectiveness;

(B) on the State's progress toward attaining its performance measures for drug and violence prevention under section 7113(a)(10) of this title; and

(C) on the State's efforts to inform parents of, and include parents in, violence and drug prevention efforts.

(2) Special rule

The report required by this subsection shall be—

(A) in the form specified by the Secretary;

(B) based on the State's ongoing evaluation activities, and shall include data on the incidence and prevalence, age of onset, perception of health risk, and perception of

[10] Public Law 89–10, Title IV, § 4116, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1750.

social disapproval of drug use and violence by youth in schools and communities; and

(C) made readily available to the public.

(b) Local educational agency report

(1) In general

Each local educational agency receiving funds under this subpart shall submit to the State educational agency such information that the State requires to complete the State report required by subsection (a) of this section, including a description of how parents were informed of, and participated in, violence and drug prevention efforts.

(2) Availability

Information under paragraph (1) shall be made readily available to the public.

(3) Provision of documentation

Not later than January 1 of each year that a State is required to report under subsection (a) of this section, the Secretary shall provide to the State educational agency all of the necessary documentation required for compliance with this section.

§ 7117. Programs for Native Hawaiians [11]

(a) General authority

From the funds made available pursuant to section 7111(a)(1)(C) of this title to carry out this section, the Secretary shall make grants to or enter into cooperative agreements or contracts with organizations primarily serving and representing Native Hawaiians for the benefit of Native Hawaiians to plan, conduct, and administer programs, or portions thereof, that are authorized by and consistent with the provisions of this subpart.

(b) Definition of Native Hawaiian

For the purposes of this section, the term "Native Hawaiian" means any individual any of whose ancestors were natives, prior to 1778, of the area which now comprises the State of Hawaii.

§ 7131. Federal activities [12]

(a) Program authorized

From funds made available to carry out this subpart under section 7103(2) of this title, the Secretary, in consultation with the Secretary of Health and Human Services, the Director of the Office of National Drug Control Policy, and the Attorney General, shall carry out programs to prevent the illegal use of drugs and violence among, and promote safety and discipline for, students. The Secretary shall carry out such programs directly, or through grants,

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[11] Public Law 89–10, Title IV, § 4117, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1750.

[12] Public Law 89–10, Title IV, § 4121, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1751.

contracts, or cooperative agreements with public and private entities and individuals, or through agreements with other Federal agencies, and shall coordinate such programs with other appropriate Federal activities. Such programs may include—

(1) the development and demonstration of innovative strategies for the training of school personnel, parents, and members of the community for drug and violence prevention activities based on State and local needs;

(2) the development, demonstration, scientifically based evaluation, and dissemination of innovative and high quality drug and violence prevention programs and activities, based on State and local needs, which may include—

(A) alternative education models, either established within a school or separate and apart from an existing school, that are designed to promote drug and violence prevention, reduce disruptive behavior, reduce the need for repeat suspensions and expulsions, enable students to meet challenging State academic standards, and enable students to return to the regular classroom as soon as possible;

(B) community service and service-learning projects, designed to rebuild safe and healthy neighborhoods and increase students' sense of individual responsibility;

(C) video-based projects developed by noncommercial telecommunications entities that provide young people with models for conflict resolution and responsible decisionmaking; and

(D) child abuse education and prevention programs for elementary and secondary students;

(3) the provision of information on drug abuse education and prevention to the Secretary of Health and Human Services for dissemination;

(4) the provision of information on violence prevention and education and school safety to the Department of Justice for dissemination;

(5) technical assistance to chief executive officers, State agencies, local educational agencies, and other recipients of funding under this part to build capacity to develop and implement high-quality, effective drug and violence prevention programs consistent with the principles of effectiveness in section 7115(a) of this title;

(6) assistance to school systems that have particularly severe drug and violence problems, including hiring drug prevention and school safety coordinators, or assistance to support appropriate response efforts to crisis situations;

(7) the development of education and training programs, curricula, instructional materials, and professional training and development for preventing and reducing the incidence of crimes and conflicts motivated by hate in localities most directly affected by hate crimes;

(8) activities in communities designated as empowerment zones or enterprise communities that will connect schools to community-wide efforts to reduce drug and violence problems; and

(9) other activities in accordance with the purpose of this part, based on State and local needs.

(b) Peer review

The Secretary shall use a peer review process in reviewing applications for funds under this section.

§ 7132. Impact evaluation [13]

(a) Biennial evaluation

The Secretary, in consultation with the Safe and Drug-Free Schools and Communities Advisory Committee described in section 7134 of this title, shall conduct an independent biennial evaluation of the impact of programs assisted under this subpart and of other recent and new initiatives to combat violence and illegal drug use in schools. The evaluation shall report on whether community and local educational agency programs funded under this subpart—

(1) comply with the principles of effectiveness described in section 7115(a) of this title;

(2) have appreciably reduced the level of illegal drug, alcohol, and tobacco use, and school violence and the illegal presence of weapons at schools; and

(3) have conducted effective parent involvement and training programs.

(b) Data collection

The National Center for Education Statistics shall collect data, that is subject to independent review, to determine the incidence and prevalence of illegal drug use and violence in elementary schools and secondary schools in the States. The collected data shall include incident reports by schools officials, anonymous student surveys, and anonymous teacher surveys.

(c) Biennial report

Not later than January 1, 2003, and every 2 years thereafter, the Secretary shall submit to the President and Congress a report on the findings of the evaluation conducted under subsection (a) of this section together with the data collected under subsection (b) of this section and data available from other sources on the incidence and prevalence, age of onset, perception of health risk, and perception of social disapproval of drug use and violence in elementary schools and secondary schools in the States. The Secretary shall include data submitted by the States pursuant to subsection 7116(a) of this title.

§ 7133. Hate crime prevention [14]

(a) Grant authorization

From funds made available to carry out this subpart under section 7103(2) of this title the Secretary may make grants to local educational agencies and community-based organizations for the

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[13] Public Law 89–10, Title IV, § 4122, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1752.

[14] Public Law 89–10, Title IV, § 4123, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1752.

purpose of providing assistance to localities most directly affected by hate crimes.

(b) Use of funds

(1) Program development

Grants under this section may be used to improve elementary and secondary educational efforts, including—

(A) development of education and training programs designed to prevent and to reduce the incidence of crimes and conflicts motivated by hate;

(B) development of curricula for the purpose of improving conflict or dispute resolution skills of students, teachers, and administrators;

(C) development and acquisition of equipment and instructional materials to meet the needs of, or otherwise be part of, hate crime or conflict programs; and

(D) professional training and development for teachers and administrators on the causes, effects, and resolutions of hate crimes or hate-based conflicts.

(2) Application

In order to be eligible to receive a grant under this section for any fiscal year, a local educational agency, or a local educational agency in conjunction with a community-based organization, shall submit an application to the Secretary in such form and containing such information as the Secretary may reasonably require.

(3) Requirements

Each application under paragraph (2) shall include—

(A) a request for funds for the purpose described in this section;

(B) a description of the schools and communities to be served by the grants; and

(C) assurances that Federal funds received under this section shall be used to supplement, and not supplant, non-Federal funds.

(4) Comprehensive plan

Each application shall include a comprehensive plan that contains—

(A) a description of the hate crime or conflict problems within the schools or the community targeted for assistance;

(B) a description of the program to be developed or augmented by such Federal and matching funds;

(C) assurances that such program or activity shall be administered by or under the supervision of the applicant;

(D) procedures for the proper and efficient administration of such program; and

(E) fiscal control and fund accounting procedures as may be necessary to ensure prudent use, proper disbursement,

and accurate accounting of funds received under this section.

(c) Award of grants

(1) Selection of recipients

The Secretary shall consider the incidence of crimes and conflicts motivated by bias in the targeted schools and communities in awarding grants under this section.

(2) Geographic distribution

The Secretary shall attempt, to the extent practicable, to achieve an equitable geographic distribution of grant awards.

(3) Dissemination of information

The Secretary shall attempt, to the extent practicable, to make available information regarding successful hate crime prevention programs, including programs established or expanded with grants under this section.

(d) Reports

The Secretary shall submit to Congress a report every 2 years that shall contain a detailed statement regarding grants and awards, activities of grant recipients, and an evaluation of programs established under this section.

§ 7134. Safe and Drug-Free Schools and Communities Advisory Committee[15]

(a) Establishment

(1) In general

There is hereby established an advisory committee to be known as the "Safe and Drug Free Schools and Communities Advisory Committee" (referred to in this section as the "Advisory Committee") to—

(A) consult with the Secretary under subsection (b) of this section;

(B) Coordinate Federal school-and community-based substance abuse and violence prevention programs and reduce duplicative research or services;

(C) Develop core data sets and evaluation protocols for safe and drug-free school-and community-based programs;

(D) Provide technical assistance and training for safe and drug-free school-and community-based programs;

(E) Provide for the diffusion of scientifically based research to safe and drug-free school-and community-based programs; and

(F) review other regulations and standards developed under this subchapter.

(2) Composition

The Advisory Committee shall be composed of representatives from—

[15] Public Law 89–10, Title IV, § 4124, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1754.

(A) the Department of Education;
(B) the Centers for Disease Control and Prevention;
(C) the National Institute on Drug Abuse;
(D) the National Institute on Alcoholism and Alcohol Abuse;
(E) the Center for Substance Abuse Prevention;
(F) the Center for Mental Health Services;
(G) the Office of Juvenile Justice and Delinquency Prevention;
(H) the Office of National Drug Control Policy;
(I) State and local governments, including education agencies; and
(J) researchers and expert practitioners.

(3) Consultation

In carrying out its duties under this section, the Advisory Committee shall annually consult with interested State and local coordinators of school-and community-based substance abuse and violence prevention programs and other interested groups.

(b) Programs

(1) In general

From amounts made available under section 7103(2) of this title to carry out this subpart, the Secretary, in consultation with the Advisory Committee, shall carry out scientifically based research programs to strengthen the accountability and effectiveness of the State, chief executive officer's, and national programs under this part.

(2) Grants, contracts or cooperative agreements

The Secretary shall carry out paragraph (1) directly or through grants, contracts, or cooperative agreements with public and private entities and individuals or through agreements with other Federal agencies.

(3) Coordination

The Secretary shall coordinate programs under this section with other appropriate Federal activities.

(4) Activities

Activities that may be carried out under programs funded under this section may include—

(A) the provision of technical assistance and training, in collaboration with other Federal agencies utilizing their expertise and national and regional training systems, for Governors, State educational agencies and local educational agencies to support high quality, effective programs that—

(i) provide a thorough assessment of the substance abuse and violence problem;

(ii) utilize objective data and the knowledge of a wide range of community members;

(iii) develop measurable goals and objectives; and

(iv) implement scientifically based research activities that have been shown to be effective and that meet identified needs;

(B) the provision of technical assistance and training to foster program accountability;

(C) the diffusion and dissemination of best practices and programs;

(D) the development of core data sets and evaluation tools;

(E) program evaluations;

(F) the provision of information on drug abuse education and prevention to the Secretary of Health and Human Services for dissemination by the clearinghouse for alcohol and drug abuse information established under section 290aa(d)(16) of Title 42; and

(G) other activities that meet unmet needs related to the purpose of this part and that are undertaken in consultation with the Advisory Committee.

§ 7135. National Coordinator Program [16]

(a) In general

From funds made available to carry out this subpart under section 7103(2) of this title, the Secretary may provide for the establishment of a National Coordinator Program under which the Secretary shall award grants to local educational agencies for the hiring of drug prevention and school safety program coordinators.

(b) Use of funds

Amounts received under a grant under subsection (a) of this section shall be used by local educational agencies to recruit, hire, and train individuals to serve as drug prevention and school safety program coordinators in schools with significant drug and school safety problems. Such coordinators shall be responsible for developing, conducting, and analyzing assessments of drug and crime problems at their schools, and administering the safe and drug-free grant program at such schools.

§ 7136. Community service grant program [17]

(a) In general

From funds made available to carry out this subpart under section 7103(2) of this title, the Secretary may make grants to States to carry out programs under which students expelled or suspended from school are required to perform community service.

(b) Allocation

From the amount described in subsection (a) of this section, the Secretary shall allocate among the States—

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[16] Public Law 89–10, Title IV, § 4125, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1755.

[17] Public Law 89–10, Title IV, § 4126, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1756.

(1) one-half according to the ratio between the school-aged population of each State and the school-aged population of all the States; and

(2) one-half according to the ratio between the amount each State received under section 6334 of this title for the preceding year and the sum of such amounts received by all the States.

(c) Minimum

For any fiscal year, no State shall be allotted under this section an amount that is less than one-half of 1 percent of the total amount allotted to all the States under this section.

(d) Reallotment

The Secretary may reallot any amount of any allotment to a State if the Secretary determines that the State will be unable to use such amount within 2 years of such allotment. Such reallotments shall be made on the same basis as allotments are made under subsection (b) of this section.

(e) Definition

In this section, the term "State" means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

§ 7137. School Security Technology and Resource Center[18]

(a) Center

From funds made available to carry out this subpart under section 7103(2) of this title, the Secretary, the Attorney General, and the Secretary of Energy may enter into an agreement for the establishment at the Sandia National Laboratories, in partnership with the National Law Enforcement and Corrections Technology Center—Southeast and the National Center for Rural Law Enforcement in Little Rock, Arkansas, of a center to be known as the "School Security Technology and Resource Center" (hereafter in this section "the Center").

(b) Administration

The Center established under subsection (a) of this section shall be administered by the Attorney General.

(c) Functions

The center established under subsection (a) of this section shall be a resource to local educational agencies for school security assessments, security technology development, evaluation and implementation, and technical assistance relating to improving school security. The Center will also conduct and publish school violence research, coalesce data from victim communities, and monitor and report on schools that implement school security strategies.

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[18] Public Law 89–10, Title IV, § 4127, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1756.

§ 7138. National Center for School and Youth Safety [19]

(a) Establishment

From funds made available to carry out this subpart under section 7103(2) of this title, the Secretary of Education and the Attorney General may jointly establish a National Center for School and Youth Safety (in this section referred to as the "Center"). The Secretary of Education and the Attorney General may establish the Center at an existing facility, if the facility has a history of performing two or more of the duties described in subsection (b) of this section. The Secretary of Education and the Attorney General shall jointly appoint a Director of the Center to oversee the operation of the Center.

(b) Duties

The Center shall carry out emergency response, anonymous student hotline, consultation, and information and outreach activities with respect to elementary and secondary school safety, including the following:

(1) Emergency response

The staff of the Center, and such temporary contract employees as the Director of the Center shall determine necessary, shall offer emergency assistance to local communities to respond to school safety crises. Such assistance shall include counseling for victims and the community, assistance to law enforcement to address short-term security concerns, and advice on how to enhance school safety, prevent future incidents, and respond to future incidents.

(2) Anonymous student hotline

The Center shall establish a toll-free telephone number for students to report criminal activity, threats of criminal activity, and other high-risk behaviors such as substance abuse, gang or cult affiliation, depression, or other warning signs of potentially violent behavior. The Center shall relay the reports, without attribution, to local law enforcement or appropriate school hotlines. The Director of the Center shall work with the Attorney General to establish guidelines for Center staff to work with law enforcement around the Nation to relay information reported through the hotline.

(3) Consultation

The Center shall establish a toll-free number for the public to contact staff of the Center for consultation regarding school safety. The Director of the Center shall hire administrative staff and individuals with expertise in enhancing school safety, including individuals with backgrounds in counseling and psychology, education, law enforcement and criminal justice, and community development to assist in the consultation.

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[19] Public Law 89–10, Title IV, § 4128, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1756.

(4) Information and outreach

The Center shall compile information about the best practices in school violence prevention, intervention, and crisis management, and shall serve as a clearinghouse for model school safety program information. The staff of the Center shall work to ensure local governments, school officials, parents, students, and law enforcement officials and agencies are aware of the resources, grants, and expertise available to enhance school safety and prevent school crime. The staff of the Center shall give special attention to providing outreach to rural and impoverished communities.

§ 7139. Grants to reduce alcohol abuse [20]

(a) In general

The Secretary, in consultation with the Administrator of the Substance Abuse and Mental Health Services Administration, may award grants from funds made available to carry out this subpart under section 7103(2) of this title, on a competitive basis, to local educational agencies to enable such agencies to develop and implement innovative and effective programs to reduce alcohol abuse in secondary schools.

(b) Eligibility

To be eligible to receive a grant under subsection (a) of this section, a local educational agency shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

(1) a description of the activities to be carried out under the grant;

(2) an assurance that such activities will include one or more of the proven strategies for reducing underage alcohol abuse as determined by the Substance Abuse and Mental Health Services Administration;

(3) an explanation of how activities to be carried out under the grant that are not described in paragraph (2) will be effective in reducing underage alcohol abuse, including references to the past effectiveness of such activities;

(4) an assurance that the applicant will submit to the Secretary an annual report concerning the effectiveness of the programs and activities funded under the grant; and

(5) such other information as the Secretary determines appropriate.

(c) Streamlining of process for low-income and rural LEAs

The Secretary, in consultation with the Administrator of the Substance Abuse and Mental Health Services Administration, shall develop procedures to make the application process for grants under this section more user-friendly, particularly for low-income and rural local educational agencies.

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[20] Public Law 89–10, Title IV, § 4129, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1757.

(d) Reservations

(1) SAMHSA

The Secretary may reserve 20 percent of any amount used to carry out this section to enable the Administrator of the Substance Abuse and Mental Health Services Administration to provide alcohol abuse resources and start-up assistance to local educational agencies receiving grants under this section.

(2) Low-income and rural areas

The Secretary may reserve 25 percent of any amount used to carry out this section to award grants to low-income and rural local educational agencies.

§ 7140. Mentoring programs [21]

(a) Purpose; definitions

(1) Purpose

The purpose of this section is to make assistance available to promote mentoring programs for children with greatest need—

(A) to assist such children in receiving support and guidance from a mentor;

(B) to improve the academic achievement of such children;

(C) to improve interpersonal relationships between such children and their peers, teachers, other adults, and family members;

(D) to reduce the dropout rate of such children; and

(E) to reduce juvenile delinquency and involvement in gangs by such children.

(2) Definitions

In this part:

(A) Child with greatest need

The term "child with greatest need" means a child who is at risk of educational failure, dropping out of school, or involvement in criminal or delinquent activities, or who lacks strong positive role models.

(B) Eligible entity

The term "eligible entity" means—

(i) a local educational agency;

(ii) a nonprofit, community-based organization; or

(iii) a partnership between a local educational agency and a nonprofit, community-based organization.

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[21] Public Law 89–10, Title IV, § 4130, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1758.

(C) Mentor

The term "mentor" means a responsible adult, a postsecondary school student, or a secondary school student who works with a child—

(i) to provide a positive role model for the child;

(ii) to establish a supportive relationship with the child; and

(iii) to provide the child with academic assistance and exposure to new experiences and examples of opportunity that enhance the ability of the child to become a responsible adult.

(D) State

The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(b) Grant program

(1) In general

The Secretary may award grants from funds made available to carry out this subpart under section 7103(2) of this title to eligible entities to assist such entities in establishing and supporting mentoring programs and activities for children with greatest need that—

(A) are designed to link such children (particularly children living in rural areas, high-crime areas, or troubled home environments, or children experiencing educational failure) with mentors who—

(i) have received training and support in mentoring;

(ii) have been screened using appropriate reference checks, child and domestic abuse record checks, and criminal background checks; and

(iii) are interested in working with children with greatest need; and

(B) are intended to achieve one or more of the following goals with respect to children with greatest need:

(i) Provide general guidance.

(ii) Promote personal and social responsibility.

(iii) Increase participation in, and enhance the ability to benefit from, elementary and secondary education.

(iv) Discourage illegal use of drugs and alcohol, violence, use of dangerous weapons, promiscuous behavior, and other criminal, harmful, or potentially harmful activity.

(v) Encourage participation in community service and community activities.

(vi) Encourage setting goals and planning for the future, including encouragement of graduation from secondary school and planning for postsecondary education or training.

(viii)[22] Discourage involvement in gangs.

(2) Use of funds

(A) In general

Each eligible entity awarded a grant under this subsection shall use the grant funds for activities that establish or implement a mentoring program, that may include—

(i) hiring of mentoring coordinators and support staff;

(ii) providing for the professional development of mentoring coordinators and support staff;

(iii) recruitment, screening, and training of mentors;

(iv) reimbursement to schools, if appropriate, for the use of school materials or supplies in carrying out the mentoring program;

(v) dissemination of outreach materials;

(vi) evaluation of the mentoring program using scientifically based methods; and

(vii) such other activities as the Secretary may reasonably prescribe by rule.

(B) Prohibited uses

Notwithstanding subparagraph (A), an eligible entity awarded a grant under this section may not use the grant funds—

(i) to directly compensate mentors;

(ii) to obtain educational or other materials or equipment that would otherwise be used in the ordinary course of the eligible entity's operations;

(iii) to support litigation of any kind; or

(iv) for any other purpose reasonably prohibited by the Secretary by rule.

(3) Availability of funds

Funds made available through a grant under this section shall be available for obligation for a period not to exceed 3 years.

(4) Application

Each eligible entity seeking a grant under this section shall submit to the Secretary an application that includes—

(A) a description of the plan for the mentoring program the eligible entity proposes to carry out with such grant;

(B) information on the children expected to be served by the mentoring program for which such grant is sought;

(C) a description of the mechanism the eligible entity will use to match children with mentors based on the needs of the children;

[22] So in original. No clause (vii) was enacted.

(D) an assurance that no mentor will be assigned to mentor so many children that the assignment will undermine the mentor's ability to be an effective mentor or the mentor's ability to establish a close relationship (a one-to-one relationship, where practicable) with each mentored child;

(E) an assurance that the mentoring program will provide children with a variety of experiences and support, including—

(i) emotional support;

(ii) academic assistance; and

(iii) exposure to experiences that the children might not otherwise encounter on their own;

(F) an assurance that the mentoring program will be monitored to ensure that each child assigned a mentor benefits from that assignment and that the child will be assigned a new mentor if the relationship between the original mentor and the child is not beneficial to the child;

(G) information regarding how mentors and children will be recruited to the mentoring program;

(H) information regarding how prospective mentors will be screened;

(I) information on the training that will be provided to mentors; and

(J) information on the system that the eligible entity will use to manage and monitor information relating to the mentoring program's—

(i) reference checks;

(ii) child and domestic abuse record checks;

(iii) criminal background checks; and

(iv) procedure for matching children with mentors.

(5) Selection

(A) Competitive basis

In accordance with this subsection, the Secretary shall award grants to eligible entities on a competitive basis.

(B) Priority

In awarding grants under subparagraph (A), the Secretary shall give priority to each eligible entity that—

(i) serves children with greatest need living in rural areas, high-crime areas, or troubled home environments, or who attend schools with violence problems;

(ii) provides high quality background screening of mentors, training of mentors, and technical assistance in carrying out mentoring programs; or

(iii) proposes a school-based mentoring program.

(C) Other considerations

In awarding grants under subparagraph (A), the Secretary shall also consider—

(i) the degree to which the location of the mentoring program proposed by each eligible entity contributes to

a fair distribution of mentoring programs with respect to urban and rural locations;

(ii) the quality of the mentoring program proposed by each eligible entity, including—

(I) the resources, if any, the eligible entity will dedicate to providing children with opportunities for job training or postsecondary education;

(II) the degree to which parents, teachers, community-based organizations, and the local community have participated, or will participate, in the design and implementation of the proposed mentoring program;

(III) the degree to which the eligible entity can ensure that mentors will develop longstanding relationships with the children they mentor;

(IV) the degree to which the mentoring program will serve children with greatest need in the 4th through 8th grades; and

(V) the degree to which the mentoring program will continue to serve children from the 9th grade through graduation from secondary school, as needed; and

(iii) the capability of each eligible entity to effectively implement its mentoring program.

(D) Grant to each State

Notwithstanding any other provision of this subsection, in awarding grants under subparagraph (A), the Secretary shall select not less than one grant recipient from each State for which there is an eligible entity that submits an application of sufficient quality pursuant to paragraph (4).

(6) Model screening guidelines

(A) In general

Based on model screening guidelines developed by the Office of Juvenile Programs of the Department of Justice, the Secretary shall develop and distribute to each eligible entity awarded a grant under this section specific model guidelines for the screening of mentors who seek to participate in mentoring programs assisted under this section.

(B) Background checks

The guidelines developed under this subsection shall include, at a minimum, a requirement that potential mentors be subject to reference checks, child and domestic abuse record checks, and criminal background checks.

§ 7151. Gun-free requirements [23]

(a) Short title

This subpart may be cited as the "Gun-Free Schools Act".

[23] Public Law 89–10, Title IV, § 4141, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1762.

(b) Requirements

(1) In general

Each State receiving Federal funds under any subchapter of this chapter shall have in effect a State law requiring local educational agencies to expel from school for a period of not less than 1 year a student who is determined to have brought a firearm to a school, or to have possessed a firearm at a school, under the jurisdiction of local educational agencies in that State, except that such State law shall allow the chief administering officer of a local educational agency to modify such expulsion requirement for a student on a case-by-case basis if such modification is in writing.

(2) Construction

Nothing in this subpart shall be construed to prevent a State from allowing a local educational agency that has expelled a student from such a student's regular school setting from providing educational services to such student in an alternative setting.

(3) Definition

For the purpose of this section, the term "firearm" has the same meaning given such term in section 921(a) of Title 18.

(c) Special rule

The provisions of this section shall be construed in a manner consistent with the Individuals with Disabilities Education Act.

(d) Report to State

Each local educational agency requesting assistance from the State educational agency that is to be provided from funds made available to the State under any subchapter of this chapter shall provide to the State, in the application requesting such assistance—

(1) an assurance that such local educational agency is in compliance with the State law required by subsection (b) of this section; and

(2) a description of the circumstances surrounding any expulsions imposed under the State law required by subsection (b) of this section, including—

(A) the name of the school concerned;

(B) the number of students expelled from such school; and

(C) the type of firearms concerned.

(e) Reporting

Each State shall report the information described in subsection (d) of this section to the Secretary on an annual basis.

(f) Definition

For the purpose of subsection (d) of this section, the term "school" means any setting that is under the control and supervision of the local educational agency for the purpose of student activities approved and authorized by the local educational agency.

(g) Exception

Nothing in this section shall apply to a firearm that is lawfully stored inside a locked vehicle on school property, or if it is for activities approved and authorized by the local educational agency and the local educational agency adopts appropriate safeguards to ensure student safety.

(h) Policy regarding criminal justice system referral

(1) In general

No funds shall be made available under any subchapter of this chapter to any local educational agency unless such agency has a policy requiring referral to the criminal justice or juvenile delinquency system of any student who brings a firearm or weapon to a school served by such agency.

(2) Definition

For the purpose of this subsection, the term "school" has the same meaning given to such term by section 921(a) of Title 18.

§ 7161. Definitions[24]

In this part:

(1) Controlled substance

The term "controlled substance" means a drug or other substance identified under Schedule I, II, III, IV, or V in section 812(c) of Title 21.

(2) Drug

The term "drug" includes controlled substances; the illegal use of alcohol and tobacco; and the harmful, abusive, or addictive use of substances, including inhalants and anabolic steroids.

(3) Drug and violence prevention

The term "drug and violence prevention" means—

(A) with respect to drugs, prevention, early intervention, rehabilitation referral, or education related to the illegal use of drugs;

(B) with respect to violence, the promotion of school safety, such that students and school personnel are free from violent and disruptive acts, including sexual harassment and abuse, and victimization associated with prejudice and intolerance, on school premises, going to and from school, and at school-sponsored activities, through the creation and maintenance of a school environment that is free of

[24] Public Law 89–10, Title IV, § 4151, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1763.

weapons and fosters individual responsibility and respect for the rights of others.

(4) Hate crime

The term "hate crime" means a crime as described in section 1(b) of the Hate Crime Statistics Act of 1990.

(5) Nonprofit

The term "nonprofit", as applied to a school, agency, organization, or institution means a school, agency, organization, or institution owned and operated by one or more nonprofit corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(6) Protective factor, buffer, or asset

The terms "protective factor", "buffer", and "asset" mean any one of a number of the community, school, family, or peer-individual domains that are known, through prospective, longitudinal research efforts, or which are grounded in a well-established theoretical model of prevention, and have been shown to prevent alcohol, tobacco, or illegal drug use, as well as violent behavior, by youth in the community, and which promote positive youth development.

(7) Risk factor

The term "risk factor" means any one of a number of characteristics of the community, school, family, or peer-individual domains that are known, through prospective, longitudinal research efforts, to be predictive of alcohol, tobacco, and illegal drug use, as well as violent behavior, by youth in the school and community.

(8) School-aged population

The term "school-aged population" means the population aged five through 17, as determined by the Secretary on the basis of the most recent satisfactory data available from the Department of Commerce.

(9) School based mental health services provider

The term "school based mental health services provider" includes a State licensed or State certified school counselor, school psychologist, school social worker, or other State licensed or certified mental health professional qualified under State law to provide such services to children and adolescents.

(10) School personnel

The term "school personnel" includes teachers, principals, administrators, counselors, social workers, psychologists, nurses, librarians, and other support staff who are employed by a school or who perform services for the school on a contractual basis.

(11) School resource officer

The term "school resource officer" means a career law enforcement officer, with sworn authority, deployed in community oriented policing, and assigned by the employing police department to a local educational agency to work in collaboration with schools and community based organizations to—

(A) educate students in crime and illegal drug use prevention and safety;

(B) develop or expand community justice initiatives for students; and

(C) train students in conflict resolution, restorative justice, and crime and illegal drug use awareness.

§ 7162. Message and materials [25]

(a) "Wrong and harmful" message

Drug and violence prevention programs supported under this part shall convey a clear and consistent message that the illegal use of drugs and acts of violence are wrong and harmful.

(b) Curriculum

The Secretary shall not prescribe the use of specific curricula for programs supported under this part.

§ 7163. Parental consent [26]

Upon receipt of written notification from the parents or legal guardians of a student, the local educational agency shall withdraw such student from any program or activity funded under this part. The local educational agency shall make reasonable efforts to inform parents or legal guardians of the content of such programs or activities funded under this part, other than classroom instruction.

§ 7164. Prohibited uses of funds [27]

No funds under this part may be used for—

(1) construction (except for minor remodeling needed to accomplish the purposes of this part); or

(2) medical services, drug treatment or rehabilitation, except for pupil services or referral to treatment for students who are victims of, or witnesses to, crime or who illegally use drugs.

§ 7165. Transfer of school disciplinary records [28]

(a) Nonapplication of provisions

This section shall not apply to any disciplinary records with respect to a suspension or expulsion that are transferred from a private, parochial or other nonpublic school, person, institution, or other entity, that provides education below the college level.

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[25] Public Law 89–10, Title IV, § 4152, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1764.

[26] Public Law 89–10, Title IV, § 4153, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1765.

[27] Public Law 89–10, Title IV, § 4154, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1765.

[28] Public Law 89–10, Title IV, § 4155, as added Public Law 107–110, Title IV, § 401, Jan. 8, 2002, 115 Stat. 1765.

(b) Disciplinary records

In accordance with the Family Educational Rights and Privacy Act of 1974 (20 U.S.C. 1232g), not later than 2 years after January 8, 2002, each State receiving Federal funds under this chapter shall provide an assurance to the Secretary that the State has a procedure in place to facilitate the transfer of disciplinary records, with respect to a suspension or expulsion, by local educational agencies to any private or public elementary school or secondary school for any student who is enrolled or seeks, intends, or is instructed to enroll, on a full- or part-time basis, in the school.

21 U.S.C. § 801 note [1]

Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Public Law 106–172, sec. 6

Development of model protocols, training materials, forensic field tests, and coordination mechanism for investigations and prosecutions relating to gamma hydroxybutyric acid (GHB), other controlled substances, and designer drugs

Title 21. Food and Drugs

Chapter 13. Drug Abuse Prevention and Control

(a) IN GENERAL.—The Attorney General, in consultation with the Administrator of the Drug Enforcement Administration and the Director of the Federal Bureau of Investigation, shall—

(1) develop—

(A) model protocols for the collection of toxicology specimens and the taking of victim statements in connection with investigations into and prosecutions related to possible violations of the Controlled Substances Act [this subchapter] or other Federal or State laws that result in or contribute to rape, other crimes of violence, or other crimes involving abuse of gamma hydroxybutyric acid, other controlled substances, or so-called 'designer drugs'; and

(B) model training materials for law enforcement personnel involved in such investigations; and

(2) make such protocols and training materials available to Federal, State, and local personnel responsible for such investigations.

(b) GRANT.—

(1) IN GENERAL.—The Attorney General shall make a grant, in such amount and to such public or private person or entity as the Attorney General considers appropriate, for the development of forensic field tests to assist law enforcement officials in detecting the presence of gamma hydroxybutyric acid and related substances.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this subsection.

(c) REPORT.—Not later than 180 days after the date of the enactment of this Act [Feb. 18, 2000], the Attorney General shall submit to the Committees on the Judiciary of the Senate and House of Representatives a report on current mechanisms for coordinating Federal, State, and local investigations into and prosecutions related to possible violations of the Controlled Substances Act [this

[1] Public Law 106–172, § 6, Feb. 18, 2000, 114 Stat. 11.

subchapter] or other Federal or State laws that result in or contribute to rape, other crimes of violence, or other crimes involving the abuse of gamma hydroxybutyric acid, other controlled substances, or so-called 'designer drugs'. The report shall also include recommendations for the improvement of such mechanisms.

21 U.S.C. § 801 note [1]

Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Public Law 106–172, sec. 7

Annual report regarding date-rape drugs; national awareness campaign

(a) ANNUAL REPORT.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall periodically submit to Congress reports each of which provides an estimate of the number of incidents of the abuse of date-rape drugs (as defined in subsection (c)) that occurred during the most recent 1-year period for which data are available. The first such report shall be submitted not later than January 15, 2000, and subsequent reports shall be submitted annually thereafter.

(b) NATIONAL AWARENESS CAMPAIGN.—

(1) DEVELOPMENT OF PLAN; RECOMMENDATIONS OF ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall develop a plan for carrying out a national campaign to educate individuals described in subparagraph (B) on the following:

(i) The dangers of date-rape drugs.

(ii) The applicability of the Controlled Substances Act [this subchapter] to such drugs, including penalties under such Act.

(iii) Recognizing the symptoms that indicate an individual may be a victim of such drugs, including symptoms with respect to sexual assault.

(iv) Appropriately responding when an individual has such symptoms.

(B) INTENDED POPULATION.—The individuals referred to in subparagraph (A) are young adults, youths, law enforcement personnel, educators, school nurses, counselors of rape victims, and emergency room personnel in hospitals.

(C) ADVISORY COMMITTEE.—Not later than 180 days after the date of the enactment of this Act [Feb. 18, 2000], the Secretary shall establish an advisory committee to make recommendations to the Secretary regarding the plan under subparagraph (A). The committee shall be composed of individuals who collectively possess expertise on the effects of date-rape drugs and on detecting and controlling the drugs.

(2) IMPLEMENTATION OF PLAN.—Not later than 180 days after the date on which the advisory committee under paragraph (1) is established, the Secretary, in consultation with the Attorney General, shall commence carrying out the national campaign

[1] Public Law 106–172, § 7, Feb. 18, 2000, 114 Stat. 11.

under such paragraph in accordance with the plan developed under such paragraph. The campaign may be carried out directly by the Secretary and through grants and contracts.

(3) EVALUATION BY GENERAL ACCOUNTING OFFICE [NOW GOVERNMENT ACCOUNTABILITY OFFICE].—Not later than 2 years after the date on which the national campaign under paragraph (1) is commenced, the Comptroller General of the United States shall submit to Congress an evaluation of the effects with respect to date-rape drugs of the national campaign.

(c) DEFINITION.—For purposes of this section, the term 'date-rape drugs' means gamma hydroxybutyric acid and its salts, isomers, and salts of isomers and such other drugs or substances as the Secretary, after consultation with the Attorney General, determines to be appropriate.

21 U.S.C. § 801 note [1]

Children's Health Act of 2000, Public Law 106–310, Div. B, Title XXXVI, sec. 3671

Antidrug messages on Federal Government Internet websites

Not later than 90 days after the date of the enactment of this Act [Oct. 17, 2000], the head of each department, agency, and establishment of the Federal Government shall, in consultation with the Director of the Office of National Drug Control Policy, place antidrug messages on appropriate Internet websites controlled by such department, agency, or establishment which messages shall, where appropriate, contain an electronic hyperlink to the Internet website, if any, of the Office.

[1] Public Law 106–310, Div. B, Title XXXVI, § 3671, Oct. 17, 2000, 114 Stat. 1245.

21 U.S.C. § 801a
Psychotropic Substances Act, Public Law 95–633, sec. 101
Congressional findings on implementing the 1971 Convention on Psychotropic Substances

§ 801a. Congressional findings and declarations: psychotropic substances [1]

The Congress makes the following findings and declarations:

(1) The Congress has long recognized the danger involved in the manufacture, distribution, and use of certain psychotropic substances for nonscientific and nonmedical purposes, and has provided strong and effective legislation to control illicit trafficking and to regulate legitimate uses of psychotropic substances in this country. Abuse of psychotropic substances has become a phenomenon common to many countries, however, and is not confined to national borders. It is, therefore, essential that the United States cooperate with other nations in establishing effective controls over international traffic in such substances.

(2) The United States has joined with other countries in executing an international treaty, entitled the Convention on Psychotropic Substances and signed at Vienna, Austria, on February 21, 1971, which is designed to establish suitable controls over the manufacture, distribution, transfer, and use of certain psychotropic substances. The Convention is not self-executing, and the obligations of the United States thereunder may only be performed pursuant to appropriate legislation. It is the intent of the Congress that the amendments made by this Act, together with existing law, will enable the United States to meet all of its obligations under the Convention and that no further legislation will be necessary for that purpose.

(3) In implementing the Convention on Psychotropic Substances, the Congress intends that, consistent with the obligations of the United States under the Convention, control of psychotropic substances in the United States should be accomplished within the framework of the procedures and criteria for classification of substances provided in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.]. This will insure that (A) the availability of psychotropic substances to manufacturers, distributors, dispensers, and researchers for useful and legitimate medical and scientific purposes will not be unduly restricted; (B) nothing in the Convention will interfere with bona fide research activities; and (C) nothing in the Convention will interfere with ethical medical practice in this country as determined by the Secretary of

[1] Public Law 95–633, Title I, § 101, Nov. 10, 1978, 92 Stat. 3768; Public Law 96–88, Title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.

Health and Human Services on the basis of a consensus of the views of the American medical and scientific community.

21 U.S.C. § 802 note [1]

Comprehensive Methamphetamine Control Act of 1996, Public Law 104–237, Title IV, sec. 401(d)–(f)

Retail sales of pseudoephedrine and phenylpropanolamine

(d) REGULATION OF RETAIL SALES.—

(1) PSEUDOEPHEDRINE.—

(A) LIMIT.—

(i) IN GENERAL.—Not sooner than the effective date of this section [see section 401(g) of Public Law 104–237 set out as an Effective Date of 1996 Amendments note under this section] and subject to the requirements of clause (ii), the Attorney General may establish by regulation a single-transaction limit of 24 grams of pseudoephedrine base for retail distributors. Notwithstanding any other provision of law, the single-transaction threshold quantity for pseudoephedrine-containing compounds may not be lowered beyond that established in this paragraph.

(ii) CONDITIONS.—In order to establish a single-transaction limit of 24 grams of pseudoephedrine base, the Attorney General shall establish, following notice, comment, and an informal hearing that since the date of enactment of this Act [Oct. 3, 1996] there are a significant number of instances where ordinary over-the-counter pseudoephedrine products as established in paragraph (45) of section 102 of the Controlled Substances Act (21 U.S.C. 802(45)), as added by this Act [par. (45) of this section], sold by retail distributors as established in paragraph (46) in section 102 of the Controlled Substances Act (21 U.S.C. 802(46)) [par. (46) of this section], are being widely used as a significant source of precursor chemicals for illegal manufacture of a controlled substance for distribution or sale.

(B) VIOLATION.—Any individual or business that violates the thresholds established in this paragraph shall, with respect to the first such violation, receive a warning letter from the Attorney General and, if a business, the business shall be required to conduct mandatory education of the sales employees of the firm with regard to the legal sales of pseudoephedrine. For a second violation occurring within 2 years of the first violation, the business or individual shall be subject to a civil penalty of not more than $5,000. For any subsequent violation occurring within 2 years of the previous violation, the business or individual shall be

[1] Public Law 104–237, Title IV, § 401(d)–(f), Oct. 3, 1996, 110 Stat. 3108.

subject to a civil penalty not to exceed the amount of the previous civil penalty plus $5,000.

(2) PHENYLPROPANOLAMINE.—

(A) LIMIT.—

(i) IN GENERAL.—Not sooner than the effective date of this section and subject to the requirements of clause (ii), the Attorney General may establish by regulation a single-transaction limit of 24 grams of phenylpropanolamine base for retail distributors. Notwithstanding any other provision of law, the single-transaction threshold quantity for phenylpropanolamine-containing compounds may not be lowered beyond that established in this paragraph.

(ii) CONDITIONS.—In order to establish a single-transaction limit of 24 grams of phenylpropanolamine base, the Attorney General shall establish, following notice, comment, and an informal hearing, that since the date of enactment of this Act [Oct. 3, 1996] there are a significant number of instances where ordinary over-the-counter phenylpropanolamine products as established in paragraph (45) of section 102 of the Controlled Substances Act (21 U.S.C. 802(45)), as added by this Act [par. (45) of this section], sold by retail distributors as established in paragraph (46) in section 102 of the Controlled Substances Act (21 U.S.C. 802(46)) [par. (46) of this section], are being used as a significant source of precursor chemicals for illegal manufacture of a controlled substance in bulk.

(B) VIOLATION.—Any individual or business that violates the thresholds established in this paragraph shall, with respect to the first such violation, receive a warning letter from the Attorney General and, if a business, the business shall be required to conduct mandatory education of the sales employees of the firm with regard to the legal sales of pseudoephedrine. For a second violation occurring within 2 years of the first violation, the business or individual shall be subject to a civil penalty of not more than $5,000. For any subsequent violation occurring within 2 years of the previous violation, the business or individual shall be subject to a civil penalty not to exceed the amount of the previous civil penalty plus $5,000.

(3) SIGNIFICANT NUMBER OF INSTANCES.—

(A) IN GENERAL.—For purposes of this subsection, isolated or infrequent use, or use in insubstantial quantities, of ordinary over-the-counter pseudoephedrine or phenylpropanolamine, as defined in section 102(45) of the Controlled Substances Act, as added by section 401(b) of this Act [par. (45) of this section], and sold at the retail level for the illicit manufacture of methamphetamine or amphetamine may not be used by the Attorney General as the basis for establishing the conditions under paragraph (1)(A)(ii) of this subsection, with respect to pseudoephedrine, and paragraph (2)(A)(ii) of this subsection, with respect to phenylpropanolamine.

(B) CONSIDERATIONS AND REPORT.—The Attorney General shall—

(i) in establishing a finding under paragraph (1)(A)(ii) or (2)(A)(ii) of this subsection, consult with the Secretary of Health and Human Services in order to consider the effects on public health that would occur from the establishment of new single transaction limits as provided in such paragraph; and

(ii) upon establishing a finding, transmit a report to the Committees on the Judiciary in both, respectively, the House of Representatives and the Senate in which the Attorney General will provide the factual basis for establishing the new single transaction limits.

(4) DEFINITION OF BUSINESS.—For purposes of this subsection, the term 'business' means the entity that makes the direct sale and does not include the parent company of a business not involved in a direct sale regulated by this subsection.

(5) JUDICIAL REVIEW.—Any regulation promulgated by the Attorney General under this section shall be subject to judicial review pursuant to section 507 of the Controlled Substances Act (21 U.S.C. 877) [section 877 of Title 21].

(e) EFFECT ON THRESHOLDS.—Nothing in the amendments made by subsection (b) [amending par. (39), adding pars. (45) and (46), and redesignating par. (43) set out second as (44)] or the provisions of subsection (d) [subsec. (d) of this note] shall affect the authority of the Attorney General to modify thresholds (including cumulative thresholds) for retail distributors for products other than ordinary over-the-counter pseudoephedrine or phenylpropanolamine products (as defined in section 102(45) of the Controlled Substances Act, as added by this section) [par. (45) of this section] or for nonretail distributors, importers, or exporters.

(f) COMBINATION EPHEDRINE PRODUCTS.—

(1) IN GENERAL.—For the purposes of this section, combination ephedrine products shall be treated the same as pseudoephedrine products, except that—

(A) a single transaction limit of 24 grams shall be effective as of the date of enactment of this Act [Oct. 3, 1996] and shall apply to sales of all combination ephedrine products, notwithstanding the form in which those products are packaged, made by retail distributors or distributors required to submit a report under section 310(b)(3) of the Controlled Substances Act (as added by section 402 of this Act) [830(b)(3) of this title];

(B) for regulated transactions for combination ephedrine products other than sales described in subparagraph (A), the transaction limit shall be—

(i) 1 kilogram of ephedrine base, effective on the date of enactment of this Act [Oct. 3, 1996]; or

(ii) a threshold other than the threshold described in clause (i), if established by the Attorney General not earlier than 1 year after the date of enactment of this Act [Oct. 3, 1996]; and

(C) the penalties provided in subsection (d)(1)(B) of this section [subsec. (d)(1)(B) of this note] shall take effect on

the date of enactment of this Act [Oct. 3, 1996] for any individual or business that violates the single transaction limit of 24 grams for combination ephedrine products.

(2) DEFINITION.—For the purposes of this section, the term 'combination ephedrine product' means a drug product containing ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically significant quantities of another active medicinal ingredient.

21 U.S.C. § 802 note [1]

Children's Health Act of 2000, Public Law 106–310, Div. B, Title XXXVI, sec. 3642

Report on diversion of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products

(a) STUDY.—The Attorney General shall conduct a study of the use of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products in the clandestine production of illicit drugs. Sources of data for the study shall include the following:

(1) Information from Federal, State, and local clandestine laboratory seizures and related investigations identifying the source, type, or brand of drug products being utilized and how they were obtained for the illicit production of methamphetamine and amphetamine.

(2) Information submitted voluntarily from the pharmaceutical and retail industries involved in the manufacture, distribution, and sale of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine, including information on changes in the pattern, volume, or both, of sales of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products.

(b) REPORT.—

(1) REQUIREMENT.—Not later than 1 year after the date of the enactment of this Act [Oct. 17, 2000], the Attorney General shall submit to Congress a report on the study conducted under subsection (a).

(2) ELEMENTS.—The report shall include—

(A) the findings of the Attorney General as a result of the study; and

(B) such recommendations on the need to establish additional measures to prevent diversion of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine (such as a threshold on ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products) as the Attorney General considers appropriate.

(3) MATTERS CONSIDERED.—In preparing the report, the Attorney General shall consider the comments and recommendations including the comments on the Attorney General's proposed findings and recommendations, of State and local law enforcement and regulatory officials and of representatives of the industry described in subsection (a)(2).

(c) REGULATION OF RETAIL SALES.—

(1) IN GENERAL.—Notwithstanding section 401(d) of the Comprehensive Methamphetamine Control Act of 1996 (21 U.S.C. 802 note) and subject to paragraph (2), the Attorney General

[1] Public Law 106–310, Div. B, Title XXXVI, § 3642, Oct. 17, 2000, 114 Stat. 1237.

shall establish by regulation a single-transaction limit of not less than 24 grams of ordinary, over-the-counter pseudoephedrine or phenylpropanolamine (as the case may be) for retail distributors, if the Attorney General finds, in the report under subsection (b), that—

(A) there is a significant number of instances (as set forth in paragraph (3)(A) of such section 401(d) [set out as a note under this section] for purposes of such section) where ordinary, over-the-counter pseudoephedrine products, phenylpropanolamine products, or both such products that were purchased from retail distributors were widely used in the clandestine production of illicit drugs; and

(B) the best practical method of preventing such use is the establishment of single-transaction limits for retail distributors of either or both of such products.

(2) DUE PROCESS.—The Attorney General shall establish the single-transaction limit under paragraph (1) only after notice, comment, and an informal hearing.

21 U.S.C. § 812 note [1]

Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Public Law 106–172, sec. 2

Congressional findings regarding gamma hydroxybutyric acid (GHB)

Congress finds as follows:

(1) Gamma hydroxybutyric acid (also called G, Liquid X, Liquid Ecstasy, Grievous Bodily Harm, Georgia Home Boy, Scoop) has become a significant and growing problem in law enforcement. At least 20 States have scheduled such drug in their drug laws and law enforcement officials have been experiencing an increased presence of the drug in driving under the influence, sexual assault, and overdose cases especially at night clubs and parties.

(2) A behavioral depressant and a hypnotic, gamma hydroxybutyric acid ('GHB') is being used in conjunction with alcohol and other drugs with detrimental effects in an increasing number of cases. It is difficult to isolate the impact of such drug's ingestion since it is so typically taken with an ever-changing array of other drugs and especially alcohol which potentiates its impact.

(3) GHB takes the same path as alcohol, processes via alcohol dehydrogenase, and its symptoms at high levels of intake and as impact builds are comparable to alcohol ingestion/intoxication. Thus, aggression and violence can be expected in some individuals who use such drug.

(4) If taken for human consumption, common industrial chemicals such as gamma butyrolactone and 1.4-butanediol are swiftly converted by the body into GHB. Illicit use of these and other GHB analogues and precursor chemicals is a significant and growing law enforcement problem.

(5) A human pharmaceutical formulation of gamma hydroxybutyric acid is being developed as a treatment for cataplexy, a serious and debilitating disease. Cataplexy, which causes sudden and total loss of muscle control, affects about 65 percent of the estimated 180,000 Americans with narcolepsy, a sleep disorder. People with cataplexy often are unable to work, drive a car, hold their children or live a normal life.

(6) Abuse of illicit GHB is an imminent hazard to public safety that requires immediate regulatory action under the Controlled Substances Act (21 U.S.C. 801 et seq.).

[1] Public Law 106–172, § 2, Feb. 18, 2000, 114 Stat. 7.

21 U.S.C. § 812 note [1]

Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Public Law 106–172, sec. 3a

Emergency scheduling of gamma hydroxybutyric acid (GHB) and listing of gamma butyrolactone as list I chemical

(a) EMERGENCY SCHEDULING OF GHB.—

(1) IN GENERAL.—The Congress finds that the abuse of illicit gamma hydroxybutyric acid is an imminent hazard to the public safety. Accordingly, the Attorney General, notwithstanding sections 201(a), 201(b), 201(c), and 202 of the Controlled Substances Act [21 U.S.C. 811(a), 811(b), 811(c), and this section], shall issue, not later than 60 days after the date of the enactment of this Act [Feb. 18, 2000], a final order that schedules such drug (together with its salts, isomers, and salts of isomers) in the same schedule under section 202(c) of the Controlled Substances Act [subsec. (c) of this section] as would apply to a scheduling of a substance by the Attorney General under section 201(h)(1) of such Act [21 U.S.C. 811(h)(1)] (relating to imminent hazards to the public safety), except as follows:

(A) For purposes of any requirements that relate to the physical security of registered manufacturers and registered distributors, the final order shall treat such drug, when the drug is manufactured, distributed, or possessed in accordance with an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i)] (whether the exemption involved is authorized before, on, or after the date of the enactment of this Act [Feb. 18, 2000]), as being in the same schedule as that recommended by the Secretary of Health and Human Services for the drug when the drug is the subject of an authorized investigational new drug application (relating to such section 505(i) [21 U.S.C. 355(i)]). The recommendation referred to in the preceding sentence is contained in the first paragraph of the letter transmitted on May 19, 1999, by such Secretary (acting through the Assistant Secretary for Health) to the Attorney General (acting through the Deputy Administrator of the Drug Enforcement Administration), which letter was in response to the letter transmitted by the Attorney General (acting through such Deputy Administrator) on September 16, 1997. In publishing the final order in the Federal Register, the Attorney General shall publish a copy of the letter that was transmitted by the Secretary of Health and Human Services.

[1] Public Law 106–172, § 3(a), Feb. 18, 2000, 114 Stat. 8.

(B) In the case of gamma hydroxybutyric acid that is contained in a drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355] (whether the application involved is approved before, on, or after the date of the enactment of this Act [Feb. 18, 2000]), the final order shall schedule such drug in the same schedule as that recommended by the Secretary of Health and Human Services for authorized formulations of the drug. The recommendation referred to in the preceding sentence is contained in the last sentence of the fourth paragraph of the letter referred to in subparagraph (A) with respect to May 19, 1999.

(2) FAILURE TO ISSUE ORDER.—If the final order is not issued within the period specified in paragraph (1), gamma hydroxybutyric acid (together with its salts, isomers, and salts of isomers) is deemed to be scheduled under section 202(c) of the Controlled Substances Act [subsec. (c) of this section] in accordance with the policies described in paragraph (1), as if the Attorney General had issued a final order in accordance with such paragraph.

21 U.S.C. § § 862a–b

Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, secs. 115 and 902

Denial of assistance and benefits for certain drug-related convictions

§ 862a. Denial of assistance and benefits for certain drug-related convictions [1]

(a) In general

An individual convicted (under Federal or State law) of any offense which is classified as a felony by the law of the jurisdiction involved and which has as an element the possession, use, or distribution of a controlled substance (as defined in section 802(6) of this title) shall not be eligible for—

(1) assistance under any State program funded under part A of title IV of the Social Security Act [42 U.S.C. 601 et seq.], or

(2) benefits under the food stamp program (as defined in section 3(h) of the Food Stamp Act of 1977 [7 U.S.C. 2012(h)]) or any State program carried out under the Food Stamp Act of 1977 [7 U.S.C. 2011 et seq.].

(b) Effects on assistance and benefits for others

(1) Program of temporary assistance for needy families

The amount of assistance otherwise required to be provided under a State program funded under part A of title IV of the Social Security Act [42 U.S.C. 601 et seq.] to the family members of an individual to whom subsection (a) of this section applies shall be reduced by the amount which would have otherwise been made available to the individual under such part.

(2) Benefits under the Food Stamp Act of 1977

The amount of benefits otherwise required to be provided to a household under the food stamp program (as defined in section 3(h) of the Food Stamp Act of 1977 [7 U.S.C. 2012(h)]), or any State program carried out under the Food Stamp Act of 1977 [7 U.S.C. 2011 et seq.], shall be determined by considering the individual to whom subsection (a) of this section applies not to be a member of such household, except that the income and resources of the individual shall be considered to be income and resources of the household.

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[1] Public Law 104–193, Title I, § 115, Aug. 22, 1996, 110 Stat. 2180; Public Law 105–33, Title V, § 5516(a), Aug. 5, 1997, 111 Stat 620.

(c) Enforcement

A State that has not exercised its authority under subsection (d)(1)(A) of this section shall require each individual applying for assistance or benefits referred to in subsection (a) of this section, during the application process, to state, in writing, whether the individual, or any member of the household of the individual, has been convicted of a crime described in subsection (a) of this section.

(d) Limitations

(1) State elections

(A) Opt out

A State may, by specific reference in a law enacted after August 22, 1996, exempt any or all individuals domiciled in the State from the application of subsection (a) of this section.

(B) Limit period of prohibition

A State may, by law enacted after August 22, 1996, limit the period for which subsection (a) of this section shall apply to any or all individuals domiciled in the State.

(2) Inapplicability to a conviction if the conviction is for conduct occurring on or before August 22, 1996

Subsection (a) of this section shall not apply to a conviction if the conviction is for conduct occurring on or before August 22, 1996.

(e) "State" defined

For purposes of this section, the term "State" has the meaning given it—

(1) in section 419(5) of the Social Security Act [42 U.S.C. 619(5)], when referring to assistance provided under a State program funded under part A of title IV of the Social Security Act [42 U.S.C. 601 et seq.], and

(2) in section 3(m) of the Food Stamp Act of 1977 [7 U.S.C. 2012(m)], when referring to the food stamp program (as defined in section 3(h) of the Food Stamp Act of 1977 [7 U.S.C. 2012(h)]) or any State program carried out under the Food Stamp Act of 1977 [7 U.S.C. 2011 et seq.].

(f) Rule of interpretation

Nothing in this section shall be construed to deny the following Federal benefits:

(1) Emergency medical services under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(2) Short-term, noncash, in-kind emergency disaster relief.

(3)(A) Public health assistance for immunizations.

(B) Public health assistance for testing and treatment of communicable diseases if the Secretary of Health and Human Services determines that it is necessary to prevent the spread of such disease.

(4) Prenatal care.

(5) Job training programs.
(6) Drug treatment programs.

§ 862b. Sanctioning for testing positive for controlled substances [2]

Notwithstanding any other provision of law, States shall not be prohibited by the Federal Government from testing welfare recipients for use of controlled substances nor from sanctioning welfare recipients who test positive for use of controlled substances.

[2] Public Law 104–193, Title IX, § 902, Aug. 22, 1996, 110 Stat. 2347.

21 U.S.C. § 872 note [1]

Children's Health Act of 2000, Public Law 106–310, Div. B, Title XXXVI, sec. 3623

Training for Drug Enforcement Administration and State and local law enforcement personnel relating to clandestine laboratories

§ 872. Education and research programs of Attorney General

(a) IN GENERAL.—

(1) REQUIREMENT.—The Administrator of the Drug Enforcement Administration shall carry out the programs described in subsection (b) with respect to the law enforcement personnel of States and localities determined by the Administrator to have significant levels of methamphetamine-related or amphetamine-related crime or projected by the Administrator to have the potential for such levels of crime in the future.

(2) DURATION.—The duration of any program under that subsection may not exceed 3 years.

(b) COVERED PROGRAMS.—The programs described in this subsection are as follows:

(1) ADVANCED MOBILE CLANDESTINE LABORATORY TRAINING TEAMS.—A program of advanced mobile clandestine laboratory training teams, which shall provide information and training to State and local law enforcement personnel in techniques utilized in conducting undercover investigations and conspiracy cases, and other information designed to assist in the investigation of the illegal manufacturing and trafficking of amphetamine and methamphetamine.

(2) BASIC CLANDESTINE LABORATORY CERTIFICATION TRAINING.—A program of basic clandestine laboratory certification training, which shall provide information and training—

(A) to Drug Enforcement Administration personnel and State and local law enforcement personnel for purposes of enabling such personnel to meet any certification requirements under law with respect to the handling of wastes created by illegal amphetamine and methamphetamine laboratories; and

(B) to State and local law enforcement personnel for purposes of enabling such personnel to provide the information and training covered by subparagraph (A) to other State and local law enforcement personnel.

(3) CLANDESTINE LABORATORY RECERTIFICATION AND AWARENESS TRAINING.—A program of clandestine laboratory recertification and awareness training, which shall provide information and training to State and local law enforcement personnel for purposes of enabling such personnel to provide recertification

[1] Public Law 106–310, Div. B, title XXXVI, § 3623, Oct. 17, 2000, 114 Stat. 1231.

and awareness training relating to clandestine laboratories to additional State and local law enforcement personnel.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for each of fiscal years 2000, 2001, and 2002 amounts as follows:

(1) $1,500,000 to carry out the program described in subsection (b)(1).

(2) $3,000,000 to carry out the program described in subsection (b)(2).

(3) $1,000,000 to carry out the program described in subsection (b)(3).

21 U.S.C. § 872a

Comprehensive Methamphetamine Control Act of 1996, Public Law 104–237, sec. 503

Responsibilities of Attorney General to control precursor chemicals

§ 872a. Public-private education program [1]

(a) Advisory panel

The Attorney General shall establish an advisory panel consisting of an appropriate number of representatives from Federal, State, and local law enforcement and regulatory agencies with experience in investigating and prosecuting illegal transactions of precursor chemicals. The Attorney General shall convene the panel as often as necessary to develop and coordinate educational programs for wholesale and retail distributors of precursor chemicals and supplies.

(b) Continuation of current efforts

The Attorney General shall continue to—

(1) maintain an active program of seminars and training to educate wholesale and retail distributors of precursor chemicals and supplies regarding the identification of suspicious transactions and their responsibility to report such transactions; and

(2) provide assistance to State and local law enforcement and regulatory agencies to facilitate the establishment and maintenance of educational programs for distributors of precursor chemicals and supplies.

[1] Public Law 104–237, Title V, § 503, Oct. 3, 1996, 110 Stat. 3112.

21 U.S.C. § 873 note [1]

Department of Defense Appropriations Act, 1994, Public Law 103–139, Title VIII, sec. 8056

Establishment of National Drug Intelligence Center

During the current fiscal year and thereafter, there is established, under the direction and control of the Attorney General, the National Drug Intelligence Center, whose mission it shall be to coordinate and consolidate drug intelligence from all national security and law enforcement agencies, and produce information regarding the structure, membership, finances, communications, and activities of drug trafficking organizations: *Provided*, That funding for the operation of the National Drug Intelligence Center, including personnel costs associated therewith, shall be provided from the funds appropriated to the Department of Defense.

[1] Public Law 103–139, Title VIII, § 8056, Nov. 11, 1993, 107 Stat. 1452.

21 U.S.C. § 873 note [1]

Children's Health Act of 2000, Public Law 106–310, Div. B, Title XXXVI, sec. 3625

Combating amphetamine and methamphetamine manufacturing and trafficking

(a) ACTIVITIES.—In order to combat the illegal manufacturing and trafficking in amphetamine and methamphetamine, the Administrator of the Drug Enforcement Administration may—

(1) assist State and local law enforcement in small and mid-sized communities in all phases of investigations related to such manufacturing and trafficking, including assistance with foreign-language interpretation;

(2) staff additional regional enforcement and mobile enforcement teams related to such manufacturing and trafficking;

(3) establish additional resident offices and posts of duty to assist State and local law enforcement in rural areas in combating such manufacturing and trafficking;

(4) provide the Special Operations Division of the Administration with additional agents and staff to collect, evaluate, interpret, and disseminate critical intelligence targeting the command and control operations of major amphetamine and methamphetamine manufacturing and trafficking organizations;

(5) enhance the investigative and related functions of the Chemical Control Program of the Administration to implement more fully the provisions of the Comprehensive Methamphetamine Control Act of 1996 (Public Law 104–237);

(6) design an effective means of requiring an accurate accounting of the import and export of list I chemicals, and coordinate investigations relating to the diversion of such chemicals;

(7) develop a computer infrastructure sufficient to receive, process, analyze, and redistribute time-sensitive enforcement information from suspicious order reporting to field offices of the Administration and other law enforcement and regulatory agencies, including the continuing development of the Suspicious Order Reporting and Tracking System (SORTS) and the Chemical Transaction Database (CTRANS) of the Administration;

(8) establish an education, training, and communication process in order to alert the industry to current trends and emerging patterns in the illegal manufacturing of amphetamine and methamphetamine; and

(9) carry out such other activities as the Administrator considers appropriate.

(b) ADDITIONAL POSITIONS AND PERSONNEL.—

[1] Public Law 106–310, Div. B, Title XXXVI, § 3625, Oct. 17, 2000, 114 Stat. 1233.

(1) IN GENERAL.—In carrying out activities under subsection (a), the Administrator may establish in the Administration not more than 50 full-time positions, including not more than 31 special-agent positions, and may appoint personnel to such positions.

(2) PARTICULAR POSITIONS.—In carrying out activities under paragraphs (5) through (8) of subsection (a), the Administrator may establish in the Administration not more than 15 full-time positions, including not more than 10 diversion investigator positions, and may appoint personnel to such positions. Any positions established under this paragraph are in addition to any positions established under paragraph (1).

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the Drug Enforcement Administration for each fiscal year after fiscal year 1999, $9,500,000 for purposes of carrying out the activities authorized by subsection (a) and employing personnel in positions established under subsection (b), of which $3,000,000 shall be available for activities under paragraphs (5) through (8) of subsection (a) and for employing personnel in positions established under subsection (b)(2).

21 U.S.C. § 873 note [1]

Intelligence Authorization Act for Fiscal Year 2003, Public Law 107–306, Title VIII, § 826

Annual report on counterdrug intelligence matters

(a) ANNUAL REPORT.—The Counterdrug Intelligence Coordinating Group shall submit to the appropriate committees of Congress each year a report on current counterdrug intelligence matters. The report shall include the recommendations of the Counterdrug Intelligence Coordinating Group on the appropriate number of permanent staff, and of detailed personnel, for the staff of the Counterdrug Intelligence Executive Secretariat.

(b) SUBMITTAL DATE.—The date of the submittal each year of the report required by subsection (a) shall be the date provided in section 507 of the National Security Act of 1947 [50 U.S.C. 415b], as added by section 811 of this Act.

(c) APPROPRIATE COMMITTEES OF CONGRESS DEFINED.—In this section [this note], the term "appropriate committees of Congress" means—

(1) the Committees on Appropriations of the Senate and House of Representatives; and

(2) the congressional intelligence committees (as defined in section 3 of the National Security Act of 1947 (50 U.S.C. 401a)).

[1] Public Law 107–306, Title VIII, § 826, Nov. 27, 2002, 116 Stat. 2429.

21 U.S.C. § 873 note [1]

Intelligence Authorization Act for Fiscal Year 2004, Public Law 108–177, Title I, sec. 104(e)

National Drug Intelligence Center

(e) NATIONAL DRUG INTELLIGENCE CENTER.—

(1) IN GENERAL.—Of the amount authorized to be appropriated in subsection (a) [Public Law 108–177, Title I, § 104(a), Dec. 13, 2003, 117 Stat. 2601, which is not classified to the Code], $47,142,000 shall be available for the National Drug Intelligence Center. Within such amount, funds provided for research, development, testing, and evaluation purposes shall remain available until September 30, 2005, and funds provided for procurement purposes shall remain available until September 30, 2006.

(2) TRANSFER OF FUNDS.—The Director of Central Intelligence shall transfer to the Attorney General funds available for the National Drug Intelligence Center under paragraph (1). The Attorney General shall utilize funds so transferred for the activities of the National Drug Intelligence Center.

(3) LIMITATION.—Amounts available for the National Drug Intelligence Center may not be used in contravention of the provisions of section 103(d)(1) of the National Security Act of 1947 (50 U.S.C. 403–3(d)(1)).

(4) AUTHORITY.—Notwithstanding any other provision of law, the Attorney General shall retain full authority over the operations of the National Drug Intelligence Center.[2]

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[1] Public Law 108–177, Title I, § 104(e), Dec. 13, 2003, 117 Stat. 2602.

[2] Similar provisions were contained in the following prior appropriations acts: Public Law 107–306, Title I, § 104(e), Nov. 27, 2002, 116 Stat. 2387. Public Law 107–108, Title I, § 104(e), Dec. 28, 2001, 115 Stat. 1396. Public Law 106–567, Title I, § 104(e), Dec. 27, 2000, 114 Stat. 2834. Public Law 106–120, Title I, § 104(e), Dec. 3, 1999, 113 Stat. 1609. Public Law 105–272, Title I, § 104(e), Oct. 20, 1998, 112 Stat. 2398. Public Law 105–107, Title I, § 104(e), Nov. 20, 1997, 111 Stat. 2250. Public Law 104–293, Title I, § 104(d), Oct. 11, 1996, 110 Stat. 3464.

Public Law 103–139, Title VIII, § 8056, Nov. 11, 1993, 107 Stat. 1452, provided that: "During the current fiscal year and thereafter, there is established, under the direction and control of the Attorney General, the National Drug Intelligence Center, whose mission it shall be to coordinate and consolidate drug intelligence from all national security and law enforcement agencies, and produce information regarding the structure, membership, finances, communications, and activities of drug trafficking organizations: *Provided*, That funding for the operation of the National Drug Intelligence Center, including personnel costs associated therewith, shall be provided from the funds appropriated to the Department of Defense."

Similar provisions were contained in the following prior appropriations Act: Public Law 102–396, Title IX, § 9078, Oct. 6, 1992, 106 Stat. 1919.

21 U.S.C. § 886a
Department of Justice and Related Agencies Appropriations Act, 1993, Public Law 102–395, sec. 111(b)
Establishment of Diversion Control Fee Account

§ 886a. Diversion Control Fee Account[1]

(1) In general

There is established in the general fund of the Treasury a separate account which shall be known as the Diversion Control Fee Account. For fiscal year 1993 and thereafter:

(A) There shall be deposited as offsetting receipts into that account all fees collected by the Drug Enforcement Administration, in excess of $15,000,000, for the operation of its diversion control program.

(B) Such amounts as are deposited into the Diversion Control Fee Account shall remain available until expended and shall be refunded out of that account by the Secretary of the Treasury, at least on a quarterly basis, to reimburse the Drug Enforcement Administration for expenses incurred in the operation of the diversion control program. Such reimbursements shall be made without distinguishing between expenses related to controlled substance activities and expenses related to chemical activities.

(C) Fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.

(D) The amount required to be refunded from the Diversion Control Fee Account for fiscal year 1994 and thereafter shall be refunded in accordance with estimates made in the budget request of the Attorney General for those fiscal years. Any proposed changes in the amounts designated in said budget requests shall only be made after notification to the Committees on Appropriations of the House of Representatives and the Senate fifteen days in advance.

(2) Definitions

In this section:

(A) Diversion control program

The term "diversion control program" means the controlled substance and chemical diversion control activities of the Drug Enforcement Administration.

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[1] Public Law 102–395, Title I, § 111(b), Oct. 6, 1992, 106 Stat. 1843; Public Law 105–362, Title X, § 1001(b), Nov. 10, 1998, 112 Stat. 3291; Public Law 108–447, Div. B, Title VI, § 633(a), Dec. 8, 2004, 118 Stat. 2921.

(B) Controlled substance and chemical diversion control activities

The term "controlled substance and chemical diversion control activities" means those activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals.

21 U.S.C. §§ 967–969

Act to authorize subpenas in connection with the enforcement of the narcotic laws, Public Law 84–362

§ 967. Smuggling of controlled substances; investigations; oaths; subpenas; witnesses; evidence; production of records; territorial limits; fees and mileage of witnesses [1]

For the purpose of any investigation which, in the opinion of the Secretary of the Treasury, is necessary and proper to the enforcement of section 545 of Title 18 (relating to smuggling goods into the United States) with respect to any controlled substance (as defined in section 802 of this title), the Secretary of the Treasury may administer oaths and affirmations, subpena witnesses, compel their attendance, take evidence, and require the production of records (including books, papers, documents and tangible things which constitute or contain evidence) relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place within the customs territory of the United States, except that a witness shall not be required to appear at any hearing distant more than 100 miles from the place where he was served with subpena. Witnesses summoned by the Secretary shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. Oaths and affirmations may be made at any place subject to the jurisdiction of the United States.

§ 968. Service of subpena; proof of service [2]

A subpena of the Secretary of the Treasury may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

§ 969. Contempt proceedings [3]

In case of contumacy by, or refusal to obey a subpena issued to, any person, the Secretary of the Treasury may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, carries on business or may be found, to compel compliance with the subpena of the Secretary of the Treasury. The court

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[1] Aug. 11, 1955, c. 800, § 1, 69 Stat. 684; Oct. 27, 1970, Public Law 91–513, Title III, § 1102(t), 84 Stat. 1294.
[2] Aug. 11, 1955, c. 800, § 2, 69 Stat. 685.
[3] Aug. 11, 1955, c. 800, § 3, 69 Stat. 685.

may issue an order requiring the subpenaed person to appear before the Secretary of the Treasury there to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in the judicial district whereof the subpenaed person is an inhabitant or wherever he may be found.

21 U.S.C. § 971 note [1]

Comprehensive Methamphetamine Control Act of 1996, Public Law 104–237, Title II, sec. 204(b)

Exception for iodine to importation and exportation requirements for listed chemicals

(1) Iodine shall not be subject to the requirements for listed chemicals provided in section 1018 of the Controlled Substances Import and Export Act (21 U.S.C. 971).

(2) EFFECT OF EXCEPTION.—The exception made by paragraph (1) shall not limit the authority of the Attorney General to impose the requirements for listed chemicals provided in section 1018 of the Controlled Substances Import and Export Act (21 U.S.C. 971).

[1] Public Law 104–237, Title II, § 204(b), Oct. 3, 1996, 110 Stat. 3102.

21 U.S.C. §§ 1301–1308
President's Media Commission on Alcohol and Drug Abuse Prevention Act, Public Law 99–570, secs. 8002–8009

Chapter 18. President's Media Commission on Alcohol and Drug Abuse Prevention

§ 1301. Establishment [1]

There is established a commission to be known as the President's Media Commission on Alcohol and Drug Abuse Prevention (hereinafter in this chapter referred to as the "Commission").

§ 1302. Duties of Commission [2]

The Commission shall—

(1) examine public education programs in effect on October 27, 1986, which are—

(A) implemented through various segments of mass media; and

(B) intended to prevent alcohol and drug abuse;

(2) act as an administrative and coordinating body for the voluntary donation of resources from—

(A) television, radio, motion picture, cable communications, and print media;

(B) the recording industry;

(C) the advertising industry;

(D) the business sector of the United States; and

(E) professional sports organizations and associations;

to assist the implementation of new programs and national strategies for dissemination of information intended to prevent alcohol and drug abuse;

(3) encourage media outlets throughout the country to provide information aimed at preventing alcohol and drug abuse, including public service announcements, documentary films, and advertisements; and

(4) evaluate the effectiveness and assist in the update of programs and national strategies formulated with the assistance of the Commission.

§ 1303. Membership [3]

(a) Number and appointment

The Commission shall be composed of 12 members appointed by the President within 30 days after October 27, 1986, and should include representatives of—

(1) advertising agencies;

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[1] Public Law 99–570, Title VIII, § 8002, Oct. 27, 1986, 100 Stat. 3207–161.
[2] Public Law 99–570, Title VIII, § 8003, Oct. 27, 1986, 100 Stat. 3207–161.
[3] Public Law 99–570, Title VIII, § 8004, Oct. 27, 1986, 100 Stat. 3207–162.

(2) motion picture, television, radio, cable communications, and print media;

(3) the recording industry;

(4) other segments of the business sector of the United States;

(5) experts in the prevention of alcohol and drug abuse;

(6) professional sports organizations and associations; and

(7) other Federal agencies, as designated by the President, including the Director of the Agency for Substance Abuse Prevention of the Department of Health and Human Services.

(b) Terms

(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of 3 years.

(2) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term.

(3) A member may serve after the expiration of his term until his successor has taken office.

(c) Basic pay and expenses

(1) Except as provided in paragraph (2), members of the Commission shall serve without pay.

(2) While away from their homes or regular places of business in the performance of services for the Commission, members shall be allowed travel expenses, including a per diem allowance in lieu of subsistence, in the same manner as persons serving intermittently in the Government service are allowed travel expenses under section 5703 of Title 5.

§ 1304. Meetings [4]

(a) In general

(1) The Commission shall meet at the call of the Moderator.

(2) The Moderator shall convene the 1st meeting of the Commission within 30 days after the date of the completion of appointments under section 1303(a) of this title.

(b) Moderator

One member of the Commission shall be designated by the President to serve as Moderator of the Commission.

(c) Quorum and procedure

The Commission shall adopt rules regarding quorum requirements and meeting procedures as the Commission deems appropriate at the 1st meeting of the Commission.

(d) Voting

Decisions and official acts of the Commission shall be according to the vote of a majority of members at a properly called meeting.

[4] Public Law 99–570, Title VIII, § 8005, Oct. 27, 1986, 100 Stat. 3207–162.

§ 1305. Director and staff; experts and consultants [5]

(a) Director and staff

(1) Subject to paragraph (2), the Moderator, with the approval of the Commission, may employ and set the rate of pay for a Director and such staff as the Moderator deems necessary.

(2) Rates of pay set under paragraph (1) shall be less than the rate of basic pay payable under section 5316 of Title 5.

(b) Experts and consultants

The Moderator, with the approval of the Commission, may procure temporary and intermittent services under section 3109(b) of Title 5.

(c) Staff of Federal agencies

Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist the Commission in carrying out its duties under this chapter.

§ 1306. Powers of Commission [6]

(a) Hearings

The Commission may, for the purpose of carrying out this chapter, hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission considers appropriate.

(b) Obtaining official data

Upon the request of the Moderator of the Commission, the Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this chapter.

(c) Gifts

The Commission may accept, use, and dispose of gifts or donations of services or property.

(d) Mails

The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

(e) Administrative support services

The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

§ 1307. Report [7]

The Commission shall transmit to the President and to each House of Congress a report not later than July 31 of each year

[5] Public Law 99–570, Title VIII, § 8006, Oct. 27, 1986, 100 Stat. 3207–163.
[6] Public Law 99–570, Title VIII, § 8007, Oct. 27, 1986, 100 Stat. 3207–163.
[7] Public Law 99–570, Title VIII, § 8008, Oct. 27, 1986, 100 Stat. 3207–163.

which contains a detailed statement of the activities of the Commission during the preceding year, including a summary of the number of public service announcements produced by the Commission and published or broadcast.

§ 1308. Termination [8]

The Commission shall terminate on a date which is three years after the date on which members of the Commission are first appointed, unless the President, by Executive order, extends the authority of the Commission.

[8] Public Law 99–570, Title VIII, § 8009, Oct. 27, 1986, 100 Stat. 3207–163.

21 U.S.C. § 1509
Anti-Drug Abuse Act of 1988, Public Law 100–690, sec. 6073
Establishment of Special Forfeiture Fund

Chapter 20. National Drug Control Program

§ 1509. Establishment of Special Forfeiture Fund [1]

(a) In general

There is established in the Treasury of the United States the Special Forfeiture Fund (hereafter referred to in this section as the "Fund") which shall be available to the Director of the National Drug Control Policy without fiscal year limitation in such amounts as may be specified in appropriations acts.

(b) Deposits

There shall be deposited into the Fund the amounts specified by section 524(c)(8) of Title 28, and section 9703(g) of Title 31, and any earnings on the investments authorized by subsection (d) of this section.

(c) Super surplus

(1) Any unobligated balance up to $20,000,000 remaining in the Fund on September 30 of a fiscal year shall be available to the Director, subject to paragraph (2), to transfer to, and for obligation and expenditure in connection with drug control activities of, any Federal agency or State or local entity with responsibilities under the National Drug Control Strategy.

(2) A transfer may be made under paragraph (1) only with the advance written approval of the Committees on Appropriations of each House of Congress.

(d) Investment of Fund

Amounts in the Fund which are not currently needed for the purposes of this section shall be kept on deposit or invested in obligations of, or guaranteed by, the United States and all earnings on such investments shall be deposited in the Fund.

(e) President's budget

The President shall, in consultation with the Director for National Drug Control Policy, include, as part of the budget submitted to the Congress under section 1105(a) of Title 31, a separate and

[1] Public Law 100–690, Title VI, § 6073, Nov. 18, 1988, 102 Stat. 4323; Public Law 101–647, Title XX, § 2001(b), Nov. 29, 1990, 104 Stat. 4854; Public Law 102–393, Title VI, § 638(c), Oct. 6, 1992, 106 Stat. 1788; Public Law 103–322, Title IX, § 90205(a), (d), Sept. 13, 1994, 108 Stat. 1994, 1995; Public Law 105–277, Div. C, Title VII, § 712, Oct. 21, 1998, 112 Stat. 2681–692.

detailed request for the use of the amounts in the Fund. This request shall reflect the priorities of the National Drug Control Strategy.

(f) Funds provided supplemental

Funds disbursed under this subsection shall not be used to supplant existing funds, but shall be used to supplement the amount of funds that would be otherwise available.

21 U.S.C. § 1702 note [1]
Consolidated Appropriations Act, 2005, Public Law 108–447, Div. H, Title III
Authority of ONDCP to accept and use gifts

Chapter 22. Office of National Drug Control Policy Reauthorization

OFFICE OF NATIONAL DRUG CONTROL POLICY

SALARIES AND EXPENSES; GIFTS

*** *Provided*, That the Office [of National Drug Control Policy] is authorized to accept, hold, administer, and utilize gifts, both real and personal, public and private, without fiscal year limitation, for the purpose of aiding or facilitating the work of the Office.[2]

[1] Public Law 108–447, Div. H, Title III, Dec. 8, 2004, 118 Stat. 3249.
[2] Similar provisions were contained in the following prior appropriations acts: Public Law 108–199, Div. F, Title III, Jan. 23, 2004, 118 Stat. 324. Public Law 108–7, Div. J, Title III, Feb. 20, 2003, 117 Stat. 446. Public Law 107–67, Title III, Nov. 12, 2001, 115 Stat. 530. Public Law 106–554, § 1(a) (3) [Title III], Dec. 21, 2000, 114 Stat. 2763, 2763A–139. Public Law 106–58, Title III, Sept. 29, 1999, 113 Stat. 447. Public Law 105–277, Div. A, § 101(h) [Title III], Oct. 21, 1998, 112 Stat. 2681–496. Public Law 105–61, Title III, Oct. 10, 1997, 111 Stat. 1293.

21 U.S.C. § 1703 note [1]

Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Public Law 105–277, Div. D, Title II, sec. 221

ONDCP report to Congress on options to increase the efficacy of Federal drug prevention and treatment efforts

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the efforts of the Federal Government to reduce the demand for illegal drugs in the United States are frustrated by the fragmentation of those efforts across multiple departments and agencies; and

(2) improvement of those efforts can best be achieved through consolidation and coordination.

(b) REPORT REQUIREMENT.—

(1) IN GENERAL.—Not later than 18 months after the date of enactment of this Act [Oct. 21, 1998], the Director of the Office of National Drug Control Policy shall prepare and submit to the appropriate committees a report evaluating options for increasing the efficacy of drug prevention and treatment programs and activities by the Federal Government. Such option shall include the merits of a consolidation of programs into a single agency, transferring programs from 1 agency to another, and improving coordinating mechanisms and authorities. The report shall also include a thorough review of the activities and potential consolidation of existing Federal drug information clearinghouses.

(2) RECOMMENDATION AND EXPLANATORY STATEMENT.—The study submitted under paragraph (1) shall identify options that are determined by the Director to have merit, and an explanation which options should be implemented.

(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Office of National Drug Control Policy to carry out this subsection $1,000,000 for contracting, policy research, and related costs.

(c) APPROPRIATE COMMITTEES DEFINED.—In this section [this note], the term "appropriate committees" means the Committee on Appropriations, the Committee on Commerce, and the Committee on Education and the Workforce of the House of Representatives, and the Committee on Appropriations, and Committee on Labor and Human Resources of the Senate.

[1] Public Law 105–277, Div. D, Title II, § 221, Oct. 21, 1998, 112 Stat. 2681–758.

21 U.S.C. § 1706 note [1]

Treasury and General Government Appropriations Act, 2000, Public Law 106–58, Title II

Funding of drug treatment and prevention programs in High Intensity Drug Trafficking Areas

*** That, hereafter, of the amount appropriated for fiscal year 2000 or any succeeding fiscal year for the High Intensity Drug Trafficking Areas Program, the funds to be obligated or expended during such fiscal year for programs addressing the treatment or prevention of drug use as part of the approved strategy for a designated High Intensity Drug Trafficking Area (HIDTA) shall not be less than the funds obligated or expended for such programs during fiscal year 1999 for each designated HIDTA without the prior approval of the Committees on Appropriations ***

[1] Public Law 106–58, Title II, Sept. 29, 1999, 113 Stat. 448.

21 U.S.C. § 1706 note [1]

Children's Health Act of 2000, Public Law 106–310, Div. B, Title XXXVI, sec. 3624

Combating methamphetamine and amphetamine in High Intensity Drug Trafficking Areas

SEC. 3624. COMBATING METHAMPHETAMINE AND AMPHETAMINE IN HIGH INTENSITY DRUG TRAFFICKING AREAS

(a) IN GENERAL.—

(1) IN GENERAL.—The Director of National Drug Control Policy shall use amounts available under this section to combat the trafficking of methamphetamine and amphetamine in areas designated by the Director as high intensity drug trafficking areas.

(2) ACTIVITIES.—In meeting the requirement in paragraph (1), the Director shall transfer funds to appropriate Federal, State, and local governmental agencies for employing additional Federal law enforcement personnel, or facilitating the employment of additional State and local law enforcement personnel, including agents, investigators, prosecutors, laboratory technicians, chemists, investigative assistants, and drug-prevention specialists.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

(1) $15,000,000 for fiscal year 2000; and

(2) such sums as may be necessary for each of fiscal years 2001 through 2004.

(c) APPORTIONMENT OF FUNDS.—

(1) FACTORS IN APPORTIONMENT.—The Director shall apportion amounts appropriated for a fiscal year pursuant to the authorization of appropriations in subsection (b) for activities under subsection (a) among and within areas designated by the Director as high intensity drug trafficking areas based on the following factors:

(A) The number of methamphetamine manufacturing facilities and amphetamine manufacturing facilities discovered by Federal, State, or local law enforcement officials in the previous fiscal year.

(B) The number of methamphetamine prosecutions and amphetamine prosecutions in Federal, State, or local courts in the previous fiscal year.

(C) The number of methamphetamine arrests and amphetamine arrests by Federal, State, or local law enforcement officials in the previous fiscal year.

[1] Public Law 106–310, Div. B, Title XXXVI, § 3624, Oct. 17, 2000, 114 Stat. 1232.

(D) The amounts of methamphetamine, amphetamine, or listed chemicals (as that term is defined in section 102(33) of the Controlled Substances Act (21 U.S.C. 802(33)) seized by Federal, State, or local law enforcement officials in the previous fiscal year.

(E) Intelligence and predictive data from the Drug Enforcement Administration and the Department of Health and Human Services showing patterns and trends in abuse, trafficking, and transportation in methamphetamine, amphetamine, and listed chemicals (as that term is so defined).

(2) CERTIFICATION.—Before the Director apportions any funds under this subsection to a high intensity drug trafficking area, the Director shall certify that the law enforcement entities responsible for clandestine methamphetamine and amphetamine laboratory seizures in that area are providing laboratory seizure data to the national clandestine laboratory database at the El Paso Intelligence Center.

(d) LIMITATION ON ADMINISTRATIVE COSTS.—Not more than 5 percent of the amount appropriated in a fiscal year pursuant to the authorization of appropriations for that fiscal year in subsection (b) may be available in that fiscal year for administrative costs associated with activities under subsection (a).

21 U.S.C. § 1713

Western Hemisphere Drug Elimination Act, Public Law 105–277, sec. 834

Authorization to develop and use herbicides to eliminate illicit drug crops in the United States and abroad

§ 1713. Authorization of use of environmentally-approved herbicides to eliminate illicit narcotics crops[1]

The Secretary of State, the Attorney General, the Secretary of Agriculture, the Secretary of Defense, the Director of the Office of National Drug Control Policy, and the Administrator of the Environmental Protection Agency are authorized to support the development and use of environmentally-approved herbicides to eliminate illicit narcotics crops, including coca, cannabis, and opium poppy, both in the United States and in foreign countries.

[1] Public Law 105–277, Div. C, Title VIII, § 834, Oct. 21, 1998, 112 Stat. 2681–702.

21 U.S.C. §§ 1801–1804
Drug-Free Media Campaign Act, Public Law 105–277, secs. 102–105

Chapter 23. National Youth Anti-drug Media Campaign

§ 1801. Requirement to conduct national media campaign [1]

(a) In general

The Director of the Office of National Drug Control Policy (in this chapter referred to as the "Director") shall conduct a national media campaign in accordance with this chapter for the purpose of reducing and preventing drug abuse among young people in the United States.

(b) Local target requirement

The Director shall, to the maximum extent feasible, use amounts made available to carry out this chapter under section 105 for media that focuses on, or includes specific information on, prevention or treatment resources for consumers within specific local areas.

§ 1802. Use of funds [2]

(a) Authorized uses

(1) In general

Amounts made available to carry out this chapter for the support of the national media campaign may only be used for—

(A) the purchase of media time and space;

(B) talent reuse payments;

(C) out-of-pocket advertising production costs;

(D) testing and evaluation of advertising;

(E) evaluation of the effectiveness of the media campaign;

(F) the negotiated fees for the winning bidder on request for proposals issued by the Office of National Drug Control Policy;

(G) partnerships with community, civic, and professional groups, and government organizations related to the media campaign; and

(H) entertainment industry collaborations to fashion antidrug messages in motion pictures, television programing, popular music, interactive (Internet and new) media projects and activities, public information, news

[1] Public Law 105–277, Div. D, Title I, § 102, Oct. 21, 1998, 112 Stat. 2681–752.
[2] Public Law 105–277, Div. D, Title I, § 103, Oct. 21, 1998, 112 Stat. 2681–752.

media outreach, and corporate sponsorship and participation.

(2) Advertising

In carrying out this chapter, the Director shall devote sufficient funds to the advertising portion of the national media campaign to meet the stated reach and frequency goals of the campaign.

(b) Prohibitions

None of the amounts made available under section 1804 of this title may be obligated or expended—

(1) to supplant current antidrug community based coalitions;

(2) to supplant current pro bono public service time donated by national and local broadcasting networks;

(3) for partisan political purposes; or

(4) to fund media campaigns that feature any elected officials, persons seeking elected office, cabinet level officials, or other Federal officials employed pursuant to section 213 of Schedule C of title 5, Code of Federal Regulations, unless the Director provides advance notice to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Government Reform and Oversight of the House of Representatives and the Committee on the Judiciary of the Senate.

(c) Matching requirement

Amounts made available under section 1804 of this title should be matched by an equal amount of non-Federal funds for the national media campaign, or be matched with in-kind contributions to the campaign of the same value.

§ 1803. Reports to Congress [3]

The Director shall—

(1) submit to Congress on an annual basis a report on the activities for which amounts made available under section 1804 of this title have been obligated during the preceding year, including information for each quarter of such year, and on the specific parameters of the national media campaign; and

(2) not later than 1 year after October 21, 1998, submit to Congress a report on the effectiveness of the national media campaign based on measurable outcomes provided to Congress previously.

§ 1804. Authorization of appropriations [4]

There is authorized to be appropriated to the Office of National Drug Control Policy to carry out this chapter $195,000,000 for each of fiscal years 1999 through 2002.

[3] Public Law 105–277, Div. D, Title I, § 104, Oct. 21, 1998, 112 Stat. 2681–753.
[4] Public Law 105–277, Div. D, Title I, § 105, Oct. 21, 1998, 112 Stat. 2681–753.

21 U.S.C. §§ 1901–1908
Foreign Narcotics Drug Kingpin Designation Act, Public Law 106–120, secs. 802–810

Chapter 24. International Narcotics Trafficking

§ 1901. Findings and policy [1]

(a) Findings

Congress makes the following findings:

(1) Presidential Decision Directive 42, issued on October 21, 1995, ordered agencies of the executive branch of the United States Government to, inter alia, increase the priority and resources devoted to the direct and immediate threat international crime presents to national security, work more closely with other governments to develop a global response to this threat, and use aggressively and creatively all legal means available to combat international crime.

(2) Executive Order No. 12978 of October 21, 1995, provides for the use of the authorities in the International Emergency Economic Powers Act (IEEPA) (50 U.S.C. 1701 et seq.) to target and apply sanctions to four international narcotics traffickers and their organizations that operate from Colombia.

(3) IEEPA was successfully applied to international narcotics traffickers in Colombia and based on that successful case study, Congress believes similar authorities should be applied worldwide.

(4) There is a national emergency resulting from the activities of international narcotics traffickers and their organizations that threatens the national security, foreign policy, and economy of the United States.

(b) Policy

It shall be the policy of the United States to apply economic and other financial sanctions to significant foreign narcotics traffickers and their organizations worldwide to protect the national security, foreign policy, and economy of the United States from the threat described in subsection (a)(4).

§ 1902. Purpose [2]

The purpose of this chapter is to provide authority for the identification of, and application of sanctions on a worldwide basis to, significant foreign narcotics traffickers, their organizations, and the foreign persons who provide support to those significant foreign narcotics traffickers and their organizations, whose activities

[1] Public Law 106–120, Title VIII, § 802, Dec. 3, 1999, 113 Stat. 1626.
[2] Public Law 106–120, Title VIII, § 803, Dec. 3, 1999, 113 Stat. 1626.

threaten the national security, foreign policy, and economy of the United States.

§ 1903. Public identification of significant foreign narcotics traffickers and required reports [3]

(a) Provision of information to the President

The Secretary of the Treasury, the Attorney General, the Secretary of Defense, the Secretary of State, and the Director of Central Intelligence shall consult among themselves and provide the appropriate and necessary information to enable the President to submit the report under subsection (b) of this section. This information shall also be provided to the Director of the Office of National Drug Control Policy.

(b) Public identification and sanctioning of significant foreign narcotics traffickers

Not later than June 1, 2000, and not later than June 1 of each year thereafter, the President shall submit a report to the Permanent Select Committee on Intelligence, and the Committees on the Judiciary, International Relations, Armed Services, and Ways and Means of the House of Representatives; and to the Select Committee on Intelligence, and the Committees on the Judiciary, Foreign Relations, Armed Services, and Finance of the Senate—

(1) identifying publicly the foreign persons that the President determines are appropriate for sanctions pursuant to this chapter; and

(2) detailing publicly the President's intent to impose sanctions upon these significant foreign narcotics traffickers pursuant to this chapter.

The report required in this subsection shall not include information on persons upon which United States sanctions imposed under this chapter, or otherwise on account of narcotics trafficking, are already in effect.

(c) Unclassified report required

The report required by subsection (b) of this section shall be submitted in unclassified form and made available to the public.

(d) Classified report

(1) Not later than July 1, 2000, and not later than July 1 of each year thereafter, the President shall provide the Permanent Select Committee on Intelligence of the House of Representatives and the Select Committee on Intelligence of the Senate with a report in classified form describing in detail the status of the sanctions imposed under this chapter, including the personnel and resources directed towards the imposition of such sanctions during the preceding fiscal year, and providing background information with respect to newly-identified significant foreign narcotics traffickers and their activities.

(2) Such classified report shall describe actions the President intends to undertake or has undertaken with respect to such significant foreign narcotics traffickers.

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[3] Public Law 106–120, Title VIII, § 804, Dec. 3, 1999, 113 Stat. 1626.

(3) The report required under this subsection is in addition to the President's obligations to keep the intelligence committees of Congress fully and currently informed pursuant to the provisions of the National Security Act of 1947.

(e) Exclusion of certain information

(1) Intelligence

Notwithstanding any other provision of this section, the reports described in subsections (b) and (d) of this section shall not disclose the identity of any person, if the Director of Central Intelligence determines that such disclosure could compromise an intelligence operation, activity, source, or method of the United States.

(2) Law enforcement

Notwithstanding any other provision of this section, the reports described in subsections (b) and (d) of this section shall not disclose the name of any person if the Attorney General, in coordination as appropriate with the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, and the Secretary of the Treasury, determines that such disclosure could reasonably be expected to—

(A) compromise the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution that furnished information on a confidential basis;

(B) jeopardize the integrity or success of an ongoing criminal investigation or prosecution;

(C) endanger the life or physical safety of any person; or

(D) cause substantial harm to physical property.

(f) Notification required

(1) Whenever either the Director of Central Intelligence or the Attorney General makes a determination under subsection (e) of this section, the Director of Central Intelligence or the Attorney General shall notify the Permanent Select Committee on Intelligence of the House of Representatives and the Select Committee on Intelligence of the Senate, and explain the reasons for such determination.

(2) The notification required under this subsection shall be submitted to the Permanent Select Committee on Intelligence of the House of Representatives and the Select Committee on Intelligence of the Senate not later than July 1, 2000, and on an annual basis thereafter.

(g) Determinations not to apply sanctions

(1) The President may waive the application to a significant foreign narcotics trafficker of any sanction authorized by this chapter if the President determines that the application of sanctions under this chapter would significantly harm the national security of the United States.

(2) When the President determines not to apply sanctions that are authorized by this chapter to any significant foreign narcotics

trafficker, the President shall notify the Permanent Select Committee on Intelligence, and the Committees on the Judiciary, International Relations, Armed Services, and Ways and Means of the House of Representatives, and the Select Committee on Intelligence, and the Committees on the Judiciary, Foreign Relations, Armed Services, and Finance of the Senate not later than 21 days after making such determination.

(h) Changes in determinations to impose sanctions

(1) Additional determinations

(A) If at any time after the report required under subsection (b) of this section the President finds that a foreign person is a significant foreign narcotics trafficker and such foreign person has not been publicly identified in a report required under subsection (b) of this section, the President shall submit an additional public report containing the information described in subsection (b) of this section with respect to such foreign person to the Permanent Select Committee on Intelligence, and the Committees on the Judiciary, International Relations, Armed Services, and Ways and Means of the House of Representatives, and the Select Committee on Intelligence, and the Committees on the Judiciary, Foreign Relations, Armed Services, and Finance of the Senate.

(B) The President may apply sanctions authorized under this chapter to the significant foreign narcotics trafficker identified in the report submitted under subparagraph (A) as if the trafficker were originally included in the report submitted pursuant to subsection (b) of this section.

(C) The President shall notify the Secretary of the Treasury of any determination made under this paragraph.

(2) Revocation of determination

(A) Whenever the President finds that a foreign person that has been publicly identified as a significant foreign narcotics trafficker in the report required under subsection (b) of this section or this subsection no longer engages in those activities for which sanctions under this chapter may be applied, the President shall issue public notice of such a finding.

(B) Not later than the date of the public notice issued pursuant to subparagraph (A), the President shall notify, in writing and in classified or unclassified form, the Permanent Select Committee on Intelligence, and the Committees on the Judiciary, International Relations, Armed Services, and Ways and Means of the House of Representatives, and the Select Committee on Intelligence, and the Committees on the Judiciary, Foreign Relations, Armed Services, and Finance of the Senate of actions taken under this paragraph and a description of the basis for such actions.

§ 1904. Blocking assets and prohibiting transactions[4]

(a) Applicability of sanctions

A significant foreign narcotics trafficker publicly identified in the report required under subsection (b) or (h)(1) of section 1903 of this title and foreign persons designated by the Secretary of the Treasury pursuant to subsection (b) of this section shall be subject to any and all sanctions as authorized by this chapter. The application of sanctions on any foreign person pursuant to subsection (b) or (h)(1) of section 1903 of this title or subsection (b) of this section shall remain in effect until revoked pursuant to section 1903(h)(2) of this title or subsection (e)(1)(A) of this section or waived pursuant to section 1903(g)(1) of this title.

(b) Blocking of assets

Except to the extent provided in regulations, orders, instructions, licenses, or directives issued pursuant to this chapter, and notwithstanding any contract entered into or any license or permit granted prior to the date on which the President submits the report required under subsection (b) or (h)(1) of section 1903 of this title, there are blocked as of such date, and any date thereafter, all such property and interests in property within the United States, or within the possession or control of any United States person, which are owned or controlled by—

(1) any significant foreign narcotics trafficker publicly identified by the President in the report required under subsection (b) or (h)(1) of section 1903 of this title;

(2) any foreign person that the Secretary of the Treasury, in consultation with the Attorney General, the Director of Central Intelligence, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, and the Secretary of State, designates as materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a significant foreign narcotics trafficker so identified in the report required under subsection (b) or (h)(1) of section 1903 of this title, or foreign persons designated by the Secretary of the Treasury pursuant to this subsection;

(3) any foreign person that the Secretary of the Treasury, in consultation with the Attorney General, the Director of Central Intelligence, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, and the Secretary of State, designates as owned, controlled, or directed by, or acting for or on behalf of, a significant foreign narcotics trafficker so identified in the report required under subsection (b) or (h)(1) of section 1903 of this title, or foreign persons designated by the Secretary of the Treasury pursuant to this subsection; and

(4) any foreign person that the Secretary of the Treasury, in consultation with the Attorney General, the Director of Central

[4] Public Law 106–120, Title VIII, § 805, Dec. 3, 1999, 113 Stat. 1629; Public Law 107–108, Title III, § 307, Dec. 28, 2001, 115 Stat. 1399.

Intelligence, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, and the Secretary of State, designates as playing a significant role in international narcotics trafficking.

(c) Prohibited transactions

Except to the extent provided in regulations, orders, instructions, licenses, or directives issued pursuant to this chapter, and notwithstanding any contract entered into or any license or permit granted prior to the date on which the President submits the report required under subsection (b) or (h)(1) of section 1903 of this title, the following transactions are prohibited:

(1) Any transaction or dealing by a United States person, or within the United States, in property or interests in property of any significant foreign narcotics trafficker so identified in the report required pursuant to subsection (b) or (h)(1) of section 1903 of this title, and foreign persons designated by the Secretary of the Treasury pursuant to subsection (b) of this section.

(2) Any transaction or dealing by a United States person, or within the United States, that evades or avoids, or has the effect of evading or avoiding, and any endeavor, attempt, or conspiracy to violate, any of the prohibitions contained in this chapter.

(d) Law enforcement and intelligence activities not affected

Nothing in this chapter prohibits or otherwise limits the authorized law enforcement or intelligence activities of the United States, or the law enforcement activities of any State or subdivision thereof.

(e) Implementation

(1) The Secretary of the Treasury, in consultation with the Attorney General, the Director of Central Intelligence, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, and the Secretary of State, is authorized to take such actions as may be necessary to carry out this chapter, including—

(A) making those designations authorized by paragraphs (2), (3), and (4) of subsection (b) of this section and revocation thereof;

(B) promulgating rules and regulations permitted under this chapter; and

(C) employing all powers conferred on the Secretary of the Treasury under this chapter.

(2) Each agency of the United States shall take all appropriate measures within its authority to carry out the provisions of this chapter.

(3) Section 552(a)(3) of Title 5 shall not apply to any record or information obtained or created in the implementation of this chapter.

§ 1905. Authorities [5]

(a) In general

To carry out the purposes of this chapter, the Secretary of the Treasury may, under such regulations as he may prescribe, by means of instructions, licenses, or otherwise—

(1) investigate, regulate, or prohibit—

(A) any transactions in foreign exchange, currency, or securities; and

(B) transfers of credit or payments between, by, through, or to any banking institution, to the extent that such transfers or payments involve any interests of any foreign country or a national thereof; and

(2) investigate, block during the pendency of an investigation, regulate, direct and compel, nullify, void, prevent, or prohibit any acquisition, holding, withholding, use, transfer, withdrawal, transportation, placement into foreign or domestic commerce of, or dealing in, or exercising any right, power, or privilege with respect to, or transactions involving, any property in which any foreign country or a national thereof has any interest,

by any person, or with respect to any property, subject to the jurisdiction of the United States.

(b) Recordkeeping

Pursuant to subsection (a) of this section, the Secretary of the Treasury may require recordkeeping, reporting, and production of documents to carry out the purposes of this chapter.

(c) Defenses

(1) Full and actual compliance with any regulation, order, license, instruction, or direction issued under this chapter shall be a defense in any proceeding alleging a violation of any of the provisions of this chapter.

(2) No person shall be held liable in any court for or with respect to anything done or omitted in good faith in connection with the administration of, or pursuant to, and in reliance on this chapter, or any regulation, instruction, or direction issued under this chapter.

(d) Rulemaking

The Secretary of the Treasury may issue such other regulations or orders, including regulations prescribing recordkeeping, reporting, and production of documents, definitions, licenses, instructions, or directions, as may be necessary for the exercise of the authorities granted by this chapter.

§ 1906. Enforcement [6]

(a) Criminal penalties

(1) Whoever willfully violates the provisions of this chapter, or any license rule, or regulation issued pursuant to this chapter, or

[5] Public Law 106–120, Title VIII, § 806, Dec. 3, 1999, 113 Stat. 1631.
[6] Public Law 106–120, Title VIII, § 807, Dec. 3, 1999, 113 Stat. 1631.

willfully neglects or refuses to comply with any order of the President issued under this chapter shall be—

(A) imprisoned for not more than 10 years,

(B) fined in the amount provided in Title 18 or, in the case of an entity, fined not more than $10,000,000,

or both.

(2) Any officer, director, or agent of any entity who knowingly participates in a violation of the provisions of this chapter shall be imprisoned for not more than 30 years, fined not more than $5,000,000, or both.

(b) Civil penalties

A civil penalty not to exceed $1,000,000 may be imposed by the Secretary of the Treasury on any person who violates any license, order, rule, or regulation issued in compliance with the provisions of this chapter.

(c) Judicial review of civil penalty

Any penalty imposed under subsection (b) of this section shall be subject to judicial review only to the extent provided in section 702 of Title 5.

§ 1907. Definitions[7]

As used in this chapter:

(1) Entity

The term "entity" means a partnership, joint venture, association, corporation, organization, network, group, or subgroup, or any form of business collaboration.

(2) Foreign person

The term "foreign person" means any citizen or national of a foreign state or any entity not organized under the laws of the United States, but does not include a foreign state.

(3) Narcotics trafficking

The term "narcotics trafficking" means any illicit activity to cultivate, produce, manufacture, distribute, sell, finance, or transport narcotic drugs, controlled substances, or listed chemicals, or otherwise endeavor or attempt to do so, or to assist, abet, conspire, or collude with others to do so.

(4) Narcotic drug; controlled substance; listed chemical

The terms "narcotic drug", "controlled substance", and "listed chemical" have the meanings given those terms in section 802 of this title.

(5) Person

The term "person" means an individual or entity.

(6) United States person

The term "United States person" means any United States citizen or national, permanent resident alien, an entity organized under the laws of the United States (including its foreign branches), or any person within the United States.

(7) Significant foreign narcotics trafficker

The term "significant foreign narcotics trafficker" means any foreign person that plays a significant role in international narcotics trafficking, that the President has determined to be

[7] Public Law 106–120, Title VIII, § 808, Dec. 3, 1999, 113 Stat. 1632.

appropriate for sanctions pursuant to this chapter, and that the President has publicly identified in the report required under subsection (b) or (h)(1) of section 1903 of this title.

§ 1908. Judicial Review Commission on Foreign Asset Control[8]

(a) Establishment

There is established a commission to be known as the "Judicial Review Commission on Foreign Asset Control" (in this section referred to as the "Commission").

(b) Membership and procedural matters

(1) The Commission shall be composed of five members, as follows:

(A) One member shall be appointed by the Chairman of the Select Committee on Intelligence of the Senate.

(B) One member shall be appointed by the Vice Chairman of the Select Committee on Intelligence of the Senate.

(C) One member shall be appointed by the Chairman of the Permanent Select Committee on Intelligence of the House of Representatives.

(D) One member shall be appointed by the Ranking Minority Member of the Permanent Select Committee on Intelligence of the House of Representatives.

(E) One member shall be appointed jointly by the members appointed under subparagraphs (A) through (D).

(2) Each member of the Commission shall, for purposes of the activities of the Commission under this section, possess or obtain an appropriate security clearance in accordance with applicable laws and regulations regarding the handling of classified information.

(3) The members of the Commission shall choose the chairman of the Commission from among the members of the Commission.

(4) The members of the Commission shall establish rules governing the procedures and proceedings of the Commission.

(c) Duties

The Commission shall have as its duties the following:

(1) To conduct a review of the current judicial, regulatory, and administrative authorities relating to the blocking of assets of foreign persons by the United States Government.

(2) To conduct a detailed examination and evaluation of the remedies available to United States persons affected by the blocking of assets of foreign persons by the United States Government.

(d) Powers

(1) The Commission may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.

(2) The Commission may secure directly from any executive department, agency, bureau, board, commission, office, independent establishment, or instrumentality of the Government information,

[8] Public Law 106–120, Title VIII, § 810, Dec. 3, 1999, 113 Stat. 1633.

suggestions, estimates, and statistics for the purposes of this section. Each such department, agency, bureau, board, commission, office, establishment, or instrumentality shall, to the extent authorized by law, furnish such information, suggestions, estimates, and statistics directly to the Commission, upon request of the chairman of the Commission. The Commission shall handle and protect all classified information provided to it under this section in accordance with applicable statutes and regulations.

(3) The Attorney General and the Secretary of the Treasury shall provide to the Commission, on a nonreimbursable basis, such administrative services, funds, facilities, and other support services as are necessary for the performance of the Commission's duties under this section.

(4) The Commission shall receive the full and timely cooperation of any official, department, or agency of the United States Government whose assistance is necessary for the fulfillment of the duties of the Commission under this section, including the provision of full and current briefings and analyses.

(5) No department or agency of the Government may withhold information from the Commission on the grounds that providing the information to the Commission would constitute the unauthorized disclosure of classified information or information relating to intelligence sources or methods.

(6) The Commission may use the United States mails in the same manner and under the same conditions as the departments and agencies of the United States.

(e) Staff

(1) Subject to paragraph (2), the chairman of the Commission, in accordance with rules agreed upon by the Commission, shall appoint and fix the compensation of a staff director and such other personnel as may be necessary to enable the Commission to carry out its duties, without regard to the provisions of Title 5 governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III or [9] chapter 53 of such title relating to classification and General Schedule pay rates, except that no rate of pay fixed under this subsection may exceed the equivalent of that payable to a person occupying a position at level V of the Executive Schedule under section 5316 of such title.

(2)(A) Any employee of a department or agency referred to in subparagraph (B) may be detailed to the Commission without reimbursement from the Commission, and such detailee shall retain the rights, status, and privileges of his or her regular employment without interruption.

(B) The departments and agencies referred to in this subparagraph are as follows:

(i) The Department of Justice.

(ii) The Department of the Treasury.

(iii) The Central Intelligence Agency.

(3) All staff of the Commission shall possess a security clearance in accordance with applicable laws and regulations concerning the handling of classified information.

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[9] So in original. Probably should be "of".

(f) Compensation and travel expenses

(1)(A) Except as provided in subparagraph (B), each member of the Commission may be compensated at not to exceed the daily equivalent of the annual rate of basic pay in effect for a position a t level IV of the Executive Schedule under section 5315 of Title 5 for each day during which that member is engaged in the actual performance of the duties of the Commission under this section.

(B) Members of the Commission who are officers or employees of the United States shall receive no additional pay by reason of their service on the Commission.

(2) While away from their homes or regular places of business in the performance of services for the Commission, members of the Commission may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703(b)[10] of Title 5.

(g) Report

(1) Not later than 1 year after December 3, 1999, the Commissions[11] shall submit to the committees of Congress referred to in paragraph (4) a report on the activities of the Commission under this section, including the findings, conclusions, and recommendations, if any, of the Commission as a result of the review under subsection (c)(1) of this section and the examination and evaluation under subsection (c)(2) of this section.

(2) The report under paragraph (1) shall include any additional or dissenting views of a member of the Commission upon the request of the member.

(3) The report under paragraph (1) shall be submitted in unclassified form, but may include a classified annex.

(4) The committees of Congress referred to in this paragraph are the following:

(A) The Select Committee on Intelligence and the Committees on Foreign Relations and the Judiciary of the Senate.

(B) The Permanent Select Committee on Intelligence and the Committees on International Relations and the Judiciary of the House of Representatives.

(h) Termination

The Commission shall terminate at the end of the 60-day period beginning on the date on which the report required by subsection (g) of this section is submitted to the committees of Congress referred to in that subsection.

(i) Inapplicability of certain administrative provisions

(1) The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the activities of the Commission under this section.

(2) The provisions of section 552 of Title 5 (commonly referred to as the Freedom of Information Act) shall not apply to the activities, records, and proceedings of the Commission under this chapter.

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[10] So in original. Section 5703 of Title 5 does not contain a subsection (b).

[11] So in original. Probably should be "Commission".

(j) Funding

The Attorney General shall, from amounts authorized to be appropriated to the Attorney General by this Act, make available to the Commission $1,000,000 for purposes of the activities of the Commission under this section. Amounts made available to the Commission under the preceding sentence shall remain available until expended.

Uncodified provision of law related to Title 21 [1]

Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Public Law 105–277, Div. D, Title II, sec. 201

Congressional leadership in community coalitions

TITLE II—STATEMENT OF NATIONAL ANTIDRUG POLICY

SEC. 201. SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) Illegal drug use is dangerous to the physical well-being of the Nation's youth.

(2) Illegal drug use can destroy the lives of the Nation's youth by diminishing their sense of morality and with it everything in life that is important and worthwhile.

(3) According to recently released national surveys, drug use among the Nation's youth remains at alarmingly high levels.

(4) National leadership is critical to conveying to the Nation's youth the message that drug use is dangerous and wrong.

(5) National leadership can help mobilize every sector of the community to support the implementation of comprehensive, sustainable, and effective programs to reduce drug abuse.

(6) As of September 1, 1998, 76 Members of the House of Representatives were establishing community-based antidrug coalitions in their congressional districts or were actively supporting such coalitions that already existed.

(7) The individual Members of the House of Representatives can best help their constituents prevent drug use among the Nation's youth by establishing community-based antidrug coalitions in their congressional districts or by actively supporting such coalitions that already exist.

(b) SENSE OF CONGRESS.—It is the sense of Congress that the individual Members of the House of Representatives, including the Delegates and the Resident Commissioner, should establish community-based antidrug coalitions in their congressional districts or should actively support any such coalitions that have been established.

[1] Public Law 105–277, Div. D, Title II, § 201, Oct. 21, 1998, 112 Stat. 2681–757.

Uncodified provision of law related to Title 21 [1]

Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Public Law 105–277, Div. D, Title II, sec. 211
Rejection of legalization of drugs

SEC. 211. SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) Illegal drug use is harmful and wrong.

(2) Illegal drug use can kill the individuals involved or cause the individuals to hurt or kill others, and such use strips the individuals of their moral sense.

(3) The greatest threat presented by such use is to the youth of the United States, who are illegally using drugs in increasingly greater numbers.

(4) The people of the United States are more concerned about illegal drug use and crimes associated with such use than with any other current social problem.

(5) Efforts to legalize or otherwise legitimize drug use present a message to the youth of the United States that drug use is acceptable.

(6) Article VI, clause 2 of the Constitution of the United States states that ''[t]his Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and judges in every state shall be bound thereby, any thing in the Constitution or laws of any state to the contrary notwithstanding.''.

(7) The courts of the United States have repeatedly found that any State law that conflicts with a Federal law or treaty is preempted by such law or treaty.

(8) The Controlled Substances Act (21 U.S.C. 801 et seq.) strictly regulates the use and possession of drugs.

(9) The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotrophic Substances Treaty similarly regulates the use and possession of drugs.

(10) Any attempt to authorize under State law an activity prohibited under such Treaty or the Controlled Substances Act would conflict with that Treaty or Act.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the several States, and the citizens of such States, should reject the legalization of drugs through legislation, ballot proposition, constitutional amendment, or any other means; and

(2) each State should make efforts to be a drug-free State.

[1] Public Law 105–277, Div. D, Title II, § 211, Oct. 21, 1998, 112 Stat. 2681–758.

23 U.S.C. § 159
Revocation or suspension of drivers' licenses of individuals convicted of controlled substances offenses

Title 23. Highways

Chapter 1. Federal-Aid Highways

§ 159. Revocation or suspension of drivers' licenses of individuals convicted of drug offenses[1]

(a) WITHHOLDING OF APPORTIONMENTS FOR NONCOMPLIANCE.—

(1) BEGINNING IN FISCAL YEAR 1994.—For each fiscal year the Secretary shall withhold 5 percent of the amount required to be apportioned to any State under each of paragraphs (1), (3), and (5) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century) of section 104(b) on the first day of each fiscal year which begins after the second calendar year following the effective date of this section if the State does not meet the requirements of paragraph (3) on such date.

(2) BEGINNING IN FISCAL YEAR 1996.—The Secretary shall withhold 10 percent (including any amounts withheld under paragraph (1)) of the amount required to be apportioned to any State under each of paragraphs (1), (3), and (5) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century) of section 104(b) on the first day of each fiscal year which begins after the fourth calendar year following the effective date of this section if the State does not meet the requirements of paragraph (3) on the first day of such fiscal year.

(3) REQUIREMENTS.—A State meets the requirements of this paragraph if—

(A) the State has enacted and is enforcing a law that requires in all circumstances, or requires in the absence of compelling circumstances warranting an exception—

(i) the revocation, or suspension for at least 6 months, of the driver's license of any individual who is convicted, after the enactment of such law, of—

(I) any violation of the Controlled Substances Act, or

(II) any drug offense; and

(ii) a delay in the issuance or reinstatement of a driver's license to such an individual for at least 6 months after the individual applies for the issuance or

[1] Added by Public Law 102–143, Title III, § 333(a), Oct. 28, 1991, 105 Stat. 944, and amended by Public Law 102–388, Title III, § 327(a), Oct. 6, 1992, 106 Stat. 1547; Public Law 105–178, Title I, § 1103(l)(3)(E), June 9, 1998, 112 Stat. 126.

reinstatement of a driver's license if the individual does not have a driver's license, or the driver's license of the individual is suspended, at the time the individual is so convicted; or

(B) the Governor of the State—

(i) submits to the Secretary no earlier than the adjournment sine die of the first regularly scheduled session of the State's legislature which begins after the effective date of this section a written certification stating that the Governor is opposed to the enactment or enforcement in the State of a law described in subparagraph (A), relating to the revocation, suspension, issuance, or reinstatement of drivers' licenses to convicted drug offenders; and

(ii) submits to the Secretary a written certification that the legislature (including both Houses where applicable) has adopted a resolution expressing its opposition to a law described in clause (i).

(b) PERIOD OF AVAILABILITY; EFFECT OF COMPLIANCE AND NONCOMPLIANCE.—

(1) PERIOD OF AVAILABILITY OF WITHHELD FUNDS.—

(A) FUNDS WITHHELD ON OR BEFORE SEPTEMBER 30, 1995.—Any funds withheld under subsection (a) from apportionment to any State on or before September 30, 1995, shall remain available for apportionment to such State as follows:

(i) If such funds would have been apportioned under section 104(b)(5)(A) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century) but for this section, such funds shall remain available until the end of the fiscal year for which such funds are authorized to be appropriated.

(ii) If such funds would have been apportioned under section 104(b)(5)(B) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century) but for this section, such funds shall remain available until the end of the second fiscal year following the fiscal year for which such funds are authorized to be appropriated.

(iii) If such funds would have been apportioned under paragraph (1), (3), or (5) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century) of section 104(b) but for this section, such funds shall remain available until the end of the third fiscal year following the fiscal year for which such funds are authorized to be appropriated.

(B) FUNDS WITHHELD AFTER SEPTEMBER 30, 1995.—No funds withheld under this section from apportionment to any State after September 30, 1995, shall be available for apportionment to such State.

(2) APPORTIONMENT OF WITHHELD FUNDS AFTER COMPLIANCE.—If, before the last day of the period for which funds

withheld under subsection (a) from apportionment are to remain available for apportionment to a State under paragraph (1), the State meets the requirements of subsection (a)(3), the Secretary shall, on the first day on which the State meets the requirements of subsection (a)(3), apportion to the State the funds withheld under subsection (a) that remain available for apportionment to the State.

(3) PERIOD OF AVAILABILITY OF SUBSEQUENTLY APPORTIONED FUNDS.—Any funds apportioned pursuant to paragraph (2) shall remain available for expenditure as follows:

(A) Funds which would have been originally apportioned under section 104(b)(5)(A) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century) shall remain available until the end of the fiscal year succeeding the fiscal year in which such funds are apportioned under paragraph (2).

(B) Funds which would have been originally apportioned under paragraph (1), (3), or (5)(B) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century) of section 104(b) shall remain available until the end of the third fiscal year succeeding the fiscal year in which such funds are so apportioned.

Sums not obligated at the end of such period shall lapse or, in the case of funds apportioned under section 104(b)(5) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century), shall lapse and be made available by the Secretary for projects in accordance with section 118(b).

(4) EFFECT OF NONCOMPLIANCE.—If, at the end of the period for which funds withheld under subsection (a) from apportionment are available for apportionment to a State under paragraph (1), the State does not meet the requirements of subsection (a)(3), such funds shall lapse or, in the case of funds withheld from apportionment under section 104(b)(5) (as in effect on the day before the date of enactment of the Transportation Equity Act for the 21st Century), such funds shall lapse and be made available by the Secretary for projects in accordance with section 118(b).

(c) DEFINITIONS.—For purposes of this section—

(1) DRIVER'S LICENSE.—The term "driver's license" means a license issued by a State to any individual that authorizes the individual to operate a motor vehicle on highways.

(2) DRUG OFFENSE.—The term "drug offense" means any criminal offense which proscribes—

(A) the possession, distribution, manufacture, cultivation, sale, transfer, or the attempt or conspiracy to possess, distribute, manufacture, cultivate, sell, or transfer any substance the possession of which is prohibited under the Controlled Substances Act; or

(B) the operation of a motor vehicle under the influence of such a substance.

(3) CONVICTED.—The term "convicted" includes adjudicated under juvenile proceedings.

23 U.S.C. § 402
Highway safety programs to reduce death and injuries due to driving under the influence of controlled substances

Chapter 4. Highway Safety

§ 402. Highway safety programs [1]

(a) Each State shall have a highway safety program approved by the Secretary, designed to reduce traffic accidents and deaths, injuries, and property damage resulting therefrom. Such programs shall be in accordance with uniform guidelines promulgated by the Secretary. Such uniform guidelines shall be expressed in terms of performance criteria. In addition, such uniform guidelines shall include programs (1) to reduce injuries and deaths resulting from motor vehicles being driven in excess of posted speed limits, (2) to encourage the proper use of occupant protection devices (including the use of safety belts and child restraint systems) by occupants of motor vehicles and to increase public awareness of the benefit of motor vehicles equipped with airbags, (3) to reduce deaths and injuries resulting from persons driving motor vehicles while impaired by alcohol or a controlled substance, (4) to prevent accidents and reduce deaths and injuries resulting from accidents involving motor vehicles and motorcycles, (5) to reduce injuries and deaths resulting from accidents involving school buses, and (6) to improve law enforcement services in motor vehicle accident prevention, traffic supervision, and post-accident procedures. The Secretary shall establish a highway safety program for the collection and reporting of data on traffic-related deaths and injuries by the States. Under such program, the States shall collect and report such data as the Secretary may require. The purposes of the program are to ensure national uniform data on such deaths and injuries and to allow the Secretary to make determinations for use in developing programs to reduce such deaths and injuries and making recommendations to Congress concerning legislation necessary to implement such programs. The program shall provide for annual reports to the Secretary on the efforts being made by the States in reducing deaths and injuries occurring at highway construction sites and the effectiveness and results of such efforts. The Secretary shall establish

[1] Added by Public Law 89–564, Title I, § 101, Sept. 9, 1966, 80 Stat. 731, and amended by Public Law 90–495, § 13, Aug. 23, 1968, 82 Stat. 822; Public Law 91–605, Title II, § § 202(c) to (e), 203(a), Dec. 31, 1970, 84 Stat. 1740, 1741; Public Law 93–87, Title II, § § 207, 215 to 217, 219, 228, 229, 231, Aug. 13, 1973, 87 Stat. 285, 290, 293, 294; Public Law 94–280, Title II, § § 204, 208(a), 211, 212, May 5, 1976, 90 Stat. 453 to 455; Public Law 95–599, Title II, § 207(a), (b)(1), (c), (d), Nov. 6, 1978, 92 Stat. 2731, 2732; Public Law 97–35, Title XI, § 1107(c) to (e), Aug. 13, 1981, 95 Stat. 626; Public Law 97–424, Title II, § 208, Jan. 6, 1983, 96 Stat. 2140; Public Law 98–363, § § 3(a), 5, July 17, 1984, 98 Stat. 436; Public Law 100–17, Title I, § 133(b)(20), Title II, § 206, Apr. 2, 1987, 101 Stat. 172, 221; Public Law 102–240, Title II, § 2002, Dec. 18, 1991, 105 Stat. 2070; Public Law 104–66, Title I, § 1121(d), Dec. 21, 1995, 109 Stat. 724; Public Law 105–178, Title I, § 1212(a)(2)(A)(i), Title II, § 2001(a) to (e), June 9, 1998, 112 Stat. 193, 323.

minimum reporting criteria for the program. Such criteria shall include, but not be limited to, criteria on deaths and injuries resulting from police pursuits, school bus accidents, and speeding, on traffic-related deaths and injuries at highway construction sites and on the configuration of commercial motor vehicles involved in motor vehicle accidents. Such uniform guidelines shall be promulgated by the Secretary so as to improve driver performance (including, but not limited to, driver education, driver testing to determine proficiency to operate motor vehicles, driver examinations (both physical and mental) and driver licensing) and to improve pedestrian performance and bicycle safety. In addition such uniform guidelines shall include, but not be limited to, provisions for an effective record system of accidents (including injuries and deaths resulting therefrom), accident investigations to determine the probable causes of accidents, injuries, and deaths, vehicle registration, operation, and inspection, highway design and maintenance (including lighting, markings, and surface treatment), traffic control, vehicle codes and laws, surveillance of traffic for detection and correction of high or potentially high accident locations, enforcement of light transmission standards of window glazing for passenger motor vehicles and light trucks as necessary to improve highway safety, and emergency services. Such guidelines as are applicable to State highway safety programs shall, to the extent determined appropriate by the Secretary, be applicable to federally administered areas where a Federal department or agency controls the highways or supervises traffic operations.

(b) ADMINISTRATION OF STATE PROGRAMS.—

(1) ADMINISTRATIVE REQUIREMENTS.—The Secretary may not approve a State highway safety program under this section which does not—

(A) provide that the Governor of the State shall be responsible for the administration of the program through a State highway safety agency which shall have adequate powers and be suitably equipped and organized to carry out, to the satisfaction of the Secretary, such program;

(B) authorize political subdivisions of the State to carry out local highway safety programs within their jurisdictions as a part of the State highway safety program if such local highway safety programs are approved by the Governor and are in accordance with the minimum standards established by the Secretary under this section;

(C) except as provided in paragraph (3), provide that at least 40 percent of all Federal funds apportioned under this section to the State for any fiscal year will be expended by the political subdivisions of the State, including Indian tribal governments, in carrying out local highway safety programs authorized in accordance with subparagraph (B); and

(D) provide adequate and reasonable access for the safe and convenient movement of individuals with disabilities, including those in wheelchairs, across curbs constructed or replaced on or after July 1, 1976, at all pedestrian crosswalks throughout the State.

(2) WAIVER.—The Secretary may waive the requirement of paragraph (1)(C), in whole or in part, for a fiscal year for any State whenever the Secretary determines that there is an insufficient number of local highway safety programs to justify the expenditure in the State of such percentage of Federal funds during the fiscal year.

(3) USE OF TECHNOLOGY FOR TRAFFIC ENFORCEMENT.—The Secretary may encourage States to use technologically advanced traffic enforcement devices (including the use of automatic speed detection devices such as photo-radar) by law enforcement officers.

(c) Funds authorized to be appropriated to carry out this section shall be used to aid the States to conduct the highway safety programs approved in accordance with subsection (a), including development and implementation of manpower training programs, and of demonstration programs that the Secretary determines will contribute directly to the reduction of accidents, and deaths and injuries resulting therefrom. Such funds shall be subject to a deduction not to exceed 5 per centum for the necessary costs of administering the provisions of this section, and the remainder shall be apportioned among the several States. Such funds shall be apportioned 75 per centum in the ratio which the population of each State bears to the total population of all the States, as shown by the latest available Federal census, and 25 per centum in the ratio which the public road mileage in each State bears to the total public road mileage in all States. For the purposes of this subsection, a "public road" means any road under the jurisdiction of and maintained by a public authority and open to public travel. Public road mileage as used in this subsection shall be determined as of the end of the calendar year preceding the year in which the funds are apportioned and shall be certified to by the Governor of the State and subject to approval by the Secretary. The annual apportionment to each State shall not be less than one-half of 1 per centum of the total apportionment, except that the apportionment to the Secretary of the Interior shall not be less than three-fourths of 1 percent of the total apportionment and the apportionments to the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands shall not be less than one-quarter of 1 per centum of the total apportionment. The Secretary shall not apportion any funds under this subsection to any State which is not implementing a highway safety program approved by the Secretary in accordance with this section. For the purpose of the seventh sentence of this subsection, a highway safety program approved by the Secretary shall not include any requirement that a State implement such a program by adopting or enforcing any law, rule, or regulation based on a guideline promulgated by the Secretary under this section requiring any motorcycle operator eighteen years of age or older or passenger eighteen years of age or older to wear a safety helmet when operating or riding a motorcycle on the streets and highways of that State. Implementation of a highway safety program under this section shall not be construed to require the Secretary to require compliance with every uniform guideline, or with every element of every uniform guideline, in every State. Funds apportioned under this section to any State,

that does not have a highway safety program approved by the Secretary or that is not implementing an approved program, shall be reduced by amounts equal to not less than 50 per centum of the amounts that would otherwise be apportioned to the State under this section, until such time as the Secretary approves such program or determines that the State is implementing an approved program, as appropriate. The Secretary shall consider the gravity of the State's failure to have or implement an approved program in determining the amount of the reduction. The Secretary shall promptly apportion to the State the funds withheld from its apportionment if he approves the State's highway safety program or determines that the State has begun implementing an approved program, as appropriate, prior to the end of the fiscal year for which the funds were withheld. If the Secretary determines that the State did not correct its failure within such period, the Secretary shall reapportion the withheld funds to the other States in accordance with the formula specified in this subsection not later than 30 days after such determination.

(d) All provisions of chapter 1 of this title that are applicable to National Highway System highway funds other than provisions relating to the apportionment formula and provisions limiting the expenditure of such funds to the Federal-aid systems, shall apply to the highway safety funds authorized to be appropriated to carry out this section, except as determined by the Secretary to be inconsistent with this section, and except that the aggregate of all expenditures made during any fiscal year by a State and its political subdivisions (exclusive of Federal funds) for carrying out the State highway safety program (other than planning and administration) shall be available for the purpose of crediting such State during such fiscal year for the non-Federal share of the cost of any project under this section (other than one for planning or administration) without regard to whether such expenditures were actually made in connection with such project and except that, in the case of a local highway safety program carried out by an Indian tribe, if the Secretary is satisfied that an Indian tribe does not have sufficient funds available to meet the non-Federal share of the cost of such program, he may increase the Federal share of the cost thereof payable under this Act to the extent necessary. In applying such provisions of chapter 1 in carrying out this section the term ''State transportation department'' as used in such provisions shall mean the Governor of a State for the purposes of this section.

(e) Uniform guidelines promulgated by the Secretary to carry out this section shall be developed in cooperation with the States, their political subdivisions, appropriate Federal departments and agencies, and such other public and private organizations as the Secretary deems appropriate.

(f) The Secretary may make arrangements with other Federal departments and agencies for assistance in the preparation of uniform guidelines for the highway safety programs contemplated by subsection (a) and in the administration of such programs. Such departments and agencies are directed to cooperate in such preparation and administration, on a reimbursable basis.

(g) Nothing in this section authorizes the appropriation or expenditure of funds for (1) highway construction, maintenance, or

design (other than design of safety features of highways to be incorporated into guidelines) or (2) any purpose for which funds are authorized by section 403 of this title.

(i)[2] APPLICATION IN INDIAN COUNTRY.—

(1) USE OF TERMS.—For the purpose of application of this section in Indian country, the terms "State" and "Governor of a State" include the Secretary of the Interior and the term "political subdivision of a State" includes an Indian tribe.

(2) EXPENDITURES FOR LOCAL HIGHWAY PROGRAMS.—Notwithstanding subsection (b)(1)(C), 95 percent of the funds apportioned to the Secretary of the Interior under this section shall be expended by Indian tribes to carry out highway safety programs within their jurisdictions.

(3) ACCESS FOR INDIVIDUALS WITH DISABILITIES.—The requirements of subsection (b)(1)(D) shall be applicable to Indian tribes, except to those tribes with respect to which the Secretary determines that application of such provisions would not be practicable.

(4) INDIAN COUNTRY DEFINED.—In this subsection, the term "Indian country" means—

(A) all land within the limits of any Indian reservation under the jurisdiction of the United States, notwithstanding the issuance of any patent and including rights-of-way running through the reservation;

(B) all dependent Indian communities within the borders of the United States, whether within the original or subsequently acquired territory thereof and whether within or without the limits of a State; and

(C) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through such allotments.

(j) RULEMAKING PROCEEDING.—The Secretary may periodically conduct a rulemaking process to identify highway safety programs that are highly effective in reducing motor vehicle crashes, injuries, and deaths. Any such rulemaking shall take into account the major role of the States in implementing such programs. When a rule promulgated in accordance with this section takes effect, States shall consider these highly effective programs when developing their highway safety programs.

(k)(1) Subject to the provisions of this subsection, the Secretary shall make a grant to any State which includes, as part of its highway safety program under section 402 of this title, the use of a comprehensive computerized safety recordkeeping system designed to correlate data regarding traffic accidents, drivers, motor vehicles, and roadways. Any such grant may only be used by such State to establish and maintain a comprehensive computerized traffic safety recordkeeping system or to obtain and operate components to support highway safety priority programs identified by the Secretary under this section. Notwithstanding any other provision of law, if a report, list, schedule, or survey is prepared by or for a

[2] Subsection (h) was repealed by Public Law 97–35, Title XI, § 1107(c), Aug. 13, 1981, 95 Stat. 626.

State or political subdivision thereof under this subsection, such report, list, schedule, or survey shall not be admitted as evidence or used in any suit or action for damages arising out of any matter mentioned in such report, list, schedule, or survey.

(2) No State may receive a grant under this subsection in more than two fiscal years.

(3) The amount of the grant to any State under this subsection for the first fiscal year such State is eligible for a grant under this subsection shall equal 10 per centum of the amount apportioned to such State for fiscal year 1985 under this section. The amount of a grant to any State under this subsection for the second fiscal year such State is eligible for a grant under this subsection shall equal 10 per centum of the amount apportioned to such State for fiscal year 1986 under this section.

(4) A State is eligible for a grant under this subsection if—

(A) it certifies to the Secretary that it has in operation a computerized traffic safety recordkeeping system and identifies proposed means of upgrading the system acceptable to the Secretary; or

(B) it provides to the Secretary a plan acceptable to the Secretary for establishing and maintaining a computerized traffic safety recordkeeping system.

(5) The Secretary, after making the deduction authorized by the second sentence of subsection (c) of this section for fiscal years 1985 and 1986, shall set aside 10 per centum of the remaining funds authorized to be appropriated to carry out this section for the purpose of making grants under this subsection. Funds set aside under this subsection shall remain available for the fiscal year authorized and for the succeeding fiscal year and any amounts remaining unexpended at the end of such period shall be apportioned in accordance with the provisions of subsection (c) of this section.

25 U.S.C. §§ 2401–2455
Indian Alcohol and Substance Abuse Prevention and Treatment Act, Public Law 99–570, secs. 4202–4222
Indian alcohol and substance abuse prevention and treatment

Title 25. Indians

Chapter 26. Indian Alcohol and Substance Abuse Prevention and Treatment

§ 2401. Congressional findings [1]

The Congress finds and declares that—

(1) the Federal Government has a historical relationship and unique legal and moral responsibility to Indian tribes and their members,

(2) included in this responsibility is the treaty, statutory, and historical obligation to assist the Indian tribes in meeting the health and social needs of their members,

(3) alcoholism and alcohol and substance abuse is the most severe health and social problem facing Indian tribes and people today and nothing is more costly to Indian people than the consequences of alcohol and substance abuse measured in physical, mental, social, and economic terms,

(4) alcohol and substance abuse is the leading generic risk factor among Indians, and Indians die from alcoholism at over 4 times the age-adjusted rates for the United States population and alcohol and substance misuse results in a rate of years of potential life lost nearly 5 times that of the United States,

(5) 4 of the top 10 causes of death among Indians are alcohol and drug related injuries (18 percent of all deaths), chronic liver disease and cirrhosis (5 percent), suicide (3 percent), and homicide (3 percent),

(6) primarily because deaths from unintentional injuries and violence occur disproportionately among young people, the age-specific death rate for Indians is approximately double the United States rate for the 15 to 45 age group,

(7) Indians between the ages of 15 and 24 years of age are more than 2 times as likely to commit suicide as the general population and approximately 80 percent of those suicides are alcohol-related,

(8) Indians between the ages of 15 and 24 years of age are twice as likely as the general population to die in automobile accidents, 75 percent of which are alcohol-related,

[1] Public Law 99–570, Title IV, § 4202, Oct. 27, 1986, 100 Stat. 3207–137.

(9) the Indian Health Service, which is charged with treatment and rehabilitation efforts, has directed only 1 percent of its budget for alcohol and substance abuse problems,

(10) the Bureau of Indian Affairs, which has responsibility for programs in education, social services, law enforcement, and other areas, has assumed little responsibility for coordinating its various efforts to focus on the epidemic of alcohol and substance abuse among Indian people,

(11) this lack of emphasis and priority continues despite the fact that Bureau of Indian Affairs and Indian Health Service officials publicly acknowledge that alcohol and substance abuse among Indians is the most serious health and social problem facing the Indian people, and

(12) the Indian tribes have the primary responsibility for protecting and ensuring the well-being of their members and the resources made available under this chapter will assist Indian tribes in meeting that responsibility.

§ 2402. Purpose [2]

It is the purpose of this chapter to—

(1) authorize and develop a comprehensive, coordinated attack upon the illegal narcotics traffic in Indian country and the deleterious impact of alcohol and substance abuse upon Indian tribes and their members,

(2) provide needed direction and guidance to those Federal agencies responsible for Indian programs to identify and focus existing programs and resources, including those made available by this chapter, upon this problem,

(3) provide authority and opportunities for Indian tribes to develop and implement a coordinated program for the prevention and treatment of alcohol and substance abuse at the local level, and

(4) to [3] modify or supplement existing programs and authorities in the areas of education, family and social services, law enforcement and judicial services, and health services to further the purposes of this chapter.

§ 2403. Definitions [4]

For purposes of this chapter—

(1) The term "agency" means the local administrative entity of the Bureau of Indian Affairs serving one or more Indian tribes within a defined geographic area.

(2) The term "youth" shall have the meaning given it in any particular Tribal Action Plan adopted pursuant to section 2411 of this title, except that, for purposes of statistical reporting under this chapter, it shall mean a person who is 19 years or younger or who is in attendance at a secondary school.

(3) The term "Indian tribe" means any Indian tribe, band, nation, or other organized group or community of Indians (including any Alaska Native village or regional or village corporation as defined in, or established pursuant to, the Alaska

[2] Public Law 99–570, Title IV, § 4203, Oct. 27, 1986, 100 Stat. 3207–138.
[3] So in original.
[4] Public Law 99–570, Title IV, § 4204, Oct. 27, 1986, 100 Stat. 3207–138; Public Law 100–690, Title II, § 2202, Nov. 18, 1988, 102 Stat. 4217.

Native Claims Settlement Act (43 U.S.C. 1601 et seq.)) which is recognized as eligible for special programs and services provided by the United States to Indians because of their status as Indians.

(4) The term "prevention and treatment" includes, as appropriate—

(A) efforts to identify, and the identification of, Indians who are at risk with respect to, or who are abusers of, alcohol or controlled substances,

(B) intervention into cases of on-going alcohol and substance abuse to halt a further progression of such abuse,

(C) prevention through education and the provision of alternative activities,

(D) treatment for alcohol and substance abusers to help abstain from, and alleviate the effects of, abuse,

(E) rehabilitation to provide on-going assistance, either on an inpatient or outpatient basis, to help Indians reform or abstain from alcohol or substance abuse,

(F) follow-up or after-care to provide the appropriate counseling and assistance on an outpatient basis, and

(G) referral to other sources of assistance or resources.

(5) The term "service unit" means an administrative entity within the Indian Health Service or a tribe or tribal organization operating health care programs or facilities with funds from the Indian Health Service under the Indian Self-Determination Act through which the services are provided, directly or by contract, to the eligible Indian population within a defined geographic area.

(6) The terms "Urban Indian", "Urban Center", and "Urban Indian Organization" shall have the same meaning as provided in section 1603 of this title.

§ 2411. Inter-Departmental memorandum of agreement[5]

(a) In general

Not later than 120 days after October 27, 1986, the Secretary of the Interior and the Secretary of Health and Human Services shall develop and enter into a Memorandum of Agreement which shall, among other things—

(1) determine and define the scope of the problem of alcohol and substance abuse for Indian tribes and their members and its financial and human costs, and specifically identify such problems affecting Indian youth,

(2) identify—

(A) the resources and programs of the Bureau of Indian Affairs and Indian Health Service, and

(B) other Federal, tribal, State and local, and private resources and programs,

which would be relevant to a coordinated effort to combat alcohol and substance abuse among Indian people, including those programs and resources made available by this chapter,

[5] Public Law 99–570, Title IV, § 4205, Oct. 27, 1986, 100 Stat. 3207–139.

(3) develop and establish appropriate minimum standards for each agency's program responsibilities under the Memorandum of Agreement which may be—

(A) the existing Federal or State standards in effect, or

(B) in the absence of such standards, new standards which will be developed and established in consultation with Indian tribes,

(4) coordinate the Bureau of Indian Affairs and Indian Health Service alcohol and substance abuse programs existing on October 27, 1986, with programs or efforts established by this chapter,

(5) delineate the responsibilities of the Bureau of Indian Affairs and the Indian Health Service to coordinate alcohol and substance abuse-related services at the central, area, agency, and service unit levels,

(6) direct Bureau of Indian Affairs agency and education superintendents, where appropriate, and the Indian Health Service service unit directors to cooperate fully with tribal requests made pursuant to section 2412 of this title, and

(7) provide for an annual review of such agreements by the Secretary of the Interior and the Secretary of Health and Human Services.

(b) Character of activities

To the extent that there are new activities undertaken pursuant to this chapter, those activities shall supplement, not supplant, activities, programs, and local actions that are ongoing on October 27, 1986. Such activities shall be undertaken in the manner least disruptive to tribal control, in accordance with the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.), and local control, in accordance with section 2010 of this title.

(c) Consultation

The Secretary of the Interior and the Secretary of Health and Human Services shall, in developing the Memorandum of Agreement under subsection (a) of this section, consult with and solicit the comments of—

(1) interested Indian tribes,

(2) Indian individuals,

(3) Indian organizations, and

(4) professionals in the treatment of alcohol and substance abuse.

(d) Publication

The Memorandum of Agreement under subsection (a) of this section shall be submitted to Congress and published in the Federal Register not later than 130 days after October 27, 1986. At the same time as publication in the Federal Register, the Secretary of the Interior shall provide a copy of this chapter and the Memorandum of Agreement under subsection (a) of this section to each Indian tribe.

§ 2412. Tribal Action Plans [6]

(a) In general

The governing body of any Indian tribe may, at its discretion, adopt a resolution for the establishment of a Tribal Action Plan to coordinate available resources and programs, including programs and resources made available by this chapter, in an effort to combat alcohol and substance abuse among its members. Such resolution shall be the basis for the implementation of this chapter and of the Memorandum of Agreement under section 2411 of this title.

(b) Cooperation

At the request of any Indian tribe pursuant to a resolution adopted under subsection (a) of this section, the Bureau of Indian Affairs agency and education superintendents, where appropriate, and the Indian Health Service service unit director providing services to such tribe shall cooperate with the tribe in the development of a Tribal Action Plan to coordinate resources and programs relevant to alcohol and substance abuse prevention and treatment. Upon the development of such a plan, such superintendents and director, as directed by the Memorandum of Agreement established under section 2411 of this title, shall enter into an agreement with the tribe for the implementation of the Tribal Action Plan under subsection (a) of this section.

(c) Provisions

(1) Any Tribal Action Plan entered into under subsection (b) of this section shall provide for—

(A) the establishment of a Tribal Coordinating Committee which shall—

(i) at a minimum, have as members a tribal representative who shall serve as Chairman and the Bureau of Indian Affairs agency and education superintendents, where appropriate, and the Indian Health Service service unit director, or their representatives,

(ii) have primary responsibility for the implementation of the Tribal Action Plan,

(iii) have the responsibility for on-going review and evaluation of, and the making of recommendations to the tribe relating to, the Tribal Action Plan, and

(iv) have the responsibility for scheduling Federal, tribal or other personnel for training in the prevention and treatment of alcohol and substance abuse among Indians as provided under section 2475 of this title, and

(B) the incorporation of the minimum standards for those programs and services which it encompasses which shall be—

(i) the Federal or State standards as provided in section 2411(a)(3) of this title, or

(ii) applicable tribal standards, if such standards are no less stringent than the Federal or State standards.

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[6] Public Law 99–570, Title IV, § 4206, Oct. 27, 1986, 100 Stat. 3207–140; Public Law 100–690, Title II, §§ 2203, 2204, Nov. 18, 1988, 102 Stat. 4217; Public Law 102–573, Title VII, § 703(1), Oct. 29, 1992, 106 Stat. 4582.

(2) Any Tribal Action Plan may, among other things, provide for—

(A) an assessment of the scope of the problem of alcohol and substance abuse for the Indian tribe which adopted the resolution for the Plan,

(B) the identification and coordination of available resources and programs relevant to a program of alcohol and substance abuse prevention and treatment,

(C) the establishment and prioritization of goals and the efforts needed to meet those goals,

(D) the identification of the community and family roles in any of the efforts undertaken as part of the Tribal Action Plan,

(E) the establishment of procedures for amendment and revision of the plan as may be determined necessary by the Tribal Coordinating Committee, and

(F) an evaluation component to measure the success of efforts made.

(3) All Tribal Action Plans shall be updated every 2 years.

(d) Grants

(1) The Secretary of the Interior may make grants to Indian tribes adopting a resolution pursuant to subsection (a) of this section to provide technical assistance in the development of a Tribal Action Plan. The Secretary shall allocate funds based on need.

(2) There are authorized to be appropriated for grants under this subsection not more than $2,000,000 for fiscal year 1993 and such sums as are necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

(e) Federal action

If any Indian tribe does not adopt a resolution as provided in subsection (a) of this section within 90 days after the publication of the Memorandum of Agreement in the Federal Register as provided in section 2411 of this title, the Secretary of the Interior and the Secretary of Health and Human Services shall require the Bureau of Indian Affairs agency and education superintendents, where appropriate, and the Indian Health Service service unit director serving such tribe to enter into an agreement to identify and coordinate available programs and resources to carry out the purposes of this chapter for such tribe. After such an agreement has been entered into for a tribe such tribe may adopt a resolution under subsection (a) of this section.

(f) Grants for training, education, and prevention programs

(1) The Secretary of the Interior may make grants to Indian tribes adopting a resolution pursuant to subsection (a) of this section to implement and develop community and in-school training, education, and prevention programs on alcohol and substance abuse, fetal alcohol syndrome and fetal alcohol effect.

(2) Funds provided under this section may be used for, but are not limited to, the development and implementation of tribal programs for—

(A) youth employment;

(B) youth recreation;

(C) youth cultural activities;
(D) community awareness programs; and
(E) community training and education programs.

(3) There are authorized to be appropriated to carry out the provisions of this subsection $5,000,000 for fiscal year 1993 and such sums as are necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

§ 2413. Departmental responsibility[7]

(a) Implementation

The Secretary of the Interior, acting through the Bureau of Indian Affairs, and the Secretary of Health and Human Services, acting through the Indian Health Service, shall bear equal responsibility for the implementation of this chapter in cooperation with Indian tribes.

(b) Office of Alcohol and Substance Abuse

(1) In order to better coordinate the various programs of the Bureau of Indian Affairs in carrying out this chapter, there is established within the Office of the Assistant Secretary of the Interior for Indian Affairs an Office of Alcohol and Substance Abuse. The director of such office[8] shall be appointed by the Assistant Secretary of the Interior for Indian Affairs on a permanent basis at no less than a grade GS–15 of the General Schedule.

(2) In addition to other responsibilities which may be assigned to such Office, it shall be responsible for—

(A) monitoring the performance and compliance of programs of the Bureau of Indian Affairs in meeting the goals and purposes of this chapter and the Memorandum of Agreement entered into under section 2411 of this title, and

(B) serving as a point of contact within the Bureau of Indian Affairs for Indian tribes and the Tribal Coordinating Committees regarding the implementation of this chapter, the Memorandum of Agreement, and any Tribal Action Plan established under section 2412 of this title.

(3) The Assistant Secretary of the Interior for Indian Affairs shall appoint such employees to work in the Office of Alcohol and Substance Abuse, and shall provide such funding, services, and equipment as may be necessary to enable the Office of Alcohol and Substance Abuse to carry out its responsibilities.

(c) Indian Youth Programs Officer

(1) There is established in the Office of Alcohol and Substance Abuse the position to be known as the Indian Youth Programs Officer. The Assistant Secretary of the Interior for Indian Affairs shall appoint the Indian Youth Programs Officer.

(2) The position of Indian Youth Programs Officer shall be established on a permanent basis at no less than the grade of GS-14 of the General Schedule.

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[7] Public Law 99–570, Title IV, § 4207, Oct. 27, 1986, 100 Stat. 3207–141; Public Law 100–690, Title II, § 2216, Nov. 18, 1988, 102 Stat. 4221; Public Law 102–573, Title VII, § 703(2), Oct. 29, 1992, 106 Stat. 4583.

[8] So in original. Probably should be capitalized.

(3) In addition to other responsibilities which may be assigned to the Indian Youth Programs Officer relating to Indian Youth,[9] such Officer shall be responsible for—

(A) monitoring the performance and compliance of programs of the Bureau of Indian Affairs in meeting the goals and purposes of this chapter and the Memorandum of Agreement entered into under section 2411 of this title as they relate to Indian youth efforts, and

(B) providing advice and recommendations, including recommendations submitted by Indian tribes and Tribal Coordinating Committees, to the Director of the Office of Alcohol and Substance Abuse as they relate to Indian youth.

§ 2414. Congressional intent in construction of laws[10]

It is the intent of Congress that—

(1) specific Federal laws, and administrative regulations promulgated thereunder, establishing programs of the Bureau of Indian Affairs, the Indian Health Service, and other Federal agencies, and

(2) general Federal laws, including laws limiting augmentation of Federal appropriations or encouraging joint or cooperative funding,

shall be liberally construed and administered to achieve the purposes of this chapter.

§ 2414a. Review of programs[11]

(a) In general

In the development of the Memorandum of Agreement required by section 2411 of this title, the Secretary of the Interior and the Secretary of Health and Human Services shall review and consider—

(1) the various programs established by Federal law providing health services and benefits to Indian tribes, including those relating to mental health and alcohol and substance abuse prevention and treatment,

(2) tribal, State and local, and private health resources and programs,

(3) where facilities to provide such treatment are or should be located, and

(4) the effectiveness of public and private alcohol and substance abuse treatment programs in operation on October 27, 1986,

to determine their applicability and relevance in carrying out the purposes of this chapter.

(b) Dissemination

The results of the review conducted under subsection (a) of this section shall be provided to every Indian tribe as soon as possible for their consideration and use in the development or modification of a Tribal Action Plan.

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[9] So in original. Probably should not be capitalized.

[10] Public Law 99–570, Title IV, § 4208, Oct. 27, 1986, 100 Stat. 3207–142.

[11] Public Law 99–570, Title IV, § 4208A, formerly § 4224, Oct. 27, 1986, 100 Stat. 3207–148; renumbered § 4208A, Public Law 102–573, Title VII, § 702(b)(1), Oct. 29, 1992, 106 Stat. 4582.

§ 2415. Federal facilities, property, and equipment; leasing of tribal property [12]

(a) Facility availability

In the furtherance of the purposes and goals of this chapter, the Secretary of the Interior and the Secretary of Health and Human Services shall make available for community use, to the extent permitted by law and as may be provided in a Tribal Action Plan, local Federal facilities, property, and equipment, including school facilities. Such facility availability shall include school facilities under the Secretary of the Interior's jurisdiction: *Provided* , That the use of any school facilities shall be conditioned upon approval of the local school board with jurisdiction over such school.

(b) Costs

Any additional cost associated with the use of Federal facilities, property, or equipment under subsection (a) of this section may be borne by the Secretary of the Interior and the Secretary of Health and Human Services out of available Federal, tribal, State, local, or private funds, if not otherwise prohibited by law. This subsection does not require the Secretary of the Interior nor the Secretary of Health and Human Services to expend additional funds to meet the additional costs which may be associated with the provision of such facilities, property, or equipment for community use. Where the use of Federal facilities, property, or equipment under subsection (a) of this section furthers the purposes and goals of this chapter, the use of funds other than those funds appropriated to the Department of the Interior or the Department of Health and Human Services to meet the additional costs associated with such use shall not constitute an augmentation of Federal appropriations.

(c) Leases

(1) The Secretary of the Interior and the Secretary of Health and Human Services are authorized to enter into long-term leases of tribally owned or leased facilities to house programs established by this chapter where they determine that there is no Federal facility reasonably available for such purpose and the cost of constructing a new Federal facility would exceed the cost of such Federal lease unless they determine that mitigating factors favor such a lease.

(2) A tribally owned or leased facility may be leased pursuant to this authority to house a regional treatment center to be established pursuant to section 2474(b) of this title only if all the tribes within the Indian Health Service area to be served by such regional treatment center initially consent to such Federal lease.

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[12] Public Law 99–570, Title IV, § 4209, Oct. 27, 1986, 100 Stat. 3207–142; Public Law 100–690, Title II, § 2205, Nov. 18, 1988, 102 Stat. 4217.

§ 2416. Newsletter [13]

(a) In general

The Secretary of the Interior shall publish an alcohol and substance abuse newsletter in cooperation with the Secretary of Health and Human Services and the Secretary of Education to report on Indian alcohol and substance abuse projects and programs. The newsletter shall—

(1) be published once in each calendar quarter,

(2) include reviews of programs determined by the Secretary of the Interior to be exemplary and provide sufficient information to enable interested persons to obtain further information about such programs, and

(3) be circulated without charge to—

(A) schools,

(B) tribal offices,

(C) Bureau of Indian Affairs' agency and area offices,

(D) Indian Health Service area and service unit offices,

(E) Indian Health Service alcohol programs, and

(F) other entities providing alcohol and substance abuse related services or resources to Indian people.

(b) Authorization of appropriations

There are authorized to be appropriated to carry out this section $500, 000 for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

§ 2431. Review of programs [14]

(a) Review

In the development of the Memorandum of Agreement required by section 2411 of this title, the Secretary of the Interior and the Secretary of Health and Human Services, in cooperation with the Secretary of Education shall review and consider—

(1) Federal programs providing education services or benefits to Indian children,

(2) tribal, State, local, and private educational resources and programs,

(3) Federal programs providing family and social services and benefits for Indian families and children,

(4) Federal programs relating to youth employment, recreation, cultural, and community activities, and

(5) tribal, State, local, and private resources for programs similar to those cited in paragraphs (3) and (4),

to determine their applicability and relevance in carrying out the purposes of this chapter.

(b) Publication

The results of the review conducted under subsection (a) of this section shall be provided to each Indian tribe as soon as possible

[13] Public Law 99–570, Title IV, § 4210, Oct. 27, 1986, 100 Stat. 3207–143; Public Law 100–690, Title II, § 2218, Nov. 18, 1988, 102 Stat. 4222; Public Law 102–573, Title VII, § 703(3), Oct. 29, 1992, 106 Stat. 4583.

[14] Public Law 99–570, Title IV, § 4211, Oct. 27, 1986, 100 Stat. 3207–143.

for their consideration and use in the development or modification of a Tribal Action Plan under section 2412 of this title.

§ 2432. Indian education programs[15]

(a) Pilot programs

The Assistant Secretary of Indian Affairs shall develop and implement pilot programs in selected schools funded by the Bureau of Indian Affairs (subject to the approval of the local school board or contract school board) to determine the effectiveness of summer youth programs in furthering the purposes and goals of this chapter. The Assistant Secretary shall defray all costs associated with the actual operation and support of the pilot programs in the school from funds appropriated for this section. For the pilot programs there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1993, 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

(b) Use of funds

Federal financial assistance made available to public or private schools because of the enrollment of Indian children pursuant to—

(1) the Act of April 16, 1934, as amended by the Indian Education Assistance Act (25 U.S.C. 452 et seq.),

(2) the Indian Elementary and Secondary School Assistance Act (20 U.S.C. 241aa et seq.), and

(3) the Indian Education Act (20 U.S.C. 3385),

may be used to support a program of instruction relating to alcohol and substance abuse prevention and treatment.

§ 2433. Emergency shelters[16]

(a) In general

A Tribal Action Plan adopted pursuant to section 2412 of this title may make such provisions as may be necessary and practical for the establishment, funding, licensing, and operation of emergency shelters or half-way houses for Indian youth who are alcohol or substance abusers, including youth who have been arrested for offenses directly or indirectly related to alcohol or substance abuse. Half-way houses may be used as either intake facilities or aftercare facilities for youth admitted, or to be admitted, for long-term treatment of substance abuse. The Indian Health Service, the Bureau of Indian Affairs, and the tribes are authorized to use their respective resources to adequately staff and operate any such facility.

(b) Referrals

(1) In any case where an Indian youth is arrested or detained by the Bureau of Indian Affairs or tribal law enforcement personnel for an offense relating to alcohol or substance abuse, other than for a status offense as defined by the Juvenile Justice and Delinquency

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[15] Public Law 99–570, Title IV, § 4212, Oct. 27, 1986, 100 Stat. 3207–144; Public Law 100–690, Title II, § 2206, Nov. 18, 1988, 102 Stat. 4218; Public Law 102–573, Title VII, § 703(4), Oct. 29, 1992, 106 Stat. 4583.

[16] Public Law 99–570, Title IV, § 4213, Oct. 27, 1986, 100 Stat. 3207–144; Public Law 100–690, Title II, § 2207, Nov. 18, 1988, 102 Stat. 4218; Public Law 101–272, Apr. 18, 1990, 104 Stat. 137; Public Law 102–573, Title VII, § 703(5), Oct. 29, 1992, 106 Stat. 4583.

Prevention Act of 1974 [42 U.S.C. 5601 et seq.], under circumstances where such youth may not be immediately restored to the custody of his parents or guardians and where there is space available in an appropriately licensed and supervised emergency shelter or half-way house, such youth shall be referred to such facility in lieu of incarceration in a secured facility unless such youth is deemed a danger to himself or to other persons.

(2) In any case where there is a space available in an appropriately licensed and supervised emergency shelter or half-way house, the Bureau of Indian Affairs and tribal courts are encouraged to refer Indian youth convicted of offenses directly or indirectly related to alcohol and substance abuse to such facilities in lieu of sentencing to incarceration in a secured juvenile facility.

(c) Direction to States

In the case of any State that exercises criminal jurisdiction over any part of Indian country under section 1162 of Title 18 or section 1321 of this title, such State is urged to require its law enforcement officers to—

(1) place any Indian youth arrested for any offense related to alcohol or substance abuse in a temporary emergency shelter described in subsection (d) of this section or a community-based alcohol or substance abuse treatment facility in lieu of incarceration to the extent such facilities are available, and

(2) observe the standards promulgated under subsection (d) of this section.

(d) Standards

The Assistant Secretary of Indian Affairs shall, as part of the development of the Memorandum of Agreement set out in section 2411 of this title, promulgate standards by which the emergency shelters established under a program pursuant to subsection (a) of this section shall be established and operated.

(e) Authorization

(1) For the planning and design, construction, and renovation of, or purchase or lease of land or facilities for, emergency shelters and half-way houses to provide emergency care for Indian youth, there are authorized to be appropriated $10,000,000 for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

(2) For the staffing and operation of emergency shelters and half-way houses, there are authorized to be appropriated $5,000,000 for fiscal year 1993 and $7,000,000 for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

(3) The Secretary of the Interior shall allocate funds appropriated pursuant to this subsection on the basis of priority of need of the various Indian tribes and such funds, when allocated, shall be subject to contracting or available for grants pursuant to the Indian Self-Determination Act [25 U.S.C. 450f et seq.].

(4) Funds appropriated under the authority of this subsection may be used by any Indian tribe or tribal organization to purchase or lease any land or facilities if—

(A) the Secretary of the Interior determines that no Federal land or facilities are reasonably available for emergency shelters or halfway [17] houses described in subsection (a) of this section to serve the needs of that Indian tribe or tribal organization, and

(B) the Indian tribe or tribal organization enters into an agreement with the Secretary of the Interior that requires the Indian tribe or tribal organization to use the land or facilities for emergency shelters or half-way houses described in subsection (a) of this section.

(5) Nothing in this chapter may be construed—

(A) to limit the authority for contracts with, or grants to, Indian tribes or tribal organizations under the Indian Self-Determination Act [25 U.S.C. 450f et seq.] for the construction, improvement, renovation, operation, repair, land acquisition, or maintenance of tribal juvenile detention facilities, emergency shelters, or half-way houses, or

(B) to require a lease of tribal facilities to the United States to qualify for financial assistance for the facilities under this or any other Act.

§ 2434. Social services reports [18]

(a) Data

The Secretary of the Interior, with respect to the administration of any family or social services program by the Bureau of Indian Affairs directly or through contracts under the Indian Self-Determination Act [25 U.S.C. 450f et seq.], shall require the compilation of data relating to the number and types of child abuse and neglect cases seen and the type of assistance provided. Additionally, such data should also be categorized to reflect those cases that involve, or appear to involve, alcohol and substance abuse, those cases which are recurring, and those cases which involve other minor siblings.

(b) Referral of data

The data compiled pursuant to subsection (a) of this section shall be provided annually to the affected Indian tribe and Tribal Coordinating Committee to assist them in developing or modifying a Tribal Action Plan and shall also be submitted to the Indian Health Service service unit director who will have responsibility for compiling a tribal comprehensive report as provided in section 2477 of this title.

(c) Confidentiality

In carrying out the requirements of subsections (a) and (b) of this section, the Secretary shall insure that the data is compiled and reported in a manner which will preserve the confidentiality of the families and individuals.

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[17] So in original. Probably should be "half-way".

[18] Public Law 99–570, Title IV, § 4214, Oct. 27, 1986, 100 Stat. 3207–145.

§ 2441. Review of programs [19]

(a) Law enforcement and judicial services

In the development of the Memorandum of Agreement required by section 2411 of this title, the Secretary of the Interior and the Secretary of Health and Human Services, in cooperation with the Attorney General of the United States, shall review and consider—

(1) the various programs established by Federal law providing law enforcement or judicial services for Indian tribes, and

(2) tribal and State and local law enforcement and judicial programs and systems

to determine their applicability and relevance in carrying out the purposes of this chapter.

(b) Dissemination of review

The results of the review conducted pursuant to subsection (a) of this section shall be made available to every Indian tribe as soon as possible for their consideration and use in the development and modification of a Tribal Action Plan.

§ 2442. Illegal narcotics traffic on Tohono O'odham and St. Regis Reservations; source eradication [20]

(a) Investigation and control

(1) The Secretary of the Interior shall provide assistance to—

(A) the Tohono O'odham Tribe of Arizona for the investigation and control of illegal narcotics traffic on the Tohono O'odham Reservation along the border with Mexico,

(B) the St. Regis Band of Mohawk Indians of New York for the development of tribal law enforcement and judicial systems to aid in the investigation and control of illegal narcotics traffic on the St. Regis Reservation along the border with Canada, and

(C) the Makah Indian Tribe of Washington for the investigation and control of illegal narcotic traffic on the Makah Indian Reservation arising from its proximity to international waters.

(2) The Secretary shall ensure that tribal efforts under this subsection are coordinated with appropriate Federal law enforcement agencies, including the United States Custom [21] Service.

(3) For the purpose of providing the assistance required by this subsection, there are authorized to be appropriated—

(A) $500,000 under paragraph (1)(A) for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000,

(B) $500,000 under paragraph (1)(B) for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000, and

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[19] Public Law 99–570, Title IV, § 4215, Oct. 27, 1986, 100 Stat. 3207–145.

[20] Public Law 99–570, Title IV, § 4216, Oct. 27, 1986, 100 Stat. 3207–146; Public Law 100–690, Title II, § 2208, Nov. 18, 1988, 102 Stat. 4218; Public Law 102–573, Title VII, § 703(6)–(8), Oct. 29, 1992, 106 Stat. 4583.

[21] So in original. Probably should be "Customs".

(C) $500,000 under paragraph (1)(C) for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

(b) Marijuana eradication and interdiction

(1) The Secretary of the Interior, in cooperation with appropriate Federal, tribal, and State and local law enforcement agencies, shall establish and implement a program for the eradication of marijuana cultivation, and interdiction, investigation, and control of illegal narcotics trafficking within Indian country as defined in section 1152 of Title 18. The Secretary shall establish a priority for the use of funds appropriated under paragraph (2) for those Indian reservations where the scope of the problem is most critical, and such funds shall be available for contracting by Indian tribes pursuant to the Indian Self-Determination Act (25 U.S.C. 450f et seq.).

(2) For the purpose of establishing the program required by paragraph (1), there are authorized to be appropriated $2,000,000 for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

§ 2451. Bureau of Indian Affairs law enforcement and judicial training [22]

(a) In general

The Secretary of the Interior shall ensure, through the establishment of a new training program or through the supplement of existing training programs, that all Bureau of Indian Affairs and tribal law enforcement and judicial personnel shall have available training in the investigation and prosecution of offenses relating to illegal narcotics and in alcohol and substance abuse prevention and treatment. Any training provided to Bureau of Indian Affairs and tribal law enforcement and judicial personnel as provided in this subsection shall specifically include training in the problems of youth alcohol and substance abuse prevention and treatment. Such training shall be coordinated with the Indian Health Service in the carrying out of its responsibilities under section 2475 of this title.

(b) Authorization

For the purposes of providing the training required by subsection (a) of this section, there are authorized to be appropriated $2,000,000 for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999 and 2000.

§ 2452. Medical assessment and treatment of juvenile offenders [23]

(a) Development and implementation of procedures

The Memorandum of Agreement entered into pursuant to section 2411 of this title shall include a specific provision for the development and implementation at each Bureau of Indian Affair [24] agency

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[22] Public Law 99–570, Title IV, § 4218, Oct. 27, 1986, 100 Stat. 3207–146; Public Law 100–690, Title II, § 2209, Nov. 18, 1988, 102 Stat. 4219; Public Law 102–573, Title VII, § 703(9), Oct. 29, 1992, 106 Stat. 4584.

[23] Public Law 99–570, Title IV, § 4219, Oct. 27, 1986, 100 Stat. 3207–147; Public Law 100–690, Title II, § 2210, Nov. 18, 1988, 102 Stat. 4219.

[24] So in original. Probably should be "Affairs".

and Indian Health Service unit of a procedure for the emergency medical assessment and treatment of every Indian youth arrested or detained by Bureau of Indian Affairs or tribal law enforcement personnel for an offense relating to or involving alcohol or substance abuse. The medical assessment required by this subsection—

(1) shall be conducted to determine the mental or physical state of the individual assessed so that appropriate steps can be taken to protect the individual's health and well-being,

(2) shall occur as soon as possible after the arrest or detention of an Indian youth, and

(3) shall be provided by the Indian Health Service, either through its direct or contract health service.

(b) Treatment of certain committed youth

The Indian Health Service shall not refuse to provide necessary interim treatment for any Indian youth referred pursuant to subsection (a) of this section who has been charged or is being prosecuted for any crime unless such referral is prohibited by a court of competent jurisdiction or the youth is determined by a court of competent jurisdiction to be a danger to others.

§ 2453. Juvenile detention centers[25]

(a) Plan

The Secretary of the Interior shall construct or renovate and staff new or existing juvenile detention centers. The Secretary shall ensure that the construction and operation of the centers is consistent with the Juvenile Justice and Delinquency Prevention Act of 1974 [42 U.S.C. 5601 et seq.].

(b) Authorization

(1) For the purpose of constructing or renovating juvenile detention centers as provided in subsection (a) of this section, there are authorized to be appropriated $10,000,000 for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

(2) For the purpose of staffing and operating juvenile detention centers, there are authorized to be appropriated $7,000,000 for fiscal year 1993 and such sums as may be necessary for each of the fiscal years 1994, 1995, 1996, 1997, 1998, 1999, and 2000.

§ 2454. Model Indian Juvenile Code[26]

The Secretary of the Interior, either directly or by contract, shall provide for the development of a Model Indian Juvenile Code which shall be consistent with the Juvenile Justice and Delinquency Prevention Act of 1974 [42 U.S.C. 5601 et seq.] and which shall include provisions relating to the disposition of cases involving Indian youth arrested or detained by Bureau of Indian Affairs or tribal law enforcement personnel for alcohol or drug related offenses.

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[25] Public Law 99–570, Title IV, § 4220, Oct. 27, 1986, 100 Stat. 3207–147; Public Law 100–690, Title II, § 2211, Nov. 18, 1988, 102 Stat. 4219; Public Law 102–573, Title VII, § 703(10), Oct. 29, 1992, 106 Stat. 4584.

[26] Public Law 99–570, Title IV, § 4221, Oct. 27, 1986, 100 Stat. 3207–147.

The development of such model code[27] shall be accomplished in cooperation with Indian organizations having an expertise or knowledge in the field of law enforcement and judicial procedure and in consultation with Indian tribes. Upon completion of the Model Code, the Secretary shall make copies available to each Indian tribe.

§ 2455. Law enforcement and judicial report[28]

(a) Compilation of law enforcement data

The Secretary of the Interior, with respect to the administration of any law enforcement or judicial services program by the Bureau of Indian Affairs, either directly or through contracts under the Indian Self-Determination Act [25 U.S.C. 450f et seq.], shall require the compilation of data relating to calls and encounters, arrests and detentions, and disposition of cases by Bureau of Indian Affairs or tribal law enforcement or judicial personnel involving Indians where it is determined that alcohol or substance abuse is a contributing factor.

(b) Referral of data

The data compiled pursuant to subsection (a) of this section shall be provided annually to the affected Indian tribe and Tribal Coordinating Committee to assist them in developing or modifying a Tribal Action Plan and shall also be submitted to the Indian Health Service[29] unit director who will have the responsibility for compiling a tribal comprehensive report as provided in section 2477 of this title.

(c) Confidentiality

In carrying out this section, the Secretary shall insure that the data is compiled and reported in a manner which will preserve the confidentiality of the families and individuals involved.

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[27] So in original. Probably should be "Model Code".
[28] Public Law 99–570, Title IV, § 4222, Oct. 27, 1986, 100 Stat. 3207–148.
[29] So in original. Probably should be followed by "service".

25 U.S.C. § 4103(3)

Native American Housing Assistance and Self-Determination Act, Public Law 104–330, sec. 4(3)

Drug-related criminal activity is defined as various controlled substance offenses

Chapter 43. Native American Housing Assistance and Self-Determination

§ 4103. Definitions [1]

For purposes of this chapter, the following definitions shall apply:

* * * * * * *

(3) Drug-related criminal activity

The term "drug-related criminal activity" means the illegal manufacture, sale, distribution, use, or possession with intent to manufacture, sell, distribute, or use, of a controlled substance (as such term is defined in section 802 of Title 21).

* * * * * * *

[1] Public Law 104–330, § 4(3), Oct. 26, 1996, 110 Stat. 4019.

25 U.S.C. § 4137(a)(6)

Native American Housing Assistance and Self-Determination Act, Public Law 104–330, sec. 207(a)(6)

Leases relating to Native American assisted housing must provide for termination for criminal activity including drug-related criminal activity

§ 4137. Lease requirements and tenant selection [1]

(a) Leases

Except to the extent otherwise provided by or inconsistent with tribal law, in renting dwelling units in affordable housing assisted with grant amounts provided under this chapter, the owner or manager of the housing shall utilize leases that—

* * * * * * *

(6) provide that the owner or manager may terminate the tenancy of a resident for any activity, engaged in by the resident, any member of the household of the resident, or any guest or other person under the control of the resident, that—

(A) threatens the health or safety of, or right to peaceful enjoyment of the premises by, other residents or employees of the owner or manager of the housing;

(B) threatens the health or safety of, or right to peaceful enjoyment of their premises by, persons residing in the immediate vicinity of the premises; or

(C) is criminal activity (including drug-related criminal activity) on or off the premises.

* * * * * * *

[1] Public Law 104–330, Title II, § 207(a)(6), Oct. 26, 1996, 110 Stat. 4034.

25 U.S.C. § 4233(a)(6)

Native American Housing Assistance and Self-Determination Act, Public Law 104–330, sec. 814

Leases relating to Native Hawaiian assisted housing must provide for termination for criminal activity including drug-related criminal activity

§ 4233. Lease requirements and tenant selection [1]

(a) Leases

Except to the extent otherwise provided by or inconsistent with the laws of the State of Hawaii, in renting dwelling units in affordable housing assisted with grant amounts provided under this subchapter, the Director, owner, or manager shall use leases that—

* * * * * * *

(6) provide that the Director, owner, or manager may terminate the tenancy of a resident for any activity, engaged in by the resident, any member of the household of the resident, or any guest or other person under the control of the resident, that—

(A) threatens the health or safety of, or right to peaceful enjoyment of the premises by, other residents or employees of the Department, owner, or manager;

(B) threatens the health or safety of, or right to peaceful enjoyment of their premises by, persons residing in the immediate vicinity of the premises; or

(C) is criminal activity (including drug-related criminal activity) on or off the premises.

* * * * * * *

[1] Public Law 104–330, Title VIII, § 814, as added Public Law 106–568, Title II, § 203, Dec. 27, 2000, 114 Stat. 2889, and as added Public Law 106–569, Title V, § 513, Dec. 27, 2000, 114 Stat. 2983.

26 U.S.C. § 25A
Internal Revenue Code, sec. 25A
Hope Scholarship tax credit denied for conviction of felony controlled substance offenses

Title 26. Internal Revenue Code

Chapter 1. Normal Taxes and Surtaxes

§ 25A. Hope and Lifetime Learning Credits [1]

(a) Allowance of credit

In the case of an individual, there shall be allowed as a credit against the tax imposed by this chapter for the taxable year the amount equal to the sum of—

(1) the Hope Scholarship Credit, plus

(2) the Lifetime Learning Credit.

(b) Hope Scholarship Credit

(1) Per student credit

In the case of any eligible student for whom an election is in effect under this section for any taxable year, the Hope Scholarship Credit is an amount equal to the sum of—

(A) 100 percent of so much of the qualified tuition and related expenses paid by the taxpayer during the taxable year (for education furnished to the eligible student during any academic period beginning in such taxable year) as does not exceed $1,000, plus

(B) 50 percent of such expenses so paid as exceeds $1,000 but does not exceed the applicable limit.

(2) Limitations applicable to Hope Scholarship Credit

(A) Credit allowed only for 2 taxable years

An election to have this section apply with respect to any eligible student for purposes of the Hope Scholarship Credit under subsection (a)(1) may not be made for any taxable year if such an election (by the taxpayer or any other individual) is in effect with respect to such student for any 2 prior taxable years.

(B) Credit allowed for year only if individual is at least ½ time student for portion of year

The Hope Scholarship Credit under subsection (a)(1) shall not be allowed for a taxable year with respect to the

[1] Added by Public Law 105–34, Title II, § 201(a), Aug. 5, 1997, 111 Stat. 799, and amended by Public Law 107–16, Title IV, § 401(g)(2)(A), June 7, 2001, 115 Stat. 60.

qualified tuition and related expenses of an individual unless such individual is an eligible student for at least one academic period which begins during such year.

(C) Credit allowed only for first 2 years of postsecondary education

The Hope Scholarship Credit under subsection (a)(1) shall not be allowed for a taxable year with respect to the qualified tuition and related expenses of an eligible student if the student has completed (before the beginning of such taxable year) the first 2 years of postsecondary education at an eligible educational institution.

(D) Denial of credit if student convicted of a felony drug offense

The Hope Scholarship Credit under subsection (a)(1) shall not be allowed for qualified tuition and related expenses for the enrollment or attendance of a student for any academic period if such student has been convicted of a Federal or State felony offense consisting of the possession or distribution of a controlled substance before the end of the taxable year with or within which such period ends.

(3) Eligible student

For purposes of this subsection, the term "eligible student" means, with respect to any academic period, a student who—

(A) meets the requirements of section 484(a)(1) of the Higher Education Act of 1965 (20 U.S.C. 1091(a)(1)), as in effect on the date of the enactment of this section, and

(B) is carrying at least ½ the normal full-time work load for the course of study the student is pursuing.

(4) Applicable limit

For purposes of paragraph (1)(B), the applicable limit for any taxable year is an amount equal to 2 times the dollar amount in effect under paragraph (1)(A) for such taxable year.

(c) Lifetime Learning Credit

(1) Per taxpayer credit

The Lifetime Learning Credit for any taxpayer for any taxable year is an amount equal to 20 percent of so much of the qualified tuition and related expenses paid by the taxpayer during the taxable year (for education furnished during any academic period beginning in such taxable year) as does not exceed $10,000 ($5,000 in the case of taxable years beginning before January 1, 2003).

(2) Special rules for determining expenses

(A) Coordination with Hope Scholarship

The qualified tuition and related expenses with respect to an individual who is an eligible student for whom a Hope Scholarship Credit under subsection (a)(1) is allowed

for the taxable year shall not be taken into account under this subsection.

(B) Expenses eligible for Lifetime Learning Credit

For purposes of paragraph (1), qualified tuition and related expenses shall include expenses described in subsection (f)(1) with respect to any course of instruction at an eligible educational institution to acquire or improve job skills of the individual.

(d) Limitation based on modified adjusted gross income

(1) In general

The amount which would (but for this subsection) be taken into account under subsection (a) for the taxable year shall be reduced (but not below zero) by the amount determined under paragraph (2).

(2) Amount of reduction

The amount determined under this paragraph is the amount which bears the same ratio to the amount which would be so taken into account as—

(A) the excess of—

(i) the taxpayer's modified adjusted gross income for such taxable year, over

(ii) $40,000 ($80,000 in the case of a joint return), bears to

(B) $10,000 ($20,000 in the case of a joint return).

(3) Modified adjusted gross income

The term "modified adjusted gross income" means the adjusted gross income of the taxpayer for the taxable year increased by any amount excluded from gross income under section 911, 931, or 933.

(e) Election not to have section apply

A taxpayer may elect not to have this section apply with respect to the qualified tuition and related expenses of an individual for any taxable year.

(f) Definitions

For purposes of this section—

(1) Qualified tuition and related expenses

(A) In general

The term "qualified tuition and related expenses" means tuition and fees required for the enrollment or attendance of—

(i) the taxpayer,

(ii) the taxpayer's spouse, or

(iii) any dependent of the taxpayer with respect to whom the taxpayer is allowed a deduction under section 151,

at an eligible educational institution for courses of instruction of such individual at such institution.

(B) Exception for education involving sports, etc.

Such term does not include expenses with respect to any course or other education involving sports, games, or hobbies, unless such course or other education is part of the individual's degree program.

(C) Exception for nonacademic fees

Such term does not include student activity fees, athletic fees, insurance expenses, or other expenses unrelated to an individual's academic course of instruction.

(2) Eligible educational institution

The term "eligible educational institution" means an institution—

(A) which is described in section 481 of the Higher Education Act of 1965 (20 U.S.C. 1088), as in effect on the date of the enactment of this section, and

(B) which is eligible to participate in a program under title IV of such Act.

(g) Special rules

(1) Identification requirement

No credit shall be allowed under subsection (a) to a taxpayer with respect to the qualified tuition and related expenses of an individual unless the taxpayer includes the name and taxpayer identification number of such individual on the return of tax for the taxable year.

(2) Adjustment for certain scholarships, etc.

The amount of qualified tuition and related expenses otherwise taken into account under subsection (a) with respect to an individual for an academic period shall be reduced (before the application of subsections (b), (c), and (d)) by the sum of any amounts paid for the benefit of such individual which are allocable to such period as—

(A) a qualified scholarship which is excludable from gross income under section 117,

(B) an educational assistance allowance under chapter 30, 31, 32, 34, or 35 of title 38, United States Code, or under chapter 1606 of title 10, United States Code, and

(C) a payment (other than a gift, bequest, devise, or inheritance within the meaning of section 102(a)) for such individual's educational expenses, or attributable to such individual's enrollment at an eligible educational institution, which is excludable from gross income under any law of the United States.

(3) Treatment of expenses paid by dependent

If a deduction under section 151 with respect to an individual is allowed to another taxpayer for a taxable year beginning in the calendar year in which such individual's taxable year begins—

(A) no credit shall be allowed under subsection (a) to such individual for such individual's taxable year, and

(B) qualified tuition and related expenses paid by such individual during such individual's taxable year shall be treated for purposes of this section as paid by such other taxpayer.

(4) Treatment of certain prepayments

If qualified tuition and related expenses are paid by the taxpayer during a taxable year for an academic period which begins during the first 3 months following such taxable year, such academic period shall be treated for purposes of this section as beginning during such taxable year.

(5) Denial of double benefit

No credit shall be allowed under this section for any expense for which a deduction is allowed under any other provision of this chapter.

(6) No credit for married individuals filing separate returns

If the taxpayer is a married individual (within the meaning of section 7703), this section shall apply only if the taxpayer and the taxpayer's spouse file a joint return for the taxable year.

(7) Nonresident aliens

If the taxpayer is a nonresident alien individual for any portion of the taxable year, this section shall apply only if such individual is treated as a resident alien of the United States for purposes of this chapter by reason of an election under subsection (g) or (h) of section 6013.

(h) Inflation adjustments

(1) Dollar limitation on amount of credit

(A) In general

In the case of a taxable year beginning after 2001, each of the $1,000 amounts under subsection (b)(1) shall be increased by an amount equal to—

(i) such dollar amount, multiplied by

(ii) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting ''calendar year 2000'' for ''calendar year 1992'' in subparagraph (B) thereof.

(B) Rounding

If any amount as adjusted under subparagraph (A) is not a multiple of $100, such amount shall be rounded to the next lowest multiple of $100.

(2) Income limits

(A) In general

In the case of a taxable year beginning after 2001, the $40,000 and $80,000 amounts in subsection (d)(2) shall each be increased by an amount equal to—

(i) such dollar amount, multiplied by

(ii) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting ''calendar year 2000'' for ''calendar year 1992'' in subparagraph (B) thereof.

(B) Rounding

If any amount as adjusted under subparagraph (A) is not a multiple of $1,000, such amount shall be rounded to the next lowest multiple of $1,000.

(i) Regulations

The Secretary may prescribe such regulations as may be necessary or appropriate to carry out this section, including regulations providing for a recapture of the credit allowed under this section in cases where there is a refund in a subsequent taxable year of any amount which was taken into account in determining the amount of such credit.

26 U.S.C. § 280E
Internal Revenue Code, sec. 280E
Expenditures in connection with illegal sale of drugs are not deductible

§ 280E. Expenditures in connection with the illegal sale of drugs [1]

No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted.

[1] Added by Public Law 97–248, Title III, § 351(a), Sept. 3, 1982, 96 Stat. 640.

26 U.S.C. § 6050I
Internal Revenue Code, sec. 6050I
Cash bail payments in excess of $10,000 must be reported by the clerk of the court with whom they are deposited

Chapter 61. Information and Returns

§ 6050I. Returns relating to cash received in trade or business, etc.[1]

(a) Cash receipts of more than $10,000

Any person—

(1) who is engaged in a trade or business, and

(2) who, in the course of such trade or business, receives more than $10,000 in cash in 1 transaction (or 2 or more related transactions),

shall make the return described in subsection (b) with respect to such transaction (or related transactions) at such time as the Secretary may by regulations prescribe.

(b) Form and manner of returns

A return is described in this subsection if such return—

(1) is in such form as the Secretary may prescribe,

(2) contains—

(A) the name, address, and TIN of the person from whom the cash was received,

(B) the amount of cash received,

(C) the date and nature of the transaction, and

(D) such other information as the Secretary may prescribe.

(c) Exceptions

(1) Cash received by financial institutions

Subsection (a) shall not apply to—

(A) cash received in a transaction reported under title 31, United States Code, if the Secretary determines that reporting under this section would duplicate the reporting to the Treasury under title 31, United States Code, or

(B) cash received by any financial institution (as defined in subparagraphs (A), (B), (C), (D), (E), (F), (G), (J), (K), (R), and (S) of section 5312(a)(2) of title 31, United States Code).

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[1] Added by Public Law 98–369, Div. A, Title I, § 146(a), July 18, 1984, 98 Stat. 685, and amended by Public Law 99–514, Title XV, § 1501(c)(12), Oct. 22, 1986, 100 Stat. 2739; Public Law 100–690, Title VII, § 7601(a)(1), Nov. 18, 1988, 102 Stat. 4503; Public Law 101–508, Title XI, § 11318(a), (c), Nov. 5, 1990, 104 Stat. 1388–458, 1388–459; Public Law 103–322, Title II, § 20415(a), (b)(3), Sept. 13, 1994, 108 Stat. 1832, 1833; Public Law 104–168, Title XII, § 1201(a)(9), July 30, 1996, 110 Stat. 1469.

(2) Transactions occurring outside the United States

Except to the extent provided in regulations prescribed by the Secretary, subsection (a) shall not apply to any transaction if the entire transaction occurs outside the United States.

(d) Cash includes foreign currency and certain monetary instruments

For purposes of this section, the term "cash" includes—

(1) foreign currency, and

(2) to the extent provided in regulations prescribed by the Secretary, any monetary instrument (whether or not in bearer form) with a face amount of not more than $10,000.

Paragraph (2) shall not apply to any check drawn on the account of the writer in a financial institution referred to in subsection (c)(1)(B).

(e) Statements to be furnished to persons with respect to whom information is required

Every person required to make a return under subsection (a) shall furnish to each person whose name is required to be set forth in such return a written statement showing—

(1) the name, address, and phone number of the information contact of the person required to make such return, and

(2) the aggregate amount of cash described in subsection (a) received by the person required to make such return.

The written statement required under the preceding sentence shall be furnished to the person on or before January 31 of the year following the calendar year for which the return under subsection (a) was required to be made.

(f) Structuring transactions to evade reporting requirements prohibited

(1) In general

No person shall for the purpose of evading the return requirements of this section—

(A) cause or attempt to cause a trade or business to fail to file a return required under this section,

(B) cause or attempt to cause a trade or business to file a return required under this section that contains a material omission or misstatement of fact, or

(C) structure or assist in structuring, or attempt to structure or assist in structuring, any transaction with one or more trades or businesses.

(2) Penalties

A person violating paragraph (1) of this subsection shall be subject to the same civil and criminal sanctions applicable to a person which fails to file or completes a false or incorrect return under this section.

(g) Cash received by criminal court clerks

(1) In general

Every clerk of a Federal or State criminal court who receives more than $10,000 in cash as bail for any individual charged with a specified criminal offense shall make a return described in paragraph (2) (at such time as the Secretary may by regulations prescribe) with respect to the receipt of such bail.

(2) Return

A return is described in this paragraph if such return—

(A) is in such form as the Secretary may prescribe, and

(B) contains—

(i) the name, address, and TIN of—

(I) the individual charged with the specified criminal offense, and

(II) each person posting the bail (other than a person licensed as a bail bondsman),

(ii) the amount of cash received,

(iii) the date the cash was received, and

(iv) such other information as the Secretary may prescribe.

(3) Specified criminal offense

For purposes of this subsection, the term ''specified criminal offense'' means—

(A) any Federal criminal offense involving a controlled substance,

(B) racketeering (as defined in section 1951, 1952, or 1955 of title 18, United States Code),

(C) money laundering (as defined in section 1956 or 1957 of such title), and

(D) any State criminal offense substantially similar to an offense described in subparagraph (A), (B), or (C).

(4) Information to Federal prosecutors

Each clerk required to include on a return under paragraph (1) the information described in paragraph (2)(B) with respect to an individual described in paragraph (2)(B)(i)(I) shall furnish (at such time as the Secretary may by regulations prescribe) a written statement showing such information to the United States Attorney for the jurisdiction in which such individual resides and the jurisdiction in which the specified criminal offense occurred.

(5) Information to payors of bail

Each clerk required to make a return under paragraph (1) shall furnish (at such time as the Secretary may by regulations prescribe) to each person whose name is required to be set forth in such return by reason of paragraph (2)(B)(i)(II) a written statement showing—

(A) the name and address of the clerk's office required to make the return, and

(B) the aggregate amount of cash described in paragraph (1) received by such clerk.

28 U.S.C. § 524

The Justice Department Asset Forfeiture Fund, which includes certain funds collected for reimbursement or restitution under the Controlled Substances Act, may be used to purchase evidence in controlled substance cases

Title 28. Judiciary and Judicial Procedure

Chapter 31. The Attorney General

§ 524. Availability of appropriations [1]

(a) Appropriations for the Department of Justice are available to the Attorney General for payment of—

(1) notarial fees, including such additional stenographic services as are required in connection therewith in the taking of depositions, and compensation and expenses of witnesses and informants, all at the rates authorized or approved by the Attorney General or the Assistant Attorney General for Administration; and

(2) when ordered by the court, actual expenses of meals and lodging for marshals, deputy marshals, or criers when acting as bailiffs in attendance on juries.

(b) Except as provided in subsection (a) of this section, a claim of not more than $500 for expenses related to litigation that is beyond the control of the Department may be paid out of appropriations currently available to the Department for expenses related to litigation when the Comptroller General settles the payment.

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[1] Added by Public Law 89–554, § 4(c), Sept. 6, 1966, 80 Stat. 615, and amended by Public Law 97–258, § 2(g)(1)(B) to (D), Sept. 13, 1982, 96 Stat. 1060; Public Law 98–473, Title II, §§ 310, 2303, Oct. 12, 1984, 98 Stat. 2052, 2193; Public Law 99–570, Title I, § 1152(a), Oct. 27, 1986, 100 Stat. 3207–12; Public Law 99–646, § 27, Nov. 10, 1986, 100 Stat. 3597; Public Law 100–202, § 101(a) [Title II, § 210(a)], Dec. 22, 1987, 101 Stat. 1329, 1329–18; Public Law 100–690, Title VI, § 6072, Nov. 18, 1988, 102 Stat. 4320; Public Law 101–509, Title III, § 1, Nov. 5, 1990, 104 Stat. 1403; Public Law 101–647, Title XVI, § 1601, Title XX, §§ 2001(a), 2002, 2005, 2006, Nov. 29, 1990, 104 Stat. 4842, 4854, 4855; Public Law 102–27, Title II, § 101, Apr. 10, 1991, 105 Stat. 135; Public Law 102–140, Title I, § 112, Oct. 28, 1991, 105 Stat. 795; Public Law 102–393, Title VI, § 638(f), Oct. 6, 1992, 106 Stat. 1788; Public Law 102–395, Title I, § 114(b), (c), Oct. 6, 1992, 106 Stat. 1845; Public Law 102–550, Title XV, § 1529, Oct. 28, 1992, 106 Stat. 4065; Public Law 103–121, Title I, § 109, Oct. 27, 1993, 107 Stat. 1164; Public Law 103–317, Title I, § 110, Aug. 26, 1994, 108 Stat. 1735; Public Law 103–322, Title IX, § 90205(b), Title XXXII, §§ 320301, 320302, 320913(a), Sept. 13, 1994, 108 Stat. 1994, 2114, 2128; Public Law 104–66, Title I, § 1091(h), Dec. 21, 1995, 109 Stat. 722; Public Law 104–91, Title I, § 101(a), Jan. 6, 1996, 110 Stat. 11; Public Law 104–99, Title II, § 211, Jan. 26, 1996, 110 Stat. 37; Public Law 104–134, Title I, § 101 [(a)][Title I, § 122], Apr. 26, 1996, 110 Stat. 1321–22; renumbered Title I Public Law 104–140, § 1(a), May 2, 1996, 110 Stat. 1327, and amended by Public Law 104–208, Div. A, Title I, § 101(a) [Title I, §§ 108, 114, 116, 117], Sept. 30, 1996, 110 Stat. 3009–18, 3009–22, 3009–23; Public Law 105–119, Title I, §§ 108, 124, Title II, § 211(b), Nov. 26, 1997, 111 Stat. 2457, 2471, 2487; Public Law 105–272, Title VI, § 605, Oct. 20, 1998, 112 Stat. 2413; Public Law 106–185, § 19, Apr. 25, 2000, 114 Stat. 223; Public Law 106–310, Div. B, Title XXXVI, §§ 3613(b), 3621(a), Oct. 17, 2000, 114 Stat. 1230; Public Law 107–273, Div. A, Title II, § 204(a), Nov. 2, 2002, 116 Stat. 1775.

(c)(1) There is established in the United States Treasury a special fund to be known as the Department of Justice Assets Forfeiture Fund (hereafter in this subsection referred to as the "Fund") which shall be available to the Attorney General without fiscal year limitation for the following law enforcement purposes—

(A) the payment, at the discretion of the Attorney General, of any expenses necessary to seize, detain, inventory, safeguard, maintain, advertise, sell, or dispose of property under seizure, detention, or forfeited pursuant to any law enforced or administered by the Department of Justice, or of any other necessary expense incident to the seizure, detention, forfeiture, or disposal of such property including—

(i) payments for—

(I) contract services;

(II) the employment of outside contractors to operate and manage properties or provide other specialized services necessary to dispose of such properties in an effort to maximize the return from such properties; and

(III) reimbursement of any Federal, State, or local agency for any expenditures made to perform the functions described in this clause;

(ii) payments to reimburse any Federal agency participating in the Fund for investigative costs leading to seizures;

(iii) payments for contracting for the services of experts and consultants needed by the Department of Justice to assist in carrying out duties related to asset seizure and forfeiture; and

(iv) payments made pursuant to guidelines promulgated by the Attorney General if such payments are necessary and directly related to seizure and forfeiture program expenses for—

(I) the purchase or lease of automatic data processing systems (not less than a majority of which use will be related to such program);

(II) training;

(III) printing;

(IV) the storage, protection, and destruction of controlled substances; and

(V) contracting for services directly related to the identification of forfeitable assets, and the processing of and accounting for forfeitures;

(B) the payment of awards for information or assistance directly relating to violations of the criminal drug laws of the United States or of sections 1956 and 1957 of title 18, sections 5313 and 5324 of title 31, and section 6050I of the Internal Revenue Code of 1986;

(C) at the discretion of the Attorney General, the payment of awards for information or assistance leading to a civil or criminal forfeiture involving any Federal agency participating in the Fund;

(D) the compromise and payment of valid liens and mortgages against property that has been forfeited pursuant to any

law enforced or administered by the Department of Justice, subject to the discretion of the Attorney General to determine the validity of any such lien or mortgage and the amount of payment to be made, and the employment of attorneys and other personnel skilled in State real estate law as necessary;

(E)(i) for disbursements authorized in connection with remission or mitigation procedures relating to property forfeited under any law enforced or administered by the Department of Justice; and

(ii) for payment for—

(I) costs incurred by or on behalf of the Department of Justice in connection with the removal, for purposes of Federal forfeiture and disposition, of any hazardous substance or pollutant or contaminant associated with the illegal manufacture of amphetamine or methamphetamine; and

(II) costs incurred by or on behalf of a State or local government in connection with such removal in any case in which such State or local government has assisted in a Federal prosecution relating to amphetamine or methamphetamine, to the extent such costs exceed equitable sharing payments made to such State or local government in such case;

(F)(i) for equipping for law enforcement functions of any Government-owned or leased vessel, vehicle, or aircraft available for official use by any Federal agency participating in the Fund;

(ii) for equipping any vessel, vehicle, or aircraft available for official use by a State or local law enforcement agency to enable the vessel, vehicle, or aircraft to assist law enforcement functions if the vessel, vehicle, or aircraft will be used in a joint law enforcement operation with a Federal agency participating in the Fund; and

(iii) payments for other equipment directly related to seizure or forfeiture, including laboratory equipment, protective equipment, communications equipment, and the operation and maintenance costs of such equipment;

(G) for purchase of evidence of any violation of the Controlled Substances Act, the Controlled Substances Import and Export Act, chapter 96 of title 18, or sections 1956 and 1957 of title 18;

(H) the payment of State and local property taxes on forfeited real property that accrued between the date of the violation giving rise to the forfeiture and the date of the forfeiture order; and

(I) payment of overtime salaries, travel, fuel, training, equipment, and other similar costs of State or local law enforcement officers that are incurred in a joint law enforcement operation with a Federal law enforcement agency participating in the Fund.

Amounts for paying the expenses authorized by subparagraphs (B), (F), and (G) shall be specified in appropriations Acts and may be used under authorities available to the organization receiving the funds. Amounts for other authorized expenditures and payments

from the Fund, including equitable sharing payments, are not required to be specified in appropriations acts. The Attorney General may exempt the procurement of contract services under subparagraph (A) under the Fund from section 3709 of the Revised Statutes of the United States (41 U.S.C. 5), title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 251 and following), and other provisions of law as may be necessary to maintain the security and confidentiality of related criminal investigations.

(2) Any award paid from the Fund, as provided in paragraph (1)(B) or (C), shall be paid at the discretion of the Attorney General or his delegate, under existing departmental delegation policies for the payment of awards, except that the authority to pay an award of $250,000 or more shall not be delegated to any person other than the Deputy Attorney General, the Associate Attorney General, the Director of the Federal Bureau of Investigation, or the Administrator of the Drug Enforcement Administration. Any award pursuant to paragraph (1)(B) shall not exceed $500,000. Any award pursuant to paragraph (1)(C) shall not exceed the lesser of $500,000 or one-fourth of the amount realized by the United States from the property forfeited, without both the personal approval of the Attorney General and written notice within 30 days thereof to the Chairmen and ranking minority members of the Committees on Appropriations and the Judiciary of the Senate and of the House of Representatives.

(3) Any amount under subparagraph (G) of paragraph (1) shall be paid at the discretion of the Attorney General or his delegate, except that the authority to pay $100,000 or more may be delegated only to the respective head of the agency involved.

(4) There shall be deposited in the Fund—

(A) all amounts from the forfeiture of property under any law enforced or administered by the Department of Justice, except all proceeds of forfeitures available for use by the Secretary of the Treasury or the Secretary of the Interior pursuant to section 11(d) of the Endangered Species Act (16 U.S.C. 1540(d)) or section 6(d) of the Lacey Act Amendments of 1981 (16 U.S.C. 3375(d)), or the Postmaster General of the United States pursuant to 39 U.S.C. 2003(b)(7);

(B) all amounts representing the Federal equitable share from the forfeiture of property under any Federal, State, local or foreign law, for any Federal agency participating in the Fund;

(C) all amounts transferred by the Secretary of the Treasury pursuant to section 9703(g)(4)(A)(ii) of title 31; and

(D) all amounts collected—

(i) by the United States pursuant to a reimbursement order under paragraph (2) of section 413(q) of the Controlled Substances Act (21 U.S.C. 853(q)); and

(ii) pursuant to a restitution order under paragraph (1) or (3) of section 413(q) of the Controlled Substances Act [21 U.S.C. 853(q)] for injuries to the United States.

(5) Amounts in the Fund, and in any holding accounts associated with the Fund, that are not currently needed for the purpose of this section shall be kept on deposit or invested in obligations of,

or guaranteed by, the United States and all earnings on such investments shall be deposited in the Fund.

(6)(A) The Attorney General shall transmit to Congress and make available to the public, not later than 4 months after the end of each fiscal year, detailed reports for the prior fiscal year as follows:

(i) A report on total deposits to the Fund by State of deposit.

(ii) A report on total expenses paid from the Fund, by category of expense and recipient agency, including equitable sharing payments.

(iii) A report describing the number, value, and types of properties placed into official use by Federal agencies, by recipient agency.

(iv) A report describing the number, value, and types of properties transferred to State and local law enforcement agencies, by recipient agency.

(v) A report, by type of disposition, describing the number, value, and types of forfeited property disposed of during the year.

(vi) A report on the year-end inventory of property under seizure, but not yet forfeited, that reflects the type of property, its estimated value, and the estimated value of liens and mortgages outstanding on the property.

(vii) A report listing each property in the year-end inventory, not yet forfeited, with an outstanding equity of not less than $1,000,000.

(B) The Attorney General shall transmit to Congress and make available to the public, not later than 2 months after final issuance, the audited financial statements for each fiscal year for the Fund.

(C) Reports under subparagraph (A) shall include information with respect to all forfeitures under any law enforced or administered by the Department of Justice.

(D) The transmittal and publication requirements in subparagraphs (A) and (B) may be satisfied by—

(i) posting the reports on an Internet website maintained by the Department of Justice for a period of not less than 2 years; and

(ii) notifying the Committees on the Judiciary of the House of Representatives and the Senate when the reports are available electronically.

(7) The provisions of this subsection relating to deposits in the Fund shall apply to all property in the custody of the Department of Justice on or after the effective date of the Comprehensive Forfeiture Act of 1983.

(8)(A) There are authorized to be appropriated such sums as necessary for the purposes described in subparagraphs (B), (F), and (G) of paragraph (1).

(B) Subject to subparagraphs (C) and (D), at the end of each of fiscal years 1994, 1995, and 1996, the Attorney General shall transfer from the Fund not more than $100,000,000 to the Special Forfeiture Fund established by section 6073 of the Anti-Drug Abuse Act of 1988.

(C) Transfers under subparagraph (B) may be made only from the excess unobligated balance and may not exceed one-half of the

excess unobligated balance for any year. In addition, transfers under subparagraph (B) may be made only to the extent that the sum of the transfers in a fiscal year and one-half of the unobligated balance at the beginning of that fiscal year for the Special Forfeiture Fund does not exceed $100,000,000.

(D) For the purpose of determining amounts available for distribution at year end for any fiscal year, "excess unobligated balance" means the unobligated balance of the Fund generated by that fiscal year's operations, less any amounts that are required to be retained in the Fund to ensure the availability of amounts in the subsequent fiscal year for purposes authorized under paragraph (1).

(E) Subject to the notification procedures contained in section 605 of Public Law 103–121, and after satisfying the transfer requirement in subparagraph (B) of this paragraph, any excess unobligated balance remaining in the Fund on September 30, 1997 and thereafter shall be available to the Attorney General, without fiscal year limitation, for any Federal law enforcement, litigative/prosecutive, and correctional activities, or any other authorized purpose of the Department of Justice. Any amounts provided pursuant to this subparagraph may be used under authorities available to the organization receiving the funds.

(9)(A) Following the completion of procedures for the forfeiture of property pursuant to any law enforced or administered by the Department, the Attorney General is authorized, in her discretion, to warrant clear title to any subsequent purchaser or transferee of such property.

(B) For fiscal years 2002 and 2003, the Attorney General is authorized to transfer, under such terms and conditions as the Attorney General shall specify, real or personal property of limited or marginal value, to a State or local government agency, or its designated contractor or transferee, for use to support drug abuse treatment, drug and crime prevention and education, housing, job skills, and other community-based public health and safety programs. Each such transfer shall be subject to satisfaction by the recipient involved of any outstanding lien against the property transferred, but no such transfer shall create or confer any private right of action in any person against the United States.

(10) The Attorney General shall transfer from the Fund to the Secretary of the Treasury for deposit in the Department of the Treasury Forfeiture Fund amounts appropriate to reflect the degree of participation of the Department of the Treasury law enforcement organizations (described in section 9703(p) of title 31) in the law enforcement effort resulting in the forfeiture pursuant to laws enforced or administered by the Department of Justice.

(11) For purposes of this subsection and notwithstanding section 9703 of title 31 or any other law, property is forfeited pursuant to a law enforced or administered by the Department of Justice if it is forfeited pursuant to—

(A) a judicial forfeiture proceeding when the underlying seizure was made by an officer of a Federal law enforcement agency participating in the Department of Justice Assets Forfeiture Fund or the property was maintained by the United States Marshals Service; or

(B) a civil administrative forfeiture proceeding conducted by a Department of Justice law enforcement component or pursuant to the authority of the Secretary of Commerce.

(d)(1) The Attorney General may accept, hold, administer, and use gifts, devises, and bequests of any property or services for the purpose of aiding or facilitating the work of the Department of Justice.

(2) Gifts, devises, and bequests of money, the proceeds of sale or liquidation of any other property accepted hereunder, and any income accruing from any property accepted hereunder—

(A) shall be deposited in the Treasury in a separate fund and held in trust by the Secretary of the Treasury for the benefit of the Department of Justice; and

(B) are hereby appropriated, without fiscal year limitation, and shall be disbursed on order of the Attorney General.

(3) Upon request of the Attorney General, the Secretary of the Treasury may invest and reinvest the fund described herein in public debt securities with maturities suitable for the needs of the fund and bearing interest at rates determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States or comparable maturities.

(4) Evidences of any intangible personal property (other than money) accepted hereunder shall be deposited with the Secretary of the Treasury, who may hold or liquidate them, except that they shall be liquidated upon the request of the Attorney General.

(5) For purposes of federal income, estate, and gift taxes, property accepted hereunder shall be considered a gift, devise, or bequest to, or for the use of, the United States.

28 U.S.C. § 994

The Sentencing Commission is to ensure that the sentencing guidelines result in sentences at or near the maximum term of imprisonment for certain controlled substance offenses

Chapter 58. United States Sentencing Commission

§ 994. Duties of the Commission [1]

(a) The Commission, by affirmative vote of at least four members of the Commission, and pursuant to its rules and regulations and consistent with all pertinent provisions of any Federal statute shall promulgate and distribute to all courts of the United States and to the United States Probation System—

(1) guidelines, as described in this section, for use of a sentencing court in determining the sentence to be imposed in a criminal case, including—

(A) a determination whether to impose a sentence to probation, a fine, or a term of imprisonment;

(B) a determination as to the appropriate amount of a fine or the appropriate length of a term of probation or a term of imprisonment;

(C) a determination whether a sentence to a term of imprisonment should include a requirement that the defendant be placed on a term of supervised release after imprisonment, and, if so, the appropriate length of such a term;

(D) a determination whether multiple sentences to terms of imprisonment should be ordered to run concurrently or consecutively; and

(E) a determination under paragraphs (6) and (11) of section 3563(b) of title 18;

(2) general policy statements regarding application of the guidelines or any other aspect of sentencing or sentence implementation that in the view of the Commission would further the purposes set forth in section 3553(a)(2) of title 18, United States Code, including the appropriate use of—

(A) the sanctions set forth in sections 3554, 3555, and 3556 of title 18;

(B) the conditions of probation and supervised release set forth in sections 3563(b) and 3583(d) of title 18;

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[1] Added by Public Law 98–473, Title II, § 217(a), Oct. 12, 1984, 98 Stat. 2019, and amended by Public Law 99–217, § 3, Dec. 26, 1985, 99 Stat. 1728; Public Law 99–363, § 2, July 11, 1986, 100 Stat. 770; Public Law 99–570, Title I, §§ 1006(b), 1008, Oct. 27, 1986, 100 Stat. 3207–7; Public Law 99–646, §§ 6(b), 56, Nov. 10, 1986, 100 Stat. 3592, 3611; Public Law 100–182, §§ 16(b), 23, Dec. 7, 1987, 101 Stat. 1269, 1271; Public Law 100–690, Title VII, §§ 7083, 7103(b), 7109, Nov. 18, 1988, 102 Stat. 4408, 4417, 4419; Public Law 103–322, Title II, § 20403(b), Title XXVIII, § 280005(c)(4), Title XXXIII, § 330003(f)(1), Sept. 13, 1994, 108 Stat. 1825, 2097, 2141; Public Law 108–21, Title IV, § 401(h), (k), Apr. 30, 2003, 117 Stat. 672, 674.

(C) the sentence modification provisions set forth in sections 3563(c), 3564, 3573, and 3582(c) of title 18;

(D) the fine imposition provisions set forth in section 3572 of title 18;

(E) the authority granted under rule 11(e)(2) of the Federal Rules of Criminal Procedure to accept or reject a plea agreement entered into pursuant to rule 11(e)(1); and

(F) the temporary release provisions set forth in section 3622 of title 18, and the prerelease custody provisions set forth in section 3624(c) of title 18; and

(3) guidelines or general policy statements regarding the appropriate use of the provisions for revocation of probation set forth in section 3565 of title 18, and the provisions for modification of the term or conditions of supervised release and revocation of supervised release set forth in section 3583(e) of title 18.

(b)(1) The Commission, in the guidelines promulgated pursuant to subsection (a)(1), shall, for each category of offense involving each category of defendant, establish a sentencing range that is consistent with all pertinent provisions of title 18, United States Code.

(2) If a sentence specified by the guidelines includes a term of imprisonment, the maximum of the range established for such a term shall not exceed the minimum of that range by more than the greater of 25 percent or 6 months, except that, if the minimum term of the range is 30 years or more, the maximum may be life imprisonment.

(c) The Commission, in establishing categories of offenses for use in the guidelines and policy statements governing the imposition of sentences of probation, a fine, or imprisonment, governing the imposition of other authorized sanctions, governing the size of a fine or the length of a term of probation, imprisonment, or supervised release, and governing the conditions of probation, supervised release, or imprisonment, shall consider whether the following matters, among others, have any relevance to the nature, extent, place of service, or other incidents[2] of an appropriate sentence, and shall take them into account only to the extent that they do have relevance—

(1) the grade of the offense;

(2) the circumstances under which the offense was committed which mitigate or aggravate the seriousness of the offense;

(3) the nature and degree of the harm caused by the offense, including whether it involved property, irreplaceable property, a person, a number of persons, or a breach of public trust;

(4) the community view of the gravity of the offense;

(5) the public concern generated by the offense;

(6) the deterrent effect a particular sentence may have on the commission of the offense by others; and

(7) the current incidence of the offense in the community and in the Nation as a whole.

[2] So in original. Probably should be "incidence".

(d) The Commission in establishing categories of defendants for use in the guidelines and policy statements governing the imposition of sentences of probation, a fine, or imprisonment, governing the imposition of other authorized sanctions, governing the size of a fine or the length of a term of probation, imprisonment, or supervised release, and governing the conditions of probation, supervised release, or imprisonment, shall consider whether the following matters, among others, with respect to a defendant, have any relevance to the nature, extent, place of service, or other incidents [3] of an appropriate sentence, and shall take them into account only to the extent that they do have relevance—

(1) age;
(2) education;
(3) vocational skills;
(4) mental and emotional condition to the extent that such condition mitigates the defendant's culpability or to the extent that such condition is otherwise plainly relevant;
(5) physical condition, including drug dependence;
(6) previous employment record;
(7) family ties and responsibilities;
(8) community ties;
(9) role in the offense;
(10) criminal history; and
(11) degree of dependence upon criminal activity for a livelihood.

The Commission shall assure that the guidelines and policy statements are entirely neutral as to the race, sex, national origin, creed, and socioeconomic status of offenders.

(e) The Commission shall assure that the guidelines and policy statements, in recommending a term of imprisonment or length of a term of imprisonment, reflect the general inappropriateness of considering the education, vocational skills, employment record, family ties and responsibilities, and community ties of the defendant.

(f) The Commission, in promulgating guidelines pursuant to subsection (a)(1), shall promote the purposes set forth in section 991(b)(1), with particular attention to the requirements of subsection 991(b)(1)(B) for providing certainty and fairness in sentencing and reducing unwarranted sentence disparities.

(g) The Commission, in promulgating guidelines pursuant to subsection (a)(1) to meet the purposes of sentencing as set forth in section 3553(a)(2) of title 18, United States Code, shall take into account the nature and capacity of the penal, correctional, and other facilities and services available, and shall make recommendations concerning any change or expansion in the nature or capacity of such facilities and services that might become necessary as a result of the guidelines promulgated pursuant to the provisions of this chapter. The sentencing guidelines prescribed under this chapter shall be formulated to minimize the likelihood that the Federal prison population will exceed the capacity of the Federal prisons, as determined by the Commission.

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[3] So in original. Probably should be "incidence".

(h) The Commission shall assure that the guidelines specify a sentence to a term of imprisonment at or near the maximum term authorized for categories of defendants in which the defendant is eighteen years old or older and—

(1) has been convicted of a felony that is—

(A) a crime of violence; or

(B) an offense described in section 401 of the Controlled Substances Act (21 U.S.C. 841), sections 1002(a), 1005, and 1009 of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 955, and 959), and the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.); and

(2) has previously been convicted of two or more prior felonies, each of which is—

(A) a crime of violence; or

(B) an offense described in section 401 of the Controlled Substances Act (21 U.S.C. 841), sections 1002(a), 1005, and 1009 of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 955, and 959), and the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.).

(i) The Commission shall assure that the guidelines specify a sentence to a substantial term of imprisonment for categories of defendants in which the defendant—

(1) has a history of two or more prior Federal, State, or local felony convictions for offenses committed on different occasions;

(2) committed the offense as part of a pattern of criminal conduct from which the defendant derived a substantial portion of the defendant's income;

(3) committed the offense in furtherance of a conspiracy with three or more persons engaging in a pattern of racketeering activity in which the defendant participated in a managerial or supervisory capacity;

(4) committed a crime of violence that constitutes a felony while on release pending trial, sentence, or appeal from a Federal, State, or local felony for which he was ultimately convicted; or

(5) committed a felony that is set forth in section 401 or 1010 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 841 and 960), and that involved trafficking in a substantial quantity of a controlled substance.

(j) The Commission shall insure that the guidelines reflect the general appropriateness of imposing a sentence other than imprisonment in cases in which the defendant is a first offender who has not been convicted of a crime of violence or an otherwise serious offense, and the general appropriateness of imposing a term of imprisonment on a person convicted of a crime of violence that results in serious bodily injury.

(k) The Commission shall insure that the guidelines reflect the inappropriateness of imposing a sentence to a term of imprisonment for the purpose of rehabilitating the defendant or providing the defendant with needed educational or vocational training, medical care, or other correctional treatment.

(l) The Commission shall insure that the guidelines promulgated pursuant to subsection (a)(1) reflect—

(1) the appropriateness of imposing an incremental penalty for each offense in a case in which a defendant is convicted of—

(A) multiple offenses committed in the same course of conduct that result in the exercise of ancillary jurisdiction over one or more of the offenses; and

(B) multiple offenses committed at different times, including those cases in which the subsequent offense is a violation of section 3146 (penalty for failure to appear) or is committed while the person is released pursuant to the provisions of section 3147 (penalty for an offense committed while on release) of title 18; and

(2) the general inappropriateness of imposing consecutive terms of imprisonment for an offense of conspiring to commit an offense or soliciting commission of an offense and for an offense that was the sole object of the conspiracy or solicitation.

(m) The Commission shall insure that the guidelines reflect the fact that, in many cases, current sentences do not accurately reflect the seriousness of the offense. This will require that, as a starting point in its development of the initial sets of guidelines for particular categories of cases, the Commission ascertain the average sentences imposed in such categories of cases prior to the creation of the Commission, and in cases involving sentences to terms of imprisonment, the length of such terms actually served. The Commission shall not be bound by such average sentences, and shall independently develop a sentencing range that is consistent with the purposes of sentencing described in section 3553(a)(2) of title 18, United States Code.

(n) The Commission shall assure that the guidelines reflect the general appropriateness of imposing a lower sentence than would otherwise be imposed, including a sentence that is lower than that established by statute as a minimum sentence, to take into account a defendant's substantial assistance in the investigation or prosecution of another person who has committed an offense.

(o) The Commission periodically shall review and revise, in consideration of comments and data coming to its attention, the guidelines promulgated pursuant to the provisions of this section. In fulfilling its duties and in exercising its powers, the Commission shall consult with authorities on, and individual and institutional representatives of, various aspects of the Federal criminal justice system. The United States Probation System, the Bureau of Prisons, the Judicial Conference of the United States, the Criminal Division of the United States Department of Justice, and a representative of the Federal Public Defenders shall submit to the Commission any observations, comments, or questions pertinent to the work of the Commission whenever they believe such communication would be useful, and shall, at least annually, submit to the Commission a written report commenting on the operation of the Commission's guidelines, suggesting changes in the guidelines that appear to be warranted, and otherwise assessing the Commission's work.

(p) The Commission, at or after the beginning of a regular session of Congress, but not later than the first day of May, may promulgate under subsection (a) of this section and submit to Congress amendments to the guidelines and modifications to previously

submitted amendments that have not taken effect, including modifications to the effective dates of such amendments. Such an amendment or modification shall be accompanied by a statement of the reasons therefor and shall take effect on a date specified by the Commission, which shall be no earlier than 180 days after being so submitted and no later than the first day of November of the calendar year in which the amendment or modification is submitted, except to the extent that the effective date is revised or the amendment is otherwise modified or disapproved by Act of Congress.

(q) The Commission and the Bureau of Prisons shall submit to Congress an analysis and recommendations concerning maximum utilization of resources to deal effectively with the Federal prison population. Such report shall be based upon consideration of a variety of alternatives, including—

(1) modernization of existing facilities;

(2) inmate classification and periodic review of such classification for use in placing inmates in the least restrictive facility necessary to ensure adequate security; and

(3) use of existing Federal facilities, such as those currently within military jurisdiction.

(r) The Commission, not later than two years after the initial set of sentencing guidelines promulgated under subsection (a) goes into effect, and thereafter whenever it finds it advisable, shall recommend to the Congress that it raise or lower the grades, or otherwise modify the maximum penalties, of those offenses for which such an adjustment appears appropriate.

(s) The Commission shall give due consideration to any petition filed by a defendant requesting modification of the guidelines utilized in the sentencing of such defendant, on the basis of changed circumstances unrelated to the defendant, including changes in—

(1) the community view of the gravity of the offense;

(2) the public concern generated by the offense; and

(3) the deterrent effect particular sentences may have on the commission of the offense by others.

(t) The Commission, in promulgating general policy statements regarding the sentencing modification provisions in section 3582(c)(1)(A) of title 18, shall describe what should be considered extraordinary and compelling reasons for sentence reduction, including the criteria to be applied and a list of specific examples. Rehabilitation of the defendant alone shall not be considered an extraordinary and compelling reason.

(u) If the Commission reduces the term of imprisonment recommended in the guidelines applicable to a particular offense or category of offenses, it shall specify in what circumstances and by what amount the sentences of prisoners serving terms of imprisonment for the offense may be reduced.

(v) The Commission shall ensure that the general policy statements promulgated pursuant to subsection (a)(2) include a policy limiting consecutive terms of imprisonment for an offense involving a violation of a general prohibition and for an offense involving a violation of a specific prohibition encompassed within the general prohibition.

(w)(1) The Chief Judge of each district court shall ensure that, within 30 days following entry of judgment in every criminal case, the sentencing court submits to the Commission a written report of the sentence, the offense for which it is imposed, the age, race, sex of the offender, and information regarding factors made relevant by the guidelines. The report shall also include—

(A) the judgment and commitment order;

(B) the statement of reasons for the sentence imposed (which shall include the reason for any departure from the otherwise applicable guideline range);

(C) any plea agreement;

(D) the indictment or other charging document;

(E) the presentence report; and

(F) any other information as the Commission finds appropriate.

(2) The Commission shall, upon request, make available to the House and Senate Committees on the Judiciary, the written reports and all underlying records accompanying those reports described in this section, as well as other records received from courts.

(3) The Commission shall submit to Congress at least annually an analysis of these documents, any recommendations for legislation that the Commission concludes is warranted by that analysis, and an accounting of those districts that the Commission believes have not submitted the appropriate information and documents required by this section.

(4) The Commission shall make available to the Attorney General, upon request, such data files as the Commission may assemble or maintain in electronic form that include any information submitted under paragraph (1). Such data files shall be made available in electronic form and shall include all data fields requested, including the identity of the sentencing judge.

(x) The provisions of section 553 of title 5, relating to publication in the Federal Register and public hearing procedure, shall apply to the promulgation of guidelines pursuant to this section.

(y) The Commission, in promulgating guidelines pursuant to subsection (a)(1), may include, as a component of a fine, the expected costs to the Government of any imprisonment, supervised release, or probation sentence that is ordered.

29 U.S.C. § 1854

Migrant and Seasonal Agricultural Worker Protection Act, Public Law 97–470, sec. 504

Expansion of statutory damages for workers injured while being transported by a driver under the influence of alcohol or controlled substances

Title 29. Labor

Chapter 20. Migrant and Seasonal Agricultural Worker Protection

§ 1854. Private right of action [1]

(a) Maintenance of civil action in district court by aggrieved person

Any person aggrieved by a violation of this chapter or any regulation under this chapter by a farm labor contractor, agricultural employer, agricultural association, or other person may file suit in any district court of the United States having jurisdiction of the parties, without respect to the amount in controversy and without regard to the citizenship of the parties and without regard to exhaustion of any alternative administrative remedies provided herein.

(b) Appointment of attorney and commencement of action

Upon application by a complainant and in such circumstances as the court may deem just, the court may appoint an attorney for such complainant and may authorize the commencement of the action.

(c) Award of damages or other equitable relief; amount; criteria; appeal

(1) If the court finds that the respondent has intentionally violated any provision of this chapter or any regulation under this chapter, it may award damages up to and including an amount equal to the amount of actual damages, or statutory damages of up to $500 per plaintiff per violation, or other equitable relief, except that (A) multiple infractions of a single provision of this chapter or of regulations under this chapter shall constitute only one violation for purposes of determining the amount of statutory damages due a plaintiff; and (B) if such complaint is certified as a class action, the court shall award no more than the lesser of up to $500 per plaintiff per violation, or up to $500,000 or other equitable relief.

[1] Public Law 97–470, Title V, § 504, Jan. 14, 1983, 96 Stat. 2597; Public Law 102–392, Title III, § 325(a), Oct. 6, 1992, 106 Stat. 1728; Public Law 104–49, § § 1(a)(2), 2(a), 3, Nov. 15, 1995, 109 Stat. 432, 433.

(2) In determining the amount of damages to be awarded under paragraph (1), the court is authorized to consider whether an attempt was made to resolve the issues in dispute before the resort to litigation.

(3) Any civil action brought under this section shall be subject to appeal as provided in chapter 83 of Title 28.

(d) Workers' compensation benefits; exclusive remedy

(1) Notwithstanding any other provision of this chapter, where a State workers' compensation law is applicable and coverage is provided for a migrant or seasonal agricultural worker, the workers' compensation benefits shall be the exclusive remedy for loss of such worker under this chapter in the case of bodily injury or death in accordance with such State's workers' compensation law.

(2) The exclusive remedy prescribed by paragraph (1) precludes the recovery under subsection (c) of this section of actual damages for loss from an injury or death but does not preclude recovery under subsection (c) of this section for statutory damages or equitable relief, except that such relief shall not include back or front pay or in any manner, directly or indirectly, expand or otherwise alter or affect (A) a recovery under a State workers' compensation law or (B) rights conferred under a State workers' compensation law.

(e) Expansion of statutory damages

If the court finds in an action which is brought by or for a worker under subsection (a) of this section in which a claim for actual damages is precluded because the worker's injury is covered by a State workers' compensation law as provided by subsection (d) of this section that—

(1)(A) the defendant in the action violated section 1841(b) of this title by knowingly requiring or permitting a driver to drive a vehicle for the transportation of migrant or seasonal agricultural workers while under the influence of alcohol or a controlled substance (as defined in section 802 of Title 21) and the defendant had actual knowledge of the driver's condition, and

(B) such violation resulted in injury to or death of the migrant or seasonal worker by or for whom the action was brought and such injury or death arose out of and in the course of employment as determined under the State workers' compensation law,

(2)(A) the defendant violated a safety standard prescribed by the Secretary under section 1841(b) of this title which the defendant was determined in a previous judicial or administrative proceeding to have violated, and

(B) such safety violation resulted in an injury or death described in paragraph (1)(B),

(3)(A)(i) the defendant willfully disabled or removed a safety device prescribed by the Secretary under section 1841(b) of this title, or

(ii) the defendant in conscious disregard of the requirements of section 1841(b) of this title failed to provide a safety device required under such section, and

(B) such disablement, removal, or failure to provide a safety device resulted in an injury or death described in paragraph (1)(B), or

(4)(A) the defendant violated a safety standard prescribed by the Secretary under section 1841(b) of this title,

(B) such safety violation resulted in an injury or death described in paragraph (1)(B), and

(C) the defendant at the time of the violation of section 1841(b) of this title also was—

(i) an unregistered farm labor contractor in violation of section 1811(a) of this title, or

(ii) a person who utilized the services of a farm labor contractor of the type specified in clause (i) without taking reasonable steps to determine that the farm labor contractor possessed a valid certificate of registration authorizing the performance of the farm labor contracting activities which the contractor was requested or permitted to perform with the knowledge of such person,

the court shall award not more than $10,000 per plaintiff per violation with respect to whom the court made the finding described in paragraph (1), (2), (3), or (4), except that multiple infractions of a single provision of this chapter shall constitute only one violation for purposes of determining the amount of statutory damages due to a plaintiff under this subsection and in the case of a class action, the court shall award not more than the lesser of up to $10,000 per plaintiff or up to $500,000 for all plaintiffs in such class action.

(f) Tolling of statute of limitations

If it is determined under a State workers' compensation law that the workers' compensation law is not applicable to a claim for bodily injury or death of a migrant or seasonal agricultural worker, the statute of limitations for bringing an action for actual damages for such injury or death under subsection (a) of this section shall be tolled for the period during which the claim for such injury or death under such State workers' compensation law was pending. The statute of limitations for an action for other actual damages, statutory damages, or equitable relief arising out of the same transaction or occurrence as the injury or death of the migrant or seasonal agricultural worker shall be tolled for the period during which the claim for such injury or death was pending under the State workers' compensation law.

29 U.S.C. § 2006
Employee Polygraph Protection Act, Public Law 100–347, sec. 7
Act's proscriptions do not preclude polygraph testing by an employer authorized to manufacture, distribute, or dispense controlled substances

Chapter 22. Employee Polygraph Protection

§ 2006. Exemptions [1]

(a) No application to governmental employers

This chapter shall not apply with respect to the United States Government, any State or local government, or any political subdivision of a State or local government.

(b) National defense and security exemption

(1) National defense

Nothing in this chapter shall be construed to prohibit the administration, by the Federal Government, in the performance of any counterintelligence function, of any lie detector test to—

(A) any expert or consultant under contract to the Department of Defense or any employee of any contractor of such Department; or

(B) any expert or consultant under contract with the Department of Energy in connection with the atomic energy defense activities of such Department or any employee of any contractor of such Department in connection with such activities.

(2) Security

Nothing in this chapter shall be construed to prohibit the administration, by the Federal Government, in the performance of any intelligence or counterintelligence function, of any lie detector test to—

(A)(i) any individual employed by, assigned to, or detailed to, the National Security Agency, the Defense Intelligence Agency, the National Geospatial-Intelligence Agency, or the Central Intelligence Agency,

(ii) any expert or consultant under contract to any such agency,

(iii) any employee of a contractor to any such agency,

(iv) any individual applying for a position in any such agency, or

[1] Public Law 100–347, § 7, June 27, 1988, 102 Stat. 648; Public Law 103–359, Title V, § 501(n), Oct. 14, 1994, 108 Stat. 3430; Public Law 104–201, Div. A, Title XI, § 1122(b)(3), Sept. 23, 1996, 110 Stat. 2687; Public Law 108–136, Div. A, Title IX, § 921(g), Nov. 24, 2003, 117 Stat. 1570.

(v) any individual assigned to a space where sensitive cryptologic information is produced, processed, or stored for any such agency; or

(B) any expert, or consultant (or employee of such expert or consultant) under contract with any Federal Government department, agency, or program whose duties involve access to information that has been classified at the level of top secret or designated as being within a special access program under section 4.2(a) of Executive Order 12356 (or a successor Executive order).

(c) FBI contractors exemption

Nothing in this chapter shall be construed to prohibit the administration, by the Federal Government, in the performance of any counterintelligence function, of any lie detector test to an employee of a contractor of the Federal Bureau of Investigation of the Department of Justice who is engaged in the performance of any work under the contract with such Bureau.

(d) Limited exemption for ongoing investigations

Subject to sections 2007 and 2009 of this title, this chapter shall not prohibit an employer from requesting an employee to submit to a polygraph test if—

(1) the test is administered in connection with an ongoing investigation involving economic loss or injury to the employer's business, such as theft, embezzlement, misappropriation, or an act of unlawful industrial espionage or sabotage;

(2) the employee had access to the property that is the subject of the investigation;

(3) the employer has a reasonable suspicion that the employee was involved in the incident or activity under investigation; and

(4) the employer executes a statement, provided to the examinee before the test, that—

(A) sets forth with particularity the specific incident or activity being investigated and the basis for testing particular employees,

(B) is signed by a person (other than a polygraph examiner) authorized to legally bind the employer,

(C) is retained by the employer for at least 3 years, and

(D) contains at a minimum—

(i) an identification of the specific economic loss or injury to the business of the employer,

(ii) a statement indicating that the employee had access to the property that is the subject of the investigation, and

(iii) a statement describing the basis of the employer's reasonable suspicion that the employee was involved in the incident or activity under investigation.

(e) Exemption for security services

(1) In general

Subject to paragraph (2) and sections 2007 and 2009 of this title, this chapter shall not prohibit the use of polygraph tests

on prospective employees by any private employer whose primary business purpose consists of providing armored car personnel, personnel engaged in the design, installation, and maintenance of security alarm systems, or other uniformed or plainclothes security personnel and whose function includes protection of—

(A) facilities, materials, or operations having a significant impact on the health or safety of any State or political subdivision thereof, or the national security of the United States, as determined under rules and regulations issued by the Secretary within 90 days after June 27, 1988, including—

(i) facilities engaged in the production, transmission, or distribution of electric or nuclear power,

(ii) public water supply facilities,

(iii) shipments or storage of radioactive or other toxic waste materials, and

(iv) public transportation, or

(B) currency, negotiable securities, precious commodities or instruments, or proprietary information.

(2) Access

The exemption provided under this subsection shall not apply if the test is administered to a prospective employee who would not be employed to protect facilities, materials, operations, or assets referred to in paragraph (1).

(f) Exemption for drug security, drug theft, or drug diversion investigations

(1) In general

Subject to paragraph (2) and sections 2007 and 2009 of this title, this chapter shall not prohibit the use of a polygraph test by any employer authorized to manufacture, distribute, or dispense a controlled substance listed in schedule I, II, III, or IV of section 812 of Title 21.

(2) Access

The exemption provided under this subsection shall apply—

(A) if the test is administered to a prospective employee who would have direct access to the manufacture, storage, distribution, or sale of any such controlled substance; or

(B) in the case of a test administered to a current employee, if—

(i) the test is administered in connection with an ongoing investigation of criminal or other misconduct involving, or potentially involving, loss or injury to the manufacture, distribution, or dispensing of any such controlled substance by such employer, and

(ii) the employee had access to the person or property that is the subject of the investigation.

29 U.S.C. § 2931
Workforce Investment Act, Public Law 105–220, sec. 152
Drug testing of Job Corps enrollees

Chapter 30. Workforce Investment Systems

§ 2931. Requirements and restrictions [1]

(a) Benefits

(1) Wages

(A) IN GENERAL

Individuals in on-the-job training or individuals employed in activities under this chapter shall be compensated at the same rates, including periodic increases, as trainees or employees who are similarly situated in similar occupations by the same employer and who have similar training, experience, and skills, and such rates shall be in accordance with applicable law, but in no event less than the higher of the rate specified in section 206(a)(1) of this title or the applicable State or local minimum wage law.

(B) RULE OF CONSTRUCTION

The reference in subparagraph (A) to section 206(a)(1) of this title—

(i) shall be deemed to be a reference to section 206(a)(3) of this title for individuals in American Samoa; and

(ii) shall not be applicable for individuals in other territorial jurisdictions in which section 206 of this title does not apply.

(2) Treatment of allowances, earnings, and payments

Allowances, earnings, and payments to individuals participating in programs under this chapter shall not be considered as income for the purposes of determining eligibility for and the amount of income transfer and in-kind aid furnished under any Federal or federally assisted program based on need, other than as provided under the Social Security Act (42 U.S.C. 301 et seq.).

(b) Labor standards

(1) Limitations on activities that impact wages of employees

No funds provided under this chapter shall be used to pay the wages of incumbent employees during their participation in

[1] Public Law 105–220, Title I, § 181, Aug. 7, 1998, 112 Stat. 1038.

economic development activities provided through a statewide workforce investment system.

(2) Displacement

(A) PROHIBITION

A participant in a program or activity authorized under this chapter (referred to in this section as a "specified activity") shall not displace (including a partial displacement, such as a reduction in the hours of nonovertime work, wages, or employment benefits) any currently employed employee (as of the date of the participation).

(B) PROHIBITION ON IMPAIRMENT OF CONTRACTS

A specified activity shall not impair an existing contract for services or collective bargaining agreement, and no such activity that would be inconsistent with the terms of a collective bargaining agreement shall be undertaken without the written concurrence of the labor organization and employer concerned.

(3) Other prohibitions

A participant in a specified activity shall not be employed in a job if—

(A) any other individual is on layoff from the same or any substantially equivalent job;

(B) the employer has terminated the employment of any regular employee or otherwise reduced the workforce of the employer with the intention of filling the vacancy so created with the participant; or

(C) the job is created in a promotional line that will infringe in any way upon the promotional opportunities of currently employed individuals (as of the date of the participation).

(4) Health and safety

Health and safety standards established under Federal and State law otherwise applicable to working conditions of employees shall be equally applicable to working conditions of participants engaged in specified activities. To the extent that a State workers' compensation law applies, workers' compensation shall be provided to participants on the same basis as the compensation is provided to other individuals in the State in similar employment.

(5) Employment conditions

Individuals in on-the-job training or individuals employed in programs and activities under this chapter, shall be provided benefits and working conditions at the same level and to the same extent as other trainees or employees working a similar length of time and doing the same type of work.

(6) Opportunity to submit comments

Interested members of the public, including representatives of businesses and of labor organizations, shall be provided an opportunity to submit comments to the Secretary with respect to programs and activities proposed to be funded under subchapter II of this chapter.

(7) No impact on union organizing

Each recipient of funds under this title shall provide to the Secretary assurances that none of such funds will be used to assist, promote, or deter union organizing.

(c) Grievance procedure

(1) In general

Each State and local area receiving an allotment under this chapter shall establish and maintain a procedure for grievances or complaints alleging violations of the requirements of this chapter from participants and other interested or affected parties. Such procedure shall include an opportunity for a hearing and be completed within 60 days after the filing of the grievance or complaint.

(2) Investigation

(A) IN GENERAL

The Secretary shall investigate an allegation of a violation described in paragraph (1) if—

(i) a decision relating to such violation has not been reached within 60 days after the date of the filing of the grievance or complaint and either party appeals to the Secretary; or

(ii) a decision relating to such violation has been reached within such 60 days and the party to which such decision is adverse appeals such decision to the Secretary.

(B) ADDITIONAL REQUIREMENT

The Secretary shall make a final determination relating to an appeal made under subparagraph (A) no later than 120 days after receiving such appeal.

(3) Remedies

Remedies that may be imposed under this section for a violation of any requirement of this chapter shall be limited—

(A) to suspension or termination of payments under this chapter;

(B) to prohibition of placement of a participant with an employer that has violated any requirement under this chapter;

(C) where applicable, to reinstatement of an employee, payment of lost wages and benefits, and reestablishment of other relevant terms, conditions, and privileges of employment; and

(D) where appropriate, to other equitable relief.

(4) Rule of construction

Nothing in paragraph (3) shall be construed to prohibit a grievant or complainant from pursuing a remedy authorized under another Federal, State, or local law for a violation of this chapter.

(d) Relocation

(1) Prohibition on use of funds to encourage or induce relocation

No funds provided under this chapter shall be used, or proposed for use, to encourage or induce the relocation of a business or part of a business if such relocation would result in a

loss of employment for any employee of such business at the original location and such original location is within the United States.

(2) Prohibition on use of funds for customized or skill training and related activities after relocation

No funds provided under this chapter for an employment and training activity shall be used for customized or skill training, on-the-job training, or company-specific assessments of job applicants or employees, for any business or part of a business that has relocated, until the date that is 120 days after the date on which such business commences operations at the new location, if the relocation of such business or part of a business results in a loss of employment for any employee of such business at the original location and such original location is within the United States.

(3) Repayment

If the Secretary determines that a violation of paragraph (1) or (2) has occurred, the Secretary shall require the State that has violated such paragraph to repay to the United States an amount equal to the amount expended in violation of such paragraph.

(e) Limitation on use of funds

No funds available under this chapter shall be used for employment generating activities, economic development activities, investment in revolving loan funds, capitalization of businesses, investment in contract bidding resource centers, and similar activities that are not directly related to training for eligible individuals under this title. No funds available under subchapter II of this chapter shall be used for foreign travel.

(f) Testing and sanctioning for use of controlled substances

(1) In general

Notwithstanding any other provision of law, a State shall not be prohibited by the Federal Government from—

(A) testing participants in programs under subchapter II of this chapter for the use of controlled substances; and

(B) sanctioning such participants who test positive for the use of such controlled substances.

(2) Additional requirements

(A) PERIOD OF SANCTION

In sanctioning participants in programs under subchapter II of this chapter who test positive for the use of controlled substances—

(i) with respect to the first occurrence for which a participant tests positive, a State may exclude the participant from the program for a period not to exceed 6 months; and

(ii) with respect to the second occurrence and each subsequent occurrence for which a participant tests positive, a State may exclude the participant from the program for a period not to exceed 2 years.

(B) APPEAL

The testing of participants and the imposition of sanctions under this subsection shall be subject to expeditious appeal in accordance with due process procedures established by the State.

(C) PRIVACY

A State shall establish procedures for testing participants for the use of controlled substances that ensure a maximum degree of privacy for the participants.

(4)[2] Funding requirement

In testing and sanctioning of participants for the use of controlled substances in accordance with this subsection, the only Federal funds that a State may use are the amounts made available for the administration of statewide workforce investment activities under section 2864(a)(3)(B) of this title.

[2] So in original. No subsection (f)(3) enacted.

Title 31. Money and Finance

Chapter 53. Monetary Transactions

§ 5311. Declaration of purpose [1]

It is the purpose of this subchapter (except section 5315) to require certain reports or records where they have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings, or in the conduct of intelligence or counterintelligence activities, including analysis, to protect against international terrorism.

§ 5312. Definitions and application [2]

(a) In this subchapter—

(1) "financial agency" means a person acting for a person (except for a country, a monetary or financial authority acting as a monetary or financial authority, or an international financial institution of which the United States Government is a member) as a financial institution, bailee, depository trustee, or agent, or acting in a similar way related to money, credit, securities, gold, or a transaction in money, credit, securities, or gold.

(2) "financial institution" means—

(A) an insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h)));

(B) a commercial bank or trust company;

(C) a private banker;

(D) an agency or branch of a foreign bank in the United States;

(E) any credit union;

(F) a thrift institution;

(G) a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.);

(H) a broker or dealer in securities or commodities;

(I) an investment banker or investment company;

(J) a currency exchange;

(K) an issuer, redeemer, or cashier of travelers' checks, checks, money orders, or similar instruments;

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[1] Public Law 97–258, Sept. 13, 1982, 96 Stat. 995; Public Law 107–56, Title III, § 358(a), Oct. 26, 2001, 115 Stat. 326.

[2] Public Law 97–258, Sept. 13, 1982, 96 Stat. 995; Public Law 99–570, Title I, § 1362, Oct. 27, 1986, 100 Stat. 3207–33; Public Law 100–690, Title VI, § 6185(a), (g)(1), Nov. 18, 1988, 102 Stat. 4354, 4357; Public Law 103–325, Title IV, §§ 405, 409, Sept. 23, 1994, 108 Stat. 2247, 2252; Public Law 107–56, Title III, §§ 321(a), (b), 359(a), 365(c)(1), (2)(A), Oct. 26, 2001, 115 Stat. 315, 328, 335; Public Law 108–458, § 6203(b), Dec. 17, 2004, 118 Stat. 3746.

(L) an operator of a credit card system;
(M) an insurance company;
(N) a dealer in precious metals, stones, or jewels;
(O) a pawnbroker;
(P) a loan or finance company;
(Q) a travel agency;
(R) a licensed sender of money or any other person who engages as a business in the transmission of funds, including any person who engages as a business in an informal money transfer system or any network of people who engage as a business in facilitating the transfer of money domestically or internationally outside of the conventional financial institutions system;
(S) a telegraph company;
(T) a business engaged in vehicle sales, including automobile, airplane, and boat sales;
(U) persons involved in real estate closings and settlements;
(V) the United States Postal Service;
(W) an agency of the United States Government or of a State or local government carrying out a duty or power of a business described in this paragraph;
(X) a casino, gambling casino, or gaming establishment with an annual gaming revenue of more than $1,000,000 which—

(i) is licensed as a casino, gambling casino, or gaming establishment under the laws of any State or any political subdivision of any State; or

(ii) is an Indian gaming operation conducted under or pursuant to the Indian Gaming Regulatory Act other than an operation which is limited to class I gaming (as defined in section 4(6) of such Act);

(Y) any business or agency which engages in any activity which the Secretary of the Treasury determines, by regulation, to be an activity which is similar to, related to, or a substitute for any activity in which any business described in this paragraph is authorized to engage; or
(Z) any other business designated by the Secretary whose cash transactions have a high degree of usefulness in criminal, tax, or regulatory matters.

(3) "monetary instruments" means—
(A) United States coins and currency;
(B) as the Secretary may prescribe by regulation, coins and currency of a foreign country, travelers' checks, bearer negotiable instruments, bearer investment securities, bearer securities, stock on which title is passed on delivery, and similar material; and
(C) as the Secretary of the Treasury shall provide by regulation for purposes of sections 5316 and 5331, checks, drafts, notes, money orders, and other similar instruments which are drawn on or by a foreign financial institution and are not in bearer form.

(4) NONFINANCIAL TRADE OR BUSINESS.—The term "nonfinancial trade or business" means any trade or business other

than a financial institution that is subject to the reporting requirements of section 5313 and regulations prescribed under such section.

(5) "person", in addition to its meaning under section 1 of title 1, includes a trustee, a representative of an estate and, when the Secretary prescribes, a governmental entity.

(6) "United States" means the States of the United States, the District of Columbia, and, when the Secretary prescribes by regulation, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, American Samoa, the Trust Territory of the Pacific Islands, a territory or possession of the United States, or a military or diplomatic establishment.

(b) In this subchapter—

(1) "domestic financial agency" and "domestic financial institution" apply to an action in the United States of a financial agency or institution.

(2) "foreign financial agency" and "foreign financial institution" apply to an action outside the United States of a financial agency or institution.

(c) ADDITIONAL DEFINITIONS.—For purposes of this subchapter, the following definitions shall apply:

(1)[3] CERTAIN INSTITUTIONS INCLUDED IN DEFINITION.—The term "financial institution" (as defined in subsection (a)) includes the following:

(A)[4] Any futures commission merchant, commodity trading advisor, or commodity pool operator registered, or required to register, under the Commodity Exchange Act [7 U.S.C. 1 et seq.].

§ 5313. Reports on domestic coins and currency transactions[5]

(a) When a domestic financial institution is involved in a transaction for the payment, receipt, or transfer of United States coins or currency (or other monetary instruments the Secretary of the Treasury prescribes), in an amount, denomination, or amount and denomination, or under circumstances the Secretary prescribes by regulation, the institution and any other participant in the transaction the Secretary may prescribe shall file a report on the transaction at the time and in the way the Secretary prescribes. A participant acting for another person shall make the report as the agent or bailee of the person and identify the person for whom the transaction is being made.

(b) The Secretary may designate a domestic financial institution as an agent of the United States Government to receive a report under this section. However, the Secretary may designate a domestic financial institution that is not insured, chartered, examined, or registered as a domestic financial institution only if the institution consents. The Secretary may suspend or revoke a designation for a violation of this subchapter or a regulation under this subchapter

[3] So in original. No paragraph (2) was enacted.
[4] So in original. No subparagraph (B) was enacted.
[5] Public Law 97–258, Sept. 13, 1982, 96 Stat. 996; Public Law 103–325, Title IV, § 402(a), Sept. 23, 1994, 108 Stat. 2243.

(except a violation of section 5315 of this title or a regulation prescribed under section 5315), section 411 of the National Housing Act (12 U.S.C. 1730d), or section 21 of the Federal Deposit Insurance Act (12 U.S.C. 1829b).

(c)(1) A person (except a domestic financial institution designated under subsection (b) of this section) required to file a report under this section shall file the report—

(A) with the institution involved in the transaction if the institution was designated;

(B) in the way the Secretary prescribes when the institution was not designated; or

(C) with the Secretary.

(2) The Secretary shall prescribe—

(A) the filing procedure for a domestic financial institution designated under subsection (b) of this section; and

(B) the way the institution shall submit reports filed with it.

(d) MANDATORY EXEMPTIONS FROM REPORTING REQUIREMENTS.—

(1) IN GENERAL.—The Secretary of the Treasury shall exempt, pursuant to section 5318(a)(6), a depository institution from the reporting requirements of subsection (a) with respect to transactions between the depository institution and the following categories of entities:

(A) Another depository institution.

(B) A department or agency of the United States, any State, or any political subdivision of any State.

(C) Any entity established under the laws of the United States, any State, or any political subdivision of any State, or under an interstate compact between 2 or more States, which exercises governmental authority on behalf of the United States or any such State or political subdivision.

(D) Any business or category of business the reports on which have little or no value for law enforcement purposes.

(2) NOTICE OF EXEMPTION.—The Secretary of the Treasury shall publish in the Federal Register at such times as the Secretary determines to be appropriate (but not less frequently than once each year) a list of all the entities whose transactions with a depository institution are exempt under this subsection from the reporting requirements of subsection (a).

(e) DISCRETIONARY EXEMPTIONS FROM REPORTING REQUIREMENTS.—

(1) IN GENERAL.—The Secretary of the Treasury may exempt, pursuant to section 5318(a)(6), a depository institution from the reporting requirements of subsection (a) with respect to transactions between the depository institution and a qualified business customer of the institution on the basis of information submitted to the Secretary by the institution in accordance with procedures which the Secretary shall establish.

(2) QUALIFIED BUSINESS CUSTOMER DEFINED.—For purposes of this subsection, the term "qualified business customer" means a business which—

(A) maintains a transaction account (as defined in section 19(b)(1)(C) of the Federal Reserve Act) at the depository institution;

(B) frequently engages in transactions with the depository institution which are subject to the reporting requirements of subsection (a); and

(C) meets criteria which the Secretary determines are sufficient to ensure that the purposes of this subchapter are carried out without requiring a report with respect to such transactions.

(3) CRITERIA FOR EXEMPTION.—The Secretary of the Treasury shall establish, by regulation, the criteria for granting and maintaining an exemption under paragraph (1).

(4) GUIDELINES.—

(A) IN GENERAL.—The Secretary of the Treasury shall establish guidelines for depository institutions to follow in selecting customers for an exemption under this subsection.

(B) CONTENTS.—The guidelines may include a description of the types of businesses or an itemization of specific businesses for which no exemption will be granted under this subsection to any depository institution.

(5) ANNUAL REVIEW.—The Secretary of the Treasury shall prescribe regulations requiring each depository institution to—

(A) review, at least once each year, the qualified business customers of such institution with respect to whom an exemption has been granted under this subsection; and

(B) upon the completion of such review, resubmit information about such customers, with such modifications as the institution determines to be appropriate, to the Secretary for the Secretary's approval.

(6) 2-YEAR PHASE-IN PROVISION.—During the 2-year period beginning on the date of enactment of the Money Laundering Suppression Act of 1994, this subsection shall be applied by the Secretary on the basis of such criteria as the Secretary determines to be appropriate to achieve an orderly implementation of the requirements of this subsection.

(f) PROVISIONS APPLICABLE TO MANDATORY AND DISCRETIONARY EXEMPTIONS.—

(1) LIMITATION ON LIABILITY OF DEPOSITORY INSTITUTIONS.—No depository institution shall be subject to any penalty which may be imposed under this subchapter for the failure of the institution to file a report with respect to a transaction with a customer for whom an exemption has been granted under subsection (d) or (e) unless the institution—

(A) knowingly files false or incomplete information to the Secretary with respect to the transaction or the customer engaging in the transaction; or

(B) has reason to believe at the time the exemption is granted or the transaction is entered into that the customer or the transaction does not meet the criteria established for granting such exemption.

(2) COORDINATION WITH OTHER PROVISIONS.—Any exemption granted by the Secretary of the Treasury under section 5318(a) in accordance with this section, and any transaction which is subject to such exemption, shall be subject to any other provision of law applicable to such exemption, including—

(A) the authority of the Secretary, under section 5318(a)(6), to revoke such exemption at any time; and

(B) any requirement to report, or any authority to require a report on, any possible violation of any law or regulation or any suspected criminal activity.

(g) DEPOSITORY INSTITUTION DEFINED.—For purposes of this section, the term "depository institution"—

(1) has the meaning given to such term in section 19(b)(1)(A) of the Federal Reserve Act; and

(2) includes—

(A) any branch, agency, or commercial lending company (as such terms are defined in section 1(b) of the International Banking Act of 1978);

(B) any corporation chartered under section 25A of the Federal Reserve Act; and

(C) any corporation having an agreement or undertaking with the Board of Governors of the Federal Reserve System under section 25 of the Federal Reserve Act.

§ 5314. Records and reports on foreign financial agency transactions [6]

(a) Considering the need to avoid impeding or controlling the export or import of monetary instruments and the need to avoid burdening unreasonably a person making a transaction with a foreign financial agency, the Secretary of the Treasury shall require a resident or citizen of the United States or a person in, and doing business in, the United States, to keep records, file reports, or keep records and file reports, when the resident, citizen, or person makes a transaction or maintains a relation for any person with a foreign financial agency. The records and reports shall contain the following information in the way and to the extent the Secretary prescribes:

(1) the identity and address of participants in a transaction or relationship.

(2) the legal capacity in which a participant is acting.

(3) the identity of real parties in interest.

(4) a description of the transaction.

(b) The Secretary may prescribe—

(1) a reasonable classification of persons subject to or exempt from a requirement under this section or a regulation under this section;

(2) a foreign country to which a requirement or a regulation under this section applies if the Secretary decides applying the requirement or regulation to all foreign countries is unnecessary or undesirable;

(3) the magnitude of transactions subject to a requirement or a regulation under this section;

(4) the kind of transaction subject to or exempt from a requirement or a regulation under this section; and

(5) other matters the Secretary considers necessary to carry out this section or a regulation under this section.

(c) A person shall be required to disclose a record required to be kept under this section or under a regulation under this section only as required by law.

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[6] Public Law 97–258, Sept. 13, 1982, 96 Stat. 997.

§ 5315. Reports on foreign currency transactions [7]

(a) Congress finds that—

(1) moving mobile capital can have a significant impact on the proper functioning of the international monetary system;

(2) it is important to have the most feasible current and complete information on the kind and source of capital flows, including transactions by large United States businesses and their foreign affiliates; and

(3) additional authority should be provided to collect information on capital flows under section 5(b) of the Trading With the Enemy Act (50 App.U.S.C. 5(b)) and section 8 of the Bretton Woods Agreement Act (22 U.S.C. 286f).

(b) In this section, "United States person" and "foreign person controlled by a United States person" have the same meanings given those terms in section 7(f)(2)(A) and (C), respectively, of the Securities and Exchange Act of 1934 (15 U.S.C. 78g(f)(2)(A), (C)).

(c) The Secretary of the Treasury shall prescribe regulations consistent with subsection (a) of this section requiring reports on foreign currency transactions conducted by a United States person or a foreign person controlled by a United States person. The regulations shall require that a report contain information and be submitted at the time and in the way, with reasonable exceptions and classifications, necessary to carry out this section.

§ 5316. Reports on exporting and importing monetary instruments [8]

(a) Except as provided in subsection (c) of this section, a person or an agent or bailee of the person shall file a report under subsection (b) of this section when the person, agent, or bailee knowingly—

(1) transports, is about to transport, or has transported, monetary instruments of more than $10,000 at one time—

(A) from a place in the United States to or through a place outside the United States; or

(B) to a place in the United States from or through a place outside the United States; or

(2) receives monetary instruments of more than $10,000 at one time transported into the United States from or through a place outside the United States.

(b) A report under this section shall be filed at the time and place the Secretary of the Treasury prescribes. The report shall contain the following information to the extent the Secretary prescribes:

(1) the legal capacity in which the person filing the report is acting.

(2) the origin, destination, and route of the monetary instruments.

(3) when the monetary instruments are not legally and beneficially owned by the person transporting the instruments, or if the person transporting the instruments personally is not

[7] Public Law 97–258, Sept. 13, 1982, 96 Stat. 997.

[8] Public Law 97–258, Sept. 13, 1982, 96 Stat. 998; Public Law 98–473, Title II, § 901(c), Oct. 12, 1984, 98 Stat. 2135; Public Law 99–570, Title I, § 1358, Title III, § 3153, Oct. 27, 1986, 100 Stat. 3207–26, 3207–94.

going to use them, the identity of the person that gave the instruments to the person transporting them, the identity of the person who is to receive them, or both.

(4) the amount and kind of monetary instruments transported.

(5) additional information.

(c) This section or a regulation under this section does not apply to a common carrier of passengers when a passenger possesses a monetary instrument, or to a common carrier of goods if the shipper does not declare the instrument.

(d) CUMULATION OF CLOSELY RELATED EVENTS.—The Secretary of the Treasury may prescribe regulations under this section defining the term "at one time" for purposes of subsection (a). Such regulations may permit the cumulation of closely related events in order that such events may collectively be considered to occur at one time for the purposes of subsection (a).

§ 5317. Search and forfeiture of monetary instruments[9]

(a) The Secretary of the Treasury may apply to a court of competent jurisdiction for a search warrant when the Secretary reasonably believes a monetary instrument is being transported and a report on the instrument under section 5316 of this title has not been filed or contains a material omission or misstatement. The Secretary shall include a statement of information in support of the warrant. On a showing of probable cause, the court may issue a search warrant for a designated person or a designated or described place or physical object. This subsection does not affect the authority of the Secretary under another law.

(b) SEARCHES AT BORDER.—For purposes of ensuring compliance with the requirements of section 5316, a customs officer may stop and search, at the border and without a search warrant, any vehicle, vessel, aircraft, or other conveyance, any envelope or other container, and any person entering or departing from the United States.

(c) FORFEITURE.—

(1) CRIMINAL FORFEITURE.—

(A) IN GENERAL.—The court in imposing sentence for any violation of section 5313, 5316, or 5324 of this title, or any conspiracy to commit such violation, shall order the defendant to forfeit all property, real or personal, involved in the offense and any property traceable thereto.

(B) PROCEDURE.—Forfeitures under this paragraph shall be governed by the procedures established in section 413 of the Controlled Substances Act.

(2) CIVIL FORFEITURE.—Any property involved in a violation of section 5313, 5316, or 5324 of this title, or any conspiracy to commit any such violation, and any property traceable to any such violation or conspiracy, may be seized and forfeited

[9] Public Law 97–258, Sept. 13, 1982, 96 Stat. 998; Public Law 98–473, Title II, § 901(d), Oct. 12, 1984, 98 Stat. 2135; Public Law 99–570, Title I, § 1355, Oct. 27, 1986, 100 Stat. 3207–22; Public Law 102–550, Title XV, § 1525(c)(2), Oct. 28, 1992, 106 Stat. 4065; Public Law 107–56, Title III, §§ 365(b)(2)(B), 372(a), Oct. 26, 2001, 115 Stat. 335, 338.

to the United States in accordance with the procedures governing civil forfeitures in money laundering cases pursuant to section 981(a)(1)(A) of title 18, United States Code.

§ 5318. Compliance, exemptions, and summons authority[10]

(a) GENERAL POWERS OF SECRETARY.—The Secretary of the Treasury may (except under section 5315 of this title and regulations prescribed under section 5315)—

(1) except as provided in subsection (b)(2), delegate duties and powers under this subchapter to an appropriate supervising agency and the United States Postal Service;

(2) require a class of domestic financial institutions or nonfinancial trades or businesses to maintain appropriate procedures to ensure compliance with this subchapter and regulations prescribed under this subchapter or to guard against money laundering;

(3) examine any books, papers, records, or other data of domestic financial institutions or nonfinancial trades or businesses relevant to the recordkeeping or reporting requirements of this subchapter;

(4) summon a financial institution or nonfinancial trade or business, an officer or employee of a financial institution or nonfinancial trade or business (including a former officer or employee), or any person having possession, custody, or care of the reports and records required under this subchapter, to appear before the Secretary of the Treasury or his delegate at a time and place named in the summons and to produce such books, papers, records, or other data, and to give testimony, under oath, as may be relevant or material to an investigation described in subsection (b);

(5) exempt from the requirements of this subchapter any class of transactions within any State if the Secretary determines that—

(A) under the laws of such State, that class of transactions is subject to requirements substantially similar to those imposed under this subchapter; and

(B) there is adequate provision for the enforcement of such requirements; and

(6) prescribe an appropriate exemption from a requirement under this subchapter and regulations prescribed under this subchapter. The Secretary may revoke an exemption under this paragraph or paragraph (5) by actually or constructively notifying the parties affected. A revocation is effective during judicial review.

(b) LIMITATIONS ON SUMMONS POWER.—

(1) SCOPE OF POWER.—The Secretary of the Treasury may take any action described in paragraph (3) or (4) of subsection

[10] Public Law 97–258, Sept. 13, 1982, 96 Stat. 999; Public Law 99–570, Title I, § 1356(a), (b), (c)(2), Oct. 27, 1986, 100 Stat. 3207–23, 3207–24; Public Law 100–690, Title VI, §§ 6185(e), 6469(c), Nov. 18, 1988, 102 Stat. 4357, 4377; Public Law 102–550, Title XV, §§ 1504(d)(1), 1513, 1517(b), Oct. 28, 1992, 106 Stat. 4055, 4058, 4059; Public Law 103–322, Title XXXIII, § 330017(b)(1), Sept. 13, 1994, 108 Stat. 2149; Public Law 103–325, Title IV, §§ 403(a), 410, 413(b)(1), Sept. 23, 1994, 108 Stat. 2245, 2252, 2254; Public Law 107–56, Title III, §§ 312(a), 313(a), 319(b), 325, 326(a), 351, 352(a), 358(b), 359(c), 365(c)(2)(B), Oct. 26, 2001, 115 Stat. 304, 306, 312, 317, 320, 322, 326, 328, 335; Public Law 108–458, §§ 6203(c), (d), 6302, Dec. 17, 2004, 118 Stat. 3746, 3747, 3748.

(a) only in connection with investigations for the purpose of civil enforcement of violations of this subchapter, section 21 of the Federal Deposit Insurance Act, section 411 of the National Housing Act, or chapter 2 of Public Law 91–508 (12 U.S.C. 1951 et seq.) or any regulation under any such provision.

(2) AUTHORITY TO ISSUE.—A summons may be issued under subsection (a)(4) only by, or with the approval of, the Secretary of the Treasury or a supervisory level delegate of the Secretary of the Treasury.

(c) ADMINISTRATIVE ASPECTS OF SUMMONS.—

(1) PRODUCTION AT DESIGNATED SITE.—A summons issued pursuant to this section may require that books, papers, records, or other data stored or maintained at any place be produced at any designated location in any State or in any territory or other place subject to the jurisdiction of the United States not more than 500 miles distant from any place where the financial institution or nonfinancial trade or business operates or conducts business in the United States.

(2) FEES AND TRAVEL EXPENSES.—Persons summoned under this section shall be paid the same fees and mileage for travel in the United States that are paid witnesses in the courts of the United States.

(3) NO LIABILITY FOR EXPENSES.—The United States shall not be liable for any expense, other than an expense described in paragraph (2), incurred in connection with the production of books, papers, records, or other data under this section.

(d) SERVICE OF SUMMONS.—Service of a summons issued under this section may be by registered mail or in such other manner calculated to give actual notice as the Secretary may prescribe by regulation.

(e) CONTUMACY OR REFUSAL.—

(1) REFERRAL TO ATTORNEY GENERAL.—In case of contumacy by a person issued a summons under paragraph (3) or (4) of subsection (a) or a refusal by such person to obey such summons, the Secretary of the Treasury shall refer the matter to the Attorney General.

(2) JURISDICTION OF COURT.—The Attorney General may invoke the aid of any court of the United States within the jurisdiction of which—

(A) the investigation which gave rise to the summons is being or has been carried on;

(B) the person summoned is an inhabitant; or

(C) the person summoned carries on business or may be found,

to compel compliance with the summons.

(3) COURT ORDER.—The court may issue an order requiring the person summoned to appear before the Secretary or his delegate to produce books, papers, records, and other data, to give testimony as may be necessary to explain how such material was compiled and maintained, and to pay the costs of the proceeding.

(4) FAILURE TO COMPLY WITH ORDER.—Any failure to obey the order of the court may be punished by the court as a contempt thereof.

(5) SERVICE OF PROCESS.—All process in any case under this subsection may be served in any judicial district in which such person may be found.

(f) WRITTEN AND SIGNED STATEMENT REQUIRED.—No person shall qualify for an exemption under subsection (a)(5) unless the relevant financial institution or nonfinancial trade or business prepares and maintains a statement which—

(1) describes in detail the reasons why such person is qualified for such exemption; and

(2) contains the signature of such person.

(g) REPORTING OF SUSPICIOUS TRANSACTIONS.—

(1) IN GENERAL.—The Secretary may require any financial institution, and any director, officer, employee, or agent of any financial institution, to report any suspicious transaction relevant to a possible violation of law or regulation.

(2) NOTIFICATION PROHIBITED.—

(A) IN GENERAL.—If a financial institution or any director, officer, employee, or agent of any financial institution, voluntarily or pursuant to this section or any other authority, reports a suspicious transaction to a government agency—

(i) the financial institution, director, officer, employee, or agent may not notify any person involved in the transaction that the transaction has been reported; and

(ii) no officer or employee of the Federal Government or of any State, local, tribal, or territorial government within the United States, who has any knowledge that such report was made may disclose to any person involved in the transaction that the transaction has been reported, other than as necessary to fulfill the official duties of such officer or employee.

(B) DISCLOSURES IN CERTAIN EMPLOYMENT REFERENCES.—

(i) RULE OF CONSTRUCTION.—Notwithstanding the application of subparagraph (A) in any other context, subparagraph (A) shall not be construed as prohibiting any financial institution, or any director, officer, employee, or agent of such institution, from including information that was included in a report to which subparagraph (A) applies—

(I) in a written employment reference that is provided in accordance with section 18(w) of the Federal Deposit Insurance Act in response to a request from another financial institution; or

(II) in a written termination notice or employment reference that is provided in accordance with the rules of a self-regulatory organization registered with the Securities and Exchange Commission or the Commodity Futures Trading Commission,

except that such written reference or notice may not disclose that such information was also included in any such report, or that such report was made.

(ii) INFORMATION NOT REQUIRED.—Clause (i) shall not be construed, by itself, to create any affirmative duty to include any information described in clause (i) in any employment reference or termination notice referred to in clause (i).

(3) LIABILITY FOR DISCLOSURES.—

(A) IN GENERAL.—Any financial institution that makes a voluntary disclosure of any possible violation of law or regulation to a government agency or makes a disclosure pursuant to this subsection or any other authority, and any director, officer, employee, or agent of such institution who makes, or requires another to make any such disclosure, shall not be liable to any person under any law or regulation of the United States, any constitution, law, or regulation of any State or political subdivision of any State, or under any contract or other legally enforceable agreement (including any arbitration agreement), for such disclosure or for any failure to provide notice of such disclosure to the person who is the subject of such disclosure or any other person identified in the disclosure.

(B) RULE OF CONSTRUCTION.—Subparagraph (A) shall not be construed as creating—

(i) any inference that the term "person", as used in such subparagraph, may be construed more broadly than its ordinary usage so as to include any government or agency of government; or

(ii) any immunity against, or otherwise affecting, any civil or criminal action brought by any government or agency of government to enforce any constitution, law, or regulation of such government or agency.

(4) SINGLE DESIGNEE FOR REPORTING SUSPICIOUS TRANSACTIONS.—

(A) IN GENERAL.—In requiring reports under paragraph (1) of suspicious transactions, the Secretary of the Treasury shall designate, to the extent practicable and appropriate, a single officer or agency of the United States to whom such reports shall be made.

(B) DUTY OF DESIGNEE.—The officer or agency of the United States designated by the Secretary of the Treasury pursuant to subparagraph (A) shall refer any report of a suspicious transaction to any appropriate law enforcement, supervisory agency, or United States intelligence agency for use in the conduct of intelligence or counterintelligence activities, including analysis, to protect against international terrorism.

(C) COORDINATION WITH OTHER REPORTING REQUIREMENTS.—Subparagraph (A) shall not be construed as precluding any supervisory agency for any financial institution from requiring the financial institution to submit any information or report to the agency or another agency pursuant to any other applicable provision of law.

(h) ANTI-MONEY LAUNDERING PROGRAMS.—

(1) IN GENERAL.—In order to guard against money laundering through financial institutions, each financial institution

shall establish anti-money laundering programs, including, at a minimum—

(A) the development of internal policies, procedures, and controls;

(B) the designation of a compliance officer;

(C) an ongoing employee training program; and

(D) an independent audit function to test programs.

(2) REGULATIONS.—The Secretary of the Treasury, after consultation with the appropriate Federal functional regulator (as defined in section 509 of the Gramm-Leach-Bliley Act), may prescribe minimum standards for programs established under paragraph (1), and may exempt from the application of those standards any financial institution that is not subject to the provisions of the rules contained in part 103 of title 31, of the Code of Federal Regulations, or any successor rule thereto, for so long as such financial institution is not subject to the provisions of such rules.

(3) CONCENTRATION ACCOUNTS.—The Secretary may prescribe regulations under this subsection that govern maintenance of concentration accounts by financial institutions, in order to ensure that such accounts are not used to prevent association of the identity of an individual customer with the movement of funds of which the customer is the direct or beneficial owner, which regulations shall, at a minimum—

(A) prohibit financial institutions from allowing clients to direct transactions that move their funds into, out of, or through the concentration accounts of the financial institution;

(B) prohibit financial institutions and their employees from informing customers of the existence of, or the means of identifying, the concentration accounts of the institution; and

(C) require each financial institution to establish written procedures governing the documentation of all transactions involving a concentration account, which procedures shall ensure that, any time a transaction involving a concentration account commingles funds belonging to 1 or more customers, the identity of, and specific amount belonging to, each customer is documented.

(i) DUE DILIGENCE FOR UNITED STATES PRIVATE BANKING AND CORRESPONDENT BANK ACCOUNTS INVOLVING FOREIGN PERSONS.—

(1) IN GENERAL.—Each financial institution that establishes, maintains, administers, or manages a private banking account or a correspondent account in the United States for a non-United States person, including a foreign individual visiting the United States, or a representative of a non-United States person shall establish appropriate, specific, and, where necessary, enhanced, due diligence policies, procedures, and controls that are reasonably designed to detect and report instances of money laundering through those accounts.

(2) ADDITIONAL STANDARDS FOR CERTAIN CORRESPONDENT ACCOUNTS.—

(A) IN GENERAL.—Subparagraph (B) shall apply if a correspondent account is requested or maintained by, or on behalf of, a foreign bank operating—

(i) under an offshore banking license; or

(ii) under a banking license issued by a foreign country that has been designated—

(I) as noncooperative with international anti-money laundering principles or procedures by an intergovernmental group or organization of which the United States is a member, with which designation the United States representative to the group or organization concurs; or

(II) by the Secretary of the Treasury as warranting special measures due to money laundering concerns.

(B) POLICIES, PROCEDURES, AND CONTROLS.—The enhanced due diligence policies, procedures, and controls required under paragraph (1) shall, at a minimum, ensure that the financial institution in the United States takes reasonable steps—

(i) to ascertain for any such foreign bank, the shares of which are not publicly traded, the identity of each of the owners of the foreign bank, and the nature and extent of the ownership interest of each such owner;

(ii) to conduct enhanced scrutiny of such account to guard against money laundering and report any suspicious transactions under subsection (g); and

(iii) to ascertain whether such foreign bank provides correspondent accounts to other foreign banks and, if so, the identity of those foreign banks and related due diligence information, as appropriate under paragraph (1).

(3) MINIMUM STANDARDS FOR PRIVATE BANKING ACCOUNTS.—If a private banking account is requested or maintained by, or on behalf of, a non-United States person, then the due diligence policies, procedures, and controls required under paragraph (1) shall, at a minimum, ensure that the financial institution takes reasonable steps—

(A) to ascertain the identity of the nominal and beneficial owners of, and the source of funds deposited into, such account as needed to guard against money laundering and report any suspicious transactions under subsection (g); and

(B) to conduct enhanced scrutiny of any such account that is requested or maintained by, or on behalf of, a senior foreign political figure, or any immediate family member or close associate of a senior foreign political figure, that is reasonably designed to detect and report transactions that may involve the proceeds of foreign corruption.

(4) DEFINITIONS.—For purposes of this subsection, the following definitions shall apply:

(A) OFFSHORE BANKING LICENSE.—The term ''offshore banking license'' means a license to conduct banking activities which, as a condition of the license, prohibits the licensed entity from conducting banking activities with the citizens of, or with the local currency of, the country which issued the license.

(B) PRIVATE BANKING ACCOUNT.—The term ''private banking account'' means an account (or any combination of accounts) that—

(i) requires a minimum aggregate deposits of funds or other assets of not less than $1,000,000;

(ii) is established on behalf of 1 or more individuals who have a direct or beneficial ownership interest in the account; and

(iii) is assigned to, or is administered or managed by, in whole or in part, an officer, employee, or agent of a financial institution acting as a liaison between the financial institution and the direct or beneficial owner of the account.

(j) PROHIBITION ON UNITED STATES CORRESPONDENT ACCOUNTS WITH FOREIGN SHELL BANKS.—

(1) IN GENERAL.—A financial institution described in subparagraphs (A) through (G) of section 5312(a)(2) (in this subsection referred to as a ''covered financial institution'') shall not establish, maintain, administer, or manage a correspondent account in the United States for, or on behalf of, a foreign bank that does not have a physical presence in any country.

(2) PREVENTION OF INDIRECT SERVICE TO FOREIGN SHELL BANKS.—A covered financial institution shall take reasonable steps to ensure that any correspondent account established, maintained, administered, or managed by that covered financial institution in the United States for a foreign bank is not being used by that foreign bank to indirectly provide banking services to another foreign bank that does not have a physical presence in any country. The Secretary of the Treasury shall, by regulation, delineate the reasonable steps necessary to comply with this paragraph.

(3) EXCEPTION.—Paragraphs (1) and (2) do not prohibit a covered financial institution from providing a correspondent account to a foreign bank, if the foreign bank—

(A) is an affiliate of a depository institution, credit union, or foreign bank that maintains a physical presence in the United States or a foreign country, as applicable; and

(B) is subject to supervision by a banking authority in the country regulating the affiliated depository institution, credit union, or foreign bank described in subparagraph (A), as applicable.

(4) DEFINITIONS.—For purposes of this subsection—

(A) the term ''affiliate'' means a foreign bank that is controlled by or is under common control with a depository institution, credit union, or foreign bank; and

(B) the term ''physical presence'' means a place of business that—

(i) is maintained by a foreign bank;

(ii) is located at a fixed address (other than solely an electronic address) in a country in which the foreign bank is authorized to conduct banking activities, at which location the foreign bank—

(I) employs 1 or more individuals on a full-time basis; and

(II) maintains operating records related to its banking activities; and

(iii) is subject to inspection by the banking authority which licensed the foreign bank to conduct banking activities.

(k) BANK RECORDS RELATED TO ANTI-MONEY LAUNDERING PROGRAMS.—

(1) DEFINITIONS.—For purposes of this subsection, the following definitions shall apply:

(A) APPROPRIATE FEDERAL BANKING AGENCY.—The term "appropriate Federal banking agency" has the same meaning as in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813).

(B) INCORPORATED TERM.—The term "correspondent account" has the same meaning as in section 5318A(e)(1)(B).

(2) 120-HOUR RULE.—Not later than 120 hours after receiving a request by an appropriate Federal banking agency for information related to anti-money laundering compliance by a covered financial institution or a customer of such institution, a covered financial institution shall provide to the appropriate Federal banking agency, or make available at a location specified by the representative of the appropriate Federal banking agency, information and account documentation for any account opened, maintained, administered or managed in the United States by the covered financial institution.

(3) FOREIGN BANK RECORDS.—

(A) SUMMONS OR SUBPOENA OF RECORDS.—

(i) IN GENERAL.—The Secretary of the Treasury or the Attorney General may issue a summons or subpoena to any foreign bank that maintains a correspondent account in the United States and request records related to such correspondent account, including records maintained outside of the United States relating to the deposit of funds into the foreign bank.

(ii) SERVICE OF SUMMONS OR SUBPOENA.—A summons or subpoena referred to in clause (i) may be served on the foreign bank in the United States if the foreign bank has a representative in the United States, or in a foreign country pursuant to any mutual legal assistance treaty, multilateral agreement, or other request for international law enforcement assistance.

(B) ACCEPTANCE OF SERVICE.—

(i) MAINTAINING RECORDS IN THE UNITED STATES.—Any covered financial institution which maintains a correspondent account in the United States for a foreign bank shall maintain records in the United States

identifying the owners of such foreign bank and the name and address of a person who resides in the United States and is authorized to accept service of legal process for records regarding the correspondent account.

(ii) LAW ENFORCEMENT REQUEST.—Upon receipt of a written request from a Federal law enforcement officer for information required to be maintained under this paragraph, the covered financial institution shall provide the information to the requesting officer not later than 7 days after receipt of the request.

(C) TERMINATION OF CORRESPONDENT RELATIONSHIP.—

(i) TERMINATION UPON RECEIPT OF NOTICE.—A covered financial institution shall terminate any correspondent relationship with a foreign bank not later than 10 business days after receipt of written notice from the Secretary or the Attorney General (in each case, after consultation with the other) that the foreign bank has failed—

(I) to comply with a summons or subpoena issued under subparagraph (A); or

(II) to initiate proceedings in a United States court contesting such summons or subpoena.

(ii) LIMITATION ON LIABILITY.—A covered financial institution shall not be liable to any person in any court or arbitration proceeding for terminating a correspondent relationship in accordance with this subsection.

(iii) FAILURE TO TERMINATE RELATIONSHIP.—Failure to terminate a correspondent relationship in accordance with this subsection shall render the covered financial institution liable for a civil penalty of up to $10,000 per day until the correspondent relationship is so terminated.

(l) IDENTIFICATION AND VERIFICATION OF ACCOUNTHOLDERS.—

(1) IN GENERAL.—Subject to the requirements of this subsection, the Secretary of the Treasury shall prescribe regulations setting forth the minimum standards for financial institutions and their customers regarding the identity of the customer that shall apply in connection with the opening of an account at a financial institution.

(2) MINIMUM REQUIREMENTS.—The regulations shall, at a minimum, require financial institutions to implement, and customers (after being given adequate notice) to comply with, reasonable procedures for—

(A) verifying the identity of any person seeking to open an account to the extent reasonable and practicable;

(B) maintaining records of the information used to verify a person's identity, including name, address, and other identifying information; and

(C) consulting lists of known or suspected terrorists or terrorist organizations provided to the financial institution by any government agency to determine whether a person seeking to open an account appears on any such list.

(3) FACTORS TO BE CONSIDERED.—In prescribing regulations under this subsection, the Secretary shall take into consideration the various types of accounts maintained by various types of financial institutions, the various methods of opening accounts, and the various types of identifying information available.

(4) CERTAIN FINANCIAL INSTITUTIONS.—In the case of any financial institution the business of which is engaging in financial activities described in section 4(k) of the Bank Holding Company Act of 1956 (including financial activities subject to the jurisdiction of the Commodity Futures Trading Commission), the regulations prescribed by the Secretary under paragraph (1) shall be prescribed jointly with each Federal functional regulator (as defined in section 509 of the Gramm-Leach-Bliley Act, including the Commodity Futures Trading Commission) appropriate for such financial institution.

(5) EXEMPTIONS.—The Secretary (and, in the case of any financial institution described in paragraph (4), any Federal agency described in such paragraph) may, by regulation or order, exempt any financial institution or type of account from the requirements of any regulation prescribed under this subsection in accordance with such standards and procedures as the Secretary may prescribe.

(6) EFFECTIVE DATE.—Final regulations prescribed under this subsection shall take effect before the end of the 1-year period beginning on the date of enactment of the International Money Laundering Abatement and Financial Anti-Terrorism Act of 2001.

(m) APPLICABILITY OF RULES.—Any rules promulgated pursuant to the authority contained in section 21 of the Federal Deposit Insurance Act (12 U.S.C. 1829b) shall apply, in addition to any other financial institution to which such rules apply, to any person that engages as a business in the transmission of funds, including any person who engages as a business in an informal money transfer system or any network of people who engage as a business in facilitating the transfer of money domestically or internationally outside of the conventional financial institutions system.

(n) REPORTING OF CERTAIN CROSS-BORDER TRANSMITTALS OF FUNDS.—

(1) IN GENERAL.—Subject to paragraphs (3) and (4), the Secretary shall prescribe regulations requiring such financial institutions as the Secretary determines to be appropriate to report to the Financial Crimes Enforcement Network certain cross-border electronic transmittals of funds, if the Secretary determines that reporting of such transmittals is reasonably necessary to conduct the efforts of the Secretary against money laundering and terrorist financing.

(2) LIMITATION ON REPORTING REQUIREMENTS.—Information required to be reported by the regulations prescribed under paragraph (1) shall not exceed the information required to be retained by the reporting financial institution pursuant to section 21 of the Federal Deposit Insurance Act and the regulations promulgated thereunder, unless—

(A) the Board of Governors of the Federal Reserve System and the Secretary jointly determine that a particular item or items of information are not currently required to be retained under such section or such regulations; and

(B) the Secretary determines, after consultation with the Board of Governors of the Federal Reserve System, that the reporting of such information is reasonably necessary to conduct the efforts of the Secretary to identify cross-border money laundering and terrorist financing.

(3) FORM AND MANNER OF REPORTS.—In prescribing the regulations required under paragraph (1), the Secretary shall, subject to paragraph (2), determine the appropriate form, manner, content, and frequency of filing of the required reports.

(4) FEASIBILITY REPORT.—

(A) IN GENERAL.—Before prescribing the regulations required under paragraph (1), and as soon as is practicable after the date of enactment of the National Intelligence Reform Act of 2004, the Secretary shall submit a report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives that—

(i) identifies the information in cross-border electronic transmittals of funds that may be found in particular cases to be reasonably necessary to conduct the efforts of the Secretary to identify money laundering and terrorist financing, and outlines the criteria to be used by the Secretary to select the situations in which reporting under this subsection may be required;

(ii) outlines the appropriate form, manner, content, and frequency of filing of the reports that may be required under such regulations;

(iii) identifies the technology necessary for the Financial Crimes Enforcement Network to receive, keep, exploit, protect the security of, and disseminate information from reports of cross-border electronic transmittals of funds to law enforcement and other entities engaged in efforts against money laundering and terrorist financing; and

(iv) discusses the information security protections required by the exercise of the Secretary's authority under this subsection.

(B) CONSULTATION.—In reporting the feasibility report under subparagraph (A), the Secretary may consult with the Bank Secrecy Act Advisory Group established by the Secretary, and any other group considered by the Secretary to be relevant.

(5) REGULATIONS.—

(A) IN GENERAL.—Subject to subparagraph (B), the regulations required by paragraph (1) shall be prescribed in final form by the Secretary, in consultation with the Board of Governors of the Federal Reserve System, before the end of the 3-year period beginning on the date of enactment of the National Intelligence Reform Act of 2004.

(B) TECHNOLOGICAL FEASIBILITY.—No regulations shall be prescribed under this subsection before the Secretary certifies to the Congress that the Financial Crimes Enforcement Network has the technological systems in place to effectively and efficiently receive, keep, exploit, protect the security of, and disseminate information from reports of cross-border electronic transmittals of funds to law enforcement and other entities engaged in efforts against money laundering and terrorist financing.

§ 5318A. Special measures for jurisdictions, financial institutions, international transactions, or types of accounts of primary money laundering concern [11]

(a) INTERNATIONAL COUNTER-MONEY LAUNDERING REQUIREMENTS.—

(1) IN GENERAL.—The Secretary of the Treasury may require domestic financial institutions and domestic financial agencies to take 1 or more of the special measures described in subsection (b) if the Secretary finds that reasonable grounds exist for concluding that a jurisdiction outside of the United States, 1 or more financial institutions operating outside of the United States, 1 or more classes of transactions within, or involving, a jurisdiction outside of the United States, or 1 or more types of accounts is of primary money laundering concern, in accordance with subsection (c).

(2) FORM OF REQUIREMENT.—The special measures described in—

(A) subsection (b) may be imposed in such sequence or combination as the Secretary shall determine;

(B) paragraphs (1) through (4) of subsection (b) may be imposed by regulation, order, or otherwise as permitted by law; and

(C) subsection (b)(5) may be imposed only by regulation.

(3) DURATION OF ORDERS; RULEMAKING.—Any order by which a special measure described in paragraphs (1) through (4) of subsection (b) is imposed (other than an order described in section 5326)—

(A) shall be issued together with a notice of proposed rulemaking relating to the imposition of such special measure; and

(B) may not remain in effect for more than 120 days, except pursuant to a rule promulgated on or before the end of the 120-day period beginning on the date of issuance of such order.

(4) PROCESS FOR SELECTING SPECIAL MEASURES.—In selecting which special measure or measures to take under this subsection, the Secretary of the Treasury—

(A) shall consult with the Chairman of the Board of Governors of the Federal Reserve System, any other appropriate Federal banking agency (as defined in section 3 of the Federal Deposit Insurance Act) [12] the Secretary of

[11] Added by Public Law 107–56, Title III, § 311(a), Oct. 26, 2001, 115 Stat. 298, and amended by Public Law 108–177, Title III, § 376, Dec. 13, 2003, 117 Stat. 2630; Public Law 108–458, § 6203(e), (f), Dec. 17, 2004, 118 Stat. 3747.

[12] So in original. Probably should be a comma following the parenthesis.

State, the Securities and Exchange Commission, the Commodity Futures Trading Commission, the National Credit Union Administration Board, and in the sole discretion of the Secretary, such other agencies and interested parties as the Secretary may find to be appropriate; and

(B) shall consider—

(i) whether similar action has been or is being taken by other nations or multilateral groups;

(ii) whether the imposition of any particular special measure would create a significant competitive disadvantage, including any undue cost or burden associated with compliance, for financial institutions organized or licensed in the United States;

(iii) the extent to which the action or the timing of the action would have a significant adverse systemic impact on the international payment, clearance, and settlement system, or on legitimate business activities involving the particular jurisdiction, institution, class of transactions, or type of account; and

(iv) the effect of the action on United States national security and foreign policy.

(5) NO LIMITATION ON OTHER AUTHORITY.—This section shall not be construed as superseding or otherwise restricting any other authority granted to the Secretary, or to any other agency, by this subchapter or otherwise.

(b) SPECIAL MEASURES.—The special measures referred to in subsection (a), with respect to a jurisdiction outside of the United States, financial institution operating outside of the United States, class of transaction within, or involving, a jurisdiction outside of the United States, or 1 or more types of accounts are as follows:

(1) RECORDKEEPING AND REPORTING OF CERTAIN FINANCIAL TRANSACTIONS.—

(A) IN GENERAL.—The Secretary of the Treasury may require any domestic financial institution or domestic financial agency to maintain records, file reports, or both, concerning the aggregate amount of transactions, or concerning each transaction, with respect to a jurisdiction outside of the United States, 1 or more financial institutions operating outside of the United States, 1 or more classes of transactions within, or involving, a jurisdiction outside of the United States, or 1 or more types of accounts if the Secretary finds any such jurisdiction, institution, class of transactions, or type of account to be of primary money laundering concern.

(B) FORM OF RECORDS AND REPORTS.—Such records and reports shall be made and retained at such time, in such manner, and for such period of time, as the Secretary shall determine, and shall include such information as the Secretary may determine, including—

(i) the identity and address of the participants in a transaction or relationship, including the identity of the originator of any funds transfer;

(ii) the legal capacity in which a participant in any transaction is acting;

(iii) the identity of the beneficial owner of the funds involved in any transaction, in accordance with such procedures as the Secretary determines to be reasonable and practicable to obtain and retain the information; and

(iv) a description of any transaction.

(2) INFORMATION RELATING TO BENEFICIAL OWNERSHIP.—In addition to any other requirement under any other provision of law, the Secretary may require any domestic financial institution or domestic financial agency to take such steps as the Secretary may determine to be reasonable and practicable to obtain and retain information concerning the beneficial ownership of any account opened or maintained in the United States by a foreign person (other than a foreign entity whose shares are subject to public reporting requirements or are listed and traded on a regulated exchange or trading market), or a representative of such a foreign person, that involves a jurisdiction outside of the United States, 1 or more financial institutions operating outside of the United States, 1 or more classes of transactions within, or involving, a jurisdiction outside of the United States, or 1 or more types of accounts if the Secretary finds any such jurisdiction, institution, or transaction or type of account to be of primary money laundering concern.

(3) INFORMATION RELATING TO CERTAIN PAYABLE-THROUGH ACCOUNTS.—If the Secretary finds a jurisdiction outside of the United States, 1 or more financial institutions operating outside of the United States, or 1 or more classes of transactions within, or involving, a jurisdiction outside of the United States to be of primary money laundering concern, the Secretary may require any domestic financial institution or domestic financial agency that opens or maintains a payable-through account in the United States for a foreign financial institution involving any such jurisdiction or any such financial institution operating outside of the United States, or a payable through account through which any such transaction may be conducted, as a condition of opening or maintaining such account—

(A) to identify each customer (and representative of such customer) of such financial institution who is permitted to use, or whose transactions are routed through, such payable-through account; and

(B) to obtain, with respect to each such customer (and each such representative), information that is substantially comparable to that which the depository institution obtains in the ordinary course of business with respect to its customers residing in the United States.

(4) INFORMATION RELATING TO CERTAIN CORRESPONDENT ACCOUNTS.—If the Secretary finds a jurisdiction outside of the United States, 1 or more financial institutions operating outside of the United States, or 1 or more classes of transactions within, or involving, a jurisdiction outside of the United States to be of primary money laundering concern, the Secretary may require any domestic financial institution or domestic financial agency that opens or maintains a correspondent account in the United States for a foreign financial institution involving any

such jurisdiction or any such financial institution operating outside of the United States, or a correspondent account through which any such transaction may be conducted, as a condition of opening or maintaining such account—

(A) to identify each customer (and representative of such customer) of any such financial institution who is permitted to use, or whose transactions are routed through, such correspondent account; and

(B) to obtain, with respect to each such customer (and each such representative), information that is substantially comparable to that which the depository institution obtains in the ordinary course of business with respect to its customers residing in the United States.

(5) PROHIBITIONS OR CONDITIONS ON OPENING OR MAINTAINING CERTAIN CORRESPONDENT OR PAYABLE-THROUGH ACCOUNTS.—If the Secretary finds a jurisdiction outside of the United States, 1 or more financial institutions operating outside of the United States, or 1 or more classes of transactions within, or involving, a jurisdiction outside of the United States to be of primary money laundering concern, the Secretary, in consultation with the Secretary of State, the Attorney General, and the Chairman of the Board of Governors of the Federal Reserve System, may prohibit, or impose conditions upon, the opening or maintaining in the United States of a correspondent account or payable-through account by any domestic financial institution or domestic financial agency for or on behalf of a foreign banking institution, if such correspondent account or payable-through account involves any such jurisdiction or institution, or if any such transaction may be conducted through such correspondent account or payable-through account.

(c) CONSULTATIONS AND INFORMATION TO BE CONSIDERED IN FINDING JURISDICTIONS, INSTITUTIONS, TYPES OF ACCOUNTS, OR TRANSACTIONS TO BE OF PRIMARY MONEY LAUNDERING CONCERN.—

(1) IN GENERAL.—In making a finding that reasonable grounds exist for concluding that a jurisdiction outside of the United States, 1 or more financial institutions operating outside of the United States, 1 or more classes of transactions within, or involving, a jurisdiction outside of the United States, or 1 or more types of accounts is of primary money laundering concern so as to authorize the Secretary of the Treasury to take 1 or more of the special measures described in subsection (b), the Secretary shall consult with the Secretary of State and the Attorney General.

(2) ADDITIONAL CONSIDERATIONS.—In making a finding described in paragraph (1), the Secretary shall consider in addition such information as the Secretary determines to be relevant, including the following potentially relevant factors:

(A) JURISDICTIONAL FACTORS.—In the case of a particular jurisdiction—

(i) evidence that organized criminal groups, international terrorists, or both, have transacted business in that jurisdiction;

(ii) the extent to which that jurisdiction or financial institutions operating in that jurisdiction offer bank secrecy or special regulatory advantages to nonresidents or nondomiciliaries of that jurisdiction;

(iii) the substance and quality of administration of the bank supervisory and counter-money laundering laws of that jurisdiction;

(iv) the relationship between the volume of financial transactions occurring in that jurisdiction and the size of the economy of the jurisdiction;

(v) the extent to which that jurisdiction is characterized as an offshore banking or secrecy haven by credible international organizations or multilateral expert groups;

(vi) whether the United States has a mutual legal assistance treaty with that jurisdiction, and the experience of United States law enforcement officials and regulatory officials in obtaining information about transactions originating in or routed through or to such jurisdiction; and

(vii) the extent to which that jurisdiction is characterized by high levels of official or institutional corruption.

(B) INSTITUTIONAL FACTORS.—In the case of a decision to apply 1 or more of the special measures described in subsection (b) only to a financial institution or institutions, or to a transaction or class of transactions, or to a type of account, or to all 3, within or involving a particular jurisdiction—

(i) the extent to which such financial institutions, transactions, or types of accounts are used to facilitate or promote money laundering in or through the jurisdiction;

(ii) the extent to which such institutions, transactions, or types of accounts are used for legitimate business purposes in the jurisdiction; and

(iii) the extent to which such action is sufficient to ensure, with respect to transactions involving the jurisdiction and institutions operating in the jurisdiction, that the purposes of this subchapter continue to be fulfilled, and to guard against international money laundering and other financial crimes.

(d) NOTIFICATION OF SPECIAL MEASURES INVOKED BY THE SECRETARY.—Not later than 10 days after the date of any action taken by the Secretary of the Treasury under subsection (a)(1), the Secretary shall notify, in writing, the Committee on Financial Services of the House of Representatives and the Committee on Banking, Housing, and Urban Affairs of the Senate of any such action.

(e) DEFINITIONS.—Notwithstanding any other provision of this subchapter, for purposes of this section and subsections (i) and (j) of section 5318, the following definitions shall apply:

(1) BANK DEFINITIONS.—The following definitions shall apply with respect to a bank:

(A) ACCOUNT.—The term ''account''—

(i) means a formal banking or business relationship established to provide regular services, dealings, and other financial transactions; and

(ii) includes a demand deposit, savings deposit, or other transaction or asset account and a credit account or other extension of credit.

(B) CORRESPONDENT ACCOUNT.—The term ''correspondent account'' means an account established to receive deposits from, make payments on behalf of a foreign financial institution, or handle other financial transactions related to such institution.

(C) PAYABLE-THROUGH ACCOUNT.—The term ''payable-through account'' means an account, including a transaction account (as defined in section 19(b)(1)(C) of the Federal Reserve Act), opened at a depository institution by a foreign financial institution by means of which the foreign financial institution permits its customers to engage, either directly or through a subaccount, in banking activities usual in connection with the business of banking in the United States.

(2) DEFINITIONS APPLICABLE TO INSTITUTIONS OTHER THAN BANKS.—With respect to any financial institution other than a bank, the Secretary shall, after consultation with the appropriate Federal functional regulators (as defined in section 509 of the Gramm-Leach-Bliley Act), define by regulation the term ''account'', and shall include within the meaning of that term, to the extent, if any, that the Secretary deems appropriate, arrangements similar to payable-through and correspondent accounts.

(3) REGULATORY DEFINITION OF BENEFICIAL OWNERSHIP.—The Secretary shall promulgate regulations defining beneficial ownership of an account for purposes of this section and subsections (i) and (j) of section 5318. Such regulations shall address issues related to an individual's authority to fund, direct, or manage the account (including, without limitation, the power to direct payments into or out of the account), and an individual's material interest in the income or corpus of the account, and shall ensure that the identification of individuals under this section or subsection (i) or (j) of section 5318 does not extend to any individual whose beneficial interest in the income or corpus of the account is immaterial.

(4) OTHER TERMS.—The Secretary may, by regulation, further define the terms in paragraphs (1), (2), and (3), and define other terms for the purposes of this section, as the Secretary deems appropriate.

(f) CLASSIFIED INFORMATION.—In any judicial review of a finding of the existence of a primary money laundering concern, or of the requirement for 1 or more special measures with respect to a primary money laundering concern, made under this section, if the designation or imposition, or both, were based on classified information (as defined in section 1(a) of the Classified Information Procedures Act (18 U.S.C. App.), such information may be submitted by the Secretary to the reviewing court ex parte and in camera.

This subsection does not confer or imply any right to judicial review of any finding made or any requirement imposed under this section.

§ 5320. Injunctions [13]

When the Secretary of the Treasury believes a person has violated, is violating, or will violate this subchapter or a regulation prescribed or order issued under this subchapter, the Secretary may bring a civil action in the appropriate district court of the United States or appropriate United States court of a territory or possession of the United States to enjoin the violation or to enforce compliance with the subchapter, regulation, or order. An injunction or temporary restraining order shall be issued without bond.

§ 5321. Civil penalties [14]

(a)(1) A domestic financial institution or nonfinancial trade or business, and a partner, director, officer, or employee of a domestic financial institution or nonfinancial trade or business, willfully violating this subchapter or a regulation prescribed or order issued under this subchapter (except sections 5314 and 5315 of this title or a regulation prescribed under sections 5314 and 5315), or willfully violating a regulation prescribed under section 21 of the Federal Deposit Insurance Act or section 123 of Public Law 91–508, is liable to the United States Government for a civil penalty of not more than the greater of the amount (not to exceed $100,000) involved in the transaction (if any) or $25,000. For a violation of section 5318(a)(2) of this title or a regulation prescribed under section 5318(a)(2), a separate violation occurs for each day the violation continues and at each office, branch, or place of business at which a violation occurs or continues.

(2) The Secretary of the Treasury may impose an additional civil penalty on a person not filing a report, or filing a report containing a material omission or misstatement, under section 5316 of this title or a regulation prescribed under section 5316. A civil penalty under this paragraph may not be more than the amount of the monetary instrument for which the report was required. A civil penalty under this paragraph is reduced by an amount forfeited under section 5317(b) of this title.

(3) A person not filing a report under a regulation prescribed under section 5315 of this title or not complying with an injunction under section 5320 of this title enjoining a violation of, or enforcing compliance with, section 5315 or a regulation prescribed under section 5315, is liable to the Government for a civil penalty of not more than $10,000.

(4) STRUCTURED TRANSACTION VIOLATION.—

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[13] Public Law 97–258, Sept. 13, 1982, 96 Stat. 999.

[14] Public Law 97–258, Sept. 13, 1982, 96 Stat. 999; Public Law 98–473, Title II, § 901(a), Oct. 12, 1984, 98 Stat. 2135; Public Law 99–570, Title I, §§ 1356(c)(1), 1357(a)-(f), (h), Oct. 27, 1986, 100 Stat. 3207–24, 3207–25, 3207–26; Public Law 100–690, Title VI, § 6185(g)(2), Nov. 18, 1988, 102 Stat. 4357; Public Law 102–550, Title XV, §§ 1511(b), 1525(b), 1535(a)(2), 1561(a), Oct. 28, 1992, 106 Stat. 4057, 4065, 4066, 4071; Public Law 103–322, Title XXXIII, § 330017(a)(1), Sept. 13, 1994, 108 Stat. 2149; Public Law 103–325, Title IV, §§ 406, 411(b), 413(a)(1), Sept. 23, 1994, 108 Stat. 2247, 2253, 2254; Public Law 104–208, Div. A, Title II, § 2223(3), Sept. 30, 1996, 110 Stat. 3009–415; Public Law 107–56, Title III, §§ 353(a), 363(a), 365(c)(2)(B)(i), Oct. 26, 2001, 115 Stat. 322, 332, 335; Public Law 108–357, § 821(a), Oct. 22, 2004, 118 Stat. 1586.

(A) PENALTY AUTHORIZED.—The Secretary of the Treasury may impose a civil money penalty on any person who violates any provision of section 5324.

(B) MAXIMUM AMOUNT LIMITATION.—The amount of any civil money penalty imposed under subparagraph (A) shall not exceed the amount of the coins and currency (or such other monetary instruments as the Secretary may prescribe) involved in the transaction with respect to which such penalty is imposed.

(C) COORDINATION WITH FORFEITURE PROVISION.—The amount of any civil money penalty imposed by the Secretary under subparagraph (A) shall be reduced by the amount of any forfeiture to the United States in connection with the transaction with respect to which such penalty is imposed.

(5) FOREIGN FINANCIAL AGENCY TRANSACTION VIOLATION.—

(A) PENALTY AUTHORIZED.—The Secretary of the Treasury may impose a civil money penalty on any person who violates, or causes any violation of, any provision of section 5314.

(B) AMOUNT OF PENALTY.—

(i) IN GENERAL.—Except as provided in subparagraph (C), the amount of any civil penalty imposed under subparagraph (A) shall not exceed $10,000.

(ii) REASONABLE CAUSE EXCEPTION.—No penalty shall be imposed under subparagraph (A) with respect to any violation if

(I) such violation was due to reasonable cause, and

(II) the amount of the transaction or the balance in the account at the time of the transaction was properly reported.

(C) WILLFUL VIOLATIONS.—In the case of any person willfully violating, or willfully causing any violation of, any provision of section 5314—

(i) the maximum penalty under subparagraph (B)(i) shall be increased to the greater of—

(I) $100,000, or

(II) 50 percent of the amount determined under subparagraph (D), and

(ii) subparagraph (B)(ii) shall not apply.

(D) AMOUNT.—The amount determined under this subparagraph is—

(i) in the case of a violation involving a transaction, the amount of the transaction, or

(ii) in the case of a violation involving a failure to report the existence of an account or any identifying information required to be provided with respect to an account, the balance in the account at the time of the violation.

(6) NEGLIGENCE.—

(A) IN GENERAL.—The Secretary of the Treasury may impose a civil money penalty of not more than $500 on any financial institution or nonfinancial trade or business which negligently violates any provision of this subchapter or any regulation prescribed under this subchapter.

(B) PATTERN OF NEGLIGENT ACTIVITY.—If any financial institution or nonfinancial trade or business engages in a pattern of negligent violations of any provision of this subchapter or

any regulation prescribed under this subchapter, the Secretary of the Treasury may, in addition to any penalty imposed under subparagraph (A) with respect to any such violation, impose a civil money penalty of not more than $50,000 on the financial institution or nonfinancial trade or business.

(7) PENALTIES FOR INTERNATIONAL COUNTER MONEY LAUNDERING VIOLATIONS.—The Secretary may impose a civil money penalty in an amount equal to not less than 2 times the amount of the transaction, but not more than $1,000,000, on any financial institution or agency that violates any provision of subsection (i) or (j) of section 5318 or any special measures imposed under section 5318A.

(b) TIME LIMITATIONS FOR ASSESSMENTS AND COMMENCEMENT OF CIVIL ACTIONS.—

(1) ASSESSMENTS.—The Secretary of the Treasury may assess a civil penalty under subsection (a) at any time before the end of the 6-year period beginning on the date of the transaction with respect to which the penalty is assessed.

(2) CIVIL ACTIONS.—The Secretary may commence a civil action to recover a civil penalty assessed under subsection (a) at any time before the end of the 2-year period beginning on the later of—

(A) the date the penalty was assessed; or

(B) the date any judgment becomes final in any criminal action under section 5322 in connection with the same transaction with respect to which the penalty is assessed.

(c) The Secretary may remit any part of a forfeiture under subsection (c) or (d)[15] of section 5317 of this title or civil penalty under subsection (a)(2) of this section.

(d) CRIMINAL PENALTY NOT EXCLUSIVE OF CIVIL PENALTY.—A civil money penalty may be imposed under subsection (a) with respect to any violation of this subchapter notwithstanding the fact that a criminal penalty is imposed with respect to the same violation.

(e) DELEGATION OF ASSESSMENT AUTHORITY TO BANKING AGENCIES.—

(1) IN GENERAL.—The Secretary of the Treasury shall delegate, in accordance with section 5318(a)(1) and subject to such terms and conditions as the Secretary may impose in accordance with paragraph (3), any authority of the Secretary to assess a civil money penalty under this section on depository institutions (as defined in section 3 of the Federal Deposit Insurance Act) to the appropriate Federal banking agencies (as defined in such section 3).

(2) AUTHORITY OF AGENCIES.—Subject to any term or condition imposed by the Secretary of the Treasury under paragraph (3), the provisions of this section shall apply to an appropriate Federal banking agency to which is delegated any authority of the Secretary under this section in the same manner such provisions apply to the Secretary.

(3) TERMS AND CONDITIONS.—

[15] So in original. Section 5317 does not contain a subsection (d).

(A) IN GENERAL.—The Secretary of the Treasury shall prescribe by regulation the terms and conditions which shall apply to any delegation under paragraph (1).

(B) MAXIMUM DOLLAR AMOUNT.—The terms and conditions authorized under subparagraph (A) may include, in the Secretary's sole discretion, a limitation on the amount of any civil penalty which may be assessed by an appropriate Federal banking agency pursuant to a delegation under paragraph (1).

§ 5322. Criminal penalties [16]

(a) A person willfully violating this subchapter or a regulation prescribed or order issued under this subchapter (except section 5315 or 5324 of this title or a regulation prescribed under section 5315 or 5324), or willfully violating a regulation prescribed under section 21 of the Federal Deposit Insurance Act or section 123 of Public Law 91–508, shall be fined not more than $250,000, or imprisoned for not more than five years, or both.

(b) A person willfully violating this subchapter or a regulation prescribed or order issued under this subchapter (except section 5315 or 5324 of this title or a regulation prescribed under section 5315 or 5324), or willfully violating a regulation prescribed under section 21 of the Federal Deposit Insurance Act or section 123 of Public Law 91–508, while violating another law of the United States or as part of a pattern of any illegal activity involving more than $100,000 in a 12-month period, shall be fined not more than $500,000, imprisoned for not more than 10 years, or both.

(c) For a violation of section 5318(a)(2) of this title or a regulation prescribed under section 5318(a)(2), a separate violation occurs for each day the violation continues and at each office, branch, or place of business at which a violation occurs or continues.

(d) A financial institution or agency that violates any provision of subsection (i) or (j) of section 5318, or any special measures imposed under section 5318A, or any regulation prescribed under subsection (i) or (j) of section 5318 or section 5318A, shall be fined in an amount equal to not less than 2 times the amount of the transaction, but not more than $1,000,000.

[16] Public Law 97–258, Sept. 13, 1982, 96 Stat. 1000; Public Law 98–473, Title II, § 901(b), Oct. 12, 1984, 98 Stat. 2135; Public Law 99–570, Title I, §§ 1356(c)(1), 1357(g), Oct. 27, 1986, 100 Stat. 3207–24, 3207–26; Public Law 102–550, Title XV, § 1504(d)(2), Oct. 28, 1992, 106 Stat. 4055; Public Law 103–325, Title IV, § 411(c)(1), Sept. 23, 1994, 108 Stat. 2253; Public Law 107–56, Title III, §§ 353(b), 363(b), Oct. 26, 2001, 115 Stat. 323, 332.

Chapter 97. Miscellaneous

§ 9703. Managerial accountability and flexibility [1]

(a) Beginning with fiscal year 1999, the performance plans required under section 1115 may include proposals to waive administrative procedural requirements and controls, including specification of personnel staffing levels, limitations on compensation or remuneration, and prohibitions or restrictions on funding transfers among budget object classification 20 and subclassifications 11, 12, 31, and 32 of each annual budget submitted under section 1105, in return for specific individual or organization accountability to achieve a performance goal. In preparing and submitting the performance plan under section 1105(a)(29), the Director of the Office of Management and Budget shall review and may approve any proposed waivers. A waiver shall take effect at the beginning of the fiscal year for which the waiver is approved.

(b) Any such proposal under subsection (a) shall describe the anticipated effects on performance resulting from greater managerial or organizational flexibility, discretion, and authority, and shall quantify the expected improvements in performance resulting from any waiver. The expected improvements shall be compared to current actual performance, and to the projected level of performance that would be achieved independent of any waiver.

(c) Any proposal waiving limitations on compensation or remuneration shall precisely express the monetary change in compensation or remuneration amounts, such as bonuses or awards, that shall result from meeting, exceeding, or failing to meet performance goals.

(d) Any proposed waiver of procedural requirements or controls imposed by an agency (other than the proposing agency or the Office of Management and Budget) may not be included in a performance plan unless it is endorsed by the agency that established the requirement, and the endorsement included in the proposing agency's performance plan.

(e) A waiver shall be in effect for one or two years as specified by the Director of the Office of Management and Budget in approving the waiver. A waiver may be renewed for a subsequent year. After a waiver has been in effect for three consecutive years, the performance plan prepared under section 1115 may propose that a waiver, other than a waiver of limitations on compensation or remuneration, be made permanent.

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[1] Added by Public Law 103–62, § 5(a), Aug. 3, 1993, 107 Stat. 289.

(f) For purposes of this section, the definitions under section 1115(f) shall apply.

Title 32. National Guard

Chapter 1. Organization

§ 112. Drug interdiction and counter-drug activities [1]

(a) FUNDING ASSISTANCE.—The Secretary of Defense may provide funds to the Governor of a State who submits to the Secretary a State drug interdiction and counter-drug activities plan satisfying the requirements of subsection (c). Such funds shall be used for the following:

(1) The pay, allowances, clothing, subsistence, gratuities, travel, and related expenses, as authorized by State law, of personnel of the National Guard of that State used, while not in Federal service, for the purpose of drug interdiction and counter-drug activities.

(2) The operation and maintenance of the equipment and facilities of the National Guard of that State used for the purpose of drug interdiction and counter-drug activities.

(3) The procurement of services and equipment, and the leasing of equipment, for the National Guard of that State used for the purpose of drug interdiction and counter-drug activities. However, the use of such funds for the procurement of equipment may not exceed $5,000 per item, unless approval for procurement of equipment in excess of that amount is granted in advance by the Secretary of Defense.

(b) USE OF PERSONNEL PERFORMING FULL-TIME NATIONAL GUARD DUTY.—(1) Under regulations prescribed by the Secretary of Defense, personnel of the National Guard of a State may, in accordance with the State drug interdiction and counter-drug activities plan referred to in subsection (c), be ordered to perform full-time National Guard duty under section 502(f) of this title for the purpose of carrying out drug interdiction and counter-drug activities.

(2)(A) A member of the National Guard serving on full-time National Guard duty under orders authorized under paragraph (1) shall participate in the training required under section 502(a) of this title in addition to the duty performed for the purpose authorized under that paragraph. The pay, allowances, and other benefits

[1] Added by Public Law 101–189, Div. A, Title XII, § 1207(a)(1), Nov. 29, 1989, 103 Stat. 1564, and amended by Public Law 102–25, Title VII, § 703, Apr. 6, 1991, 105 Stat. 118; Public Law 102–396, Title IX, § 9099A, Oct. 6, 1992, 106 Stat. 1926; Public Law 104–106, Div. A, Title X, § 1021, Feb. 10, 1996, 110 Stat. 426 to 428; Public Law 104–208, Div. C, Title VI, § 660, Sept. 30, 1996, 110 Stat. 3009–720; Public Law 105–85, Div. A, Title X, § 1031, Nov. 18, 1997, 111 Stat. 1880, 1881; Public Law 105–261, Div. A, Title X, § 1022, Oct. 17, 1998, 112 Stat. 2120 to 2122; Public Law 106–65, Div. A, Title X, § 1021, Oct. 5, 1999, 113 Stat. 746; Public Law 108–375, § 416(k), Oct. 28, 2004, 118 Stat. 1869.

of the member while participating in the training shall be the same as those to which the member is entitled while performing duty for the purpose of carrying out drug interdiction and counter-drug activities. The member is not entitled to additional pay, allowances, or other benefits for participation in training required under section 502(a)(1) of this title.

(B) Appropriations available for the Department of Defense for drug interdiction and counter-drug activities may be used for paying costs associated with a member's participation in training described in subparagraph (A). The appropriation shall be reimbursed in full, out of appropriations available for paying those costs, for the amounts paid. Appropriations available for paying those costs shall be available for making the reimbursements.

(C) To ensure that the use of units and personnel of the National Guard of a State pursuant to a State drug interdiction and counter-drug activities plan does not degrade the training and readiness of such units and personnel, the following requirements shall apply in determining the drug interdiction and counter-drug activities that units and personnel of the National Guard of a State may perform:

(i) The performance of the activities may not adversely affect the quality of that training or otherwise interfere with the ability of a member or unit of the National Guard to perform the military functions of the member or unit.

(ii) National Guard personnel will not degrade their military skills as a result of performing the activities.

(iii) The performance of the activities will not result in a significant increase in the cost of training.

(iv) In the case of drug interdiction and counter-drug activities performed by a unit organized to serve as a unit, the activities will support valid unit training requirements.

(3) A unit or member of the National Guard of a State may be used, pursuant to a State drug interdiction and counter-drug activities plan approved by the Secretary of Defense under this section, to provide services or other assistance (other than air transportation) to an organization eligible to receive services under section 508 of this title if—

(A) the State drug interdiction and counter-drug activities plan specifically recognizes the organization as being eligible to receive the services or assistance;

(B) in the case of services, the performance of the services meets the requirements of paragraphs (1) and (2) of subsection (a) of section 508 of this title; and

(C) the services or assistance is authorized under subsection (b) or (c) of such section or in the State drug interdiction and counter-drug activities plan.

(c) PLAN REQUIREMENTS.—A State drug interdiction and counter-drug activities plan shall—

(1) specify how personnel of the National Guard of that State are to be used in drug interdiction and counter-drug activities;

(2) certify that those operations are to be conducted at a time when the personnel involved are not in Federal service;

(3) certify that participation by National Guard personnel in those operations is service in addition to training required under section 502 of this title;

(4) certify that any engineer-type activities (as defined by the Secretary of Defense) under the plan will be performed only by units and members of the National Guard;

(5) include a certification by the Attorney General of the State (or, in the case of a State with no position of Attorney General, a civilian official of the State equivalent to a State attorney general) that the use of the National Guard of the State for the activities proposed under the plan is authorized by, and is consistent with, State law; and

(6) certify that the Governor of the State or a civilian law enforcement official of the State designated by the Governor has determined that any activities included in the plan that are carried out in conjunction with Federal law enforcement agencies serve a State law enforcement purpose.

(d) EXAMINATION OF PLAN.—(1) Before funds are provided to the Governor of a State under this section and before members of the National Guard of that State are ordered to full-time National Guard duty as authorized in subsection (b), the Secretary of Defense shall examine the adequacy of the plan submitted by the Governor under subsection (c). The plan as approved by the Secretary may provide for the use of personnel and equipment of the National Guard of that State to assist the Immigration and Naturalization Service in the transportation of aliens who have violated a Federal or State law prohibiting or regulating the possession, use, or distribution of a controlled substance.

(2) Except as provided in paragraph (3), the Secretary shall carry out paragraph (1) in consultation with the Director of National Drug Control Policy.

(3) Paragraph (2) shall not apply if—

(A) the Governor of a State submits a plan under subsection (c) that is substantially the same as a plan submitted for that State for a previous fiscal year; and

(B) pursuant to the plan submitted for a previous fiscal year, funds were provided to the State in accordance with subsection (a) or personnel of the National Guard of the State were ordered to perform full-time National Guard duty in accordance with subsection (b).

(e) END STRENGTH LIMITATION.—(1) Except as provided in paragraph (2), at the end of a fiscal year there may not be more than 4000 members of the National Guard—

(A) on full-time National Guard duty under section 502(f) of this title to perform drug interdiction or counter-drug activities pursuant to an order to duty; or

(B) on duty under State authority to perform drug interdiction or counter-drug activities pursuant to an order to duty with State pay and allowances being reimbursed with funds provided under subsection (a)(1).

(2) The Secretary of Defense may increase the end strength authorized under paragraph (1) by not more than 20 percent for any fiscal year if the Secretary determines that such an increase is necessary in the national security interests of the United States.

(f) ANNUAL REPORT.—The Secretary of Defense shall submit to Congress an annual report regarding assistance provided and activities carried out under this section during the preceding fiscal year. The report shall include the following:

(1) The number of members of the National Guard excluded under subsection (e) from the computation of end strengths.

(2) A description of the drug interdiction and counter-drug activities conducted under State drug interdiction and counter-drug activities plans referred to in subsection (c) with funds provided under this section.

(3) An accounting of the amount of funds provided to each State.

(4) A description of the effect on military training and readiness of using units and personnel of the National Guard to perform activities under the State drug interdiction and counter-drug activities plans.

(g) STATUTORY CONSTRUCTION.—Nothing in this section shall be construed as a limitation on the authority of any unit of the National Guard of a State, when such unit is not in Federal service, to perform law enforcement functions authorized to be performed by the National Guard by the laws of the State concerned.

(h) DEFINITIONS.—For purposes of this section:

(1) The term "drug interdiction and counter-drug activities", with respect to the National Guard of a State, means the use of National Guard personnel in drug interdiction and counter-drug law enforcement activities, including drug demand reduction activities, authorized by the law of the State and requested by the Governor of the State.

(2) The term "Governor of a State" means, in the case of the District of Columbia, the Commanding General of the National Guard of the District of Columbia.

(3) The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or possession of the United States.

38 U.S.C. § 2032

Residents in Veterans therapeutic housing may not use alcohol or controlled substances, must agree to testing, and may be removed for prohibited use

Title 38. Veterans' Benefits

Chapter 20. Benefits for Homeless Veterans

§ 2032. Therapeutic housing [1]

(a) The Secretary, in connection with the conduct of compensated work therapy programs, may operate residences and facilities as therapeutic housing.

(b) The Secretary may use such procurement procedures for the purchase, lease, or other acquisition of residential housing for purposes of this section as the Secretary considers appropriate to expedite the opening and operation of transitional housing and to protect the interests of the United States.

(c) A residence or other facility may be operated as transitional housing for veterans described in paragraphs (1) and (2) of section 1710(a) of this title under the following conditions:

(1) Only veterans described in those paragraphs and a house manager may reside in the residence or facility.

(2) Each resident, other than the house manager, shall be required to make payments that contribute to covering the expenses of board and the operational costs of the residence or facility for the period of residence in such housing.

(3) In order to foster the therapeutic and rehabilitative objectives of such housing (A) residents shall be prohibited from using alcohol or any controlled substance or item, (B) any resident violating that prohibition may be expelled from the residence or facility, and (C) each resident shall agree to undergo drug testing or such other measures as the Secretary shall prescribe to ensure compliance with that prohibition.

(4) In the establishment and operation of housing under this section, the Secretary shall consult with appropriate representatives of the community in which the housing is established and shall comply with zoning requirements, building permit requirements, and other similar requirements applicable to other real property used for similar purposes in the community.

(5) The residence or facility shall meet State and community fire and safety requirements applicable to other real property

[1] Added by Public Law 105–114, Title II, § 202(a), Nov. 21, 1997, 111 Stat. 2284, § 1772; renumbered § 2032, Public Law 107–95, § 5(b)(1), Dec. 21, 2001, 115 Stat. 918.

used for similar purposes in the community in which the transitional housing is located, but fire and safety requirements applicable to buildings of the Federal Government shall not apply to such property.

(d) The Secretary shall prescribe the qualifications for house managers for transitional housing units operated under this section. The Secretary may provide for free room and subsistence for a house manager in addition to, or instead of payment of, a fee for the services provided by the manager.

(e)(1) The Secretary may operate as transitional housing under this section—

(A) any suitable residential property acquired by the Secretary as the result of a default on a loan made, guaranteed, or insured under chapter 37 of this title;

(B) any suitable space in a facility under the jurisdiction of the Secretary that is no longer being used (i) to provide acute hospital care, or (ii) as housing for medical center employees; and

(C) any other suitable residential property purchased, leased, or otherwise acquired by the Secretary.

(2) In the case of any property referred to in paragraph (1)(A), the Secretary shall—

(A) transfer administrative jurisdiction over such property within the Department from the Veterans Benefits Administration to the Veterans Health Administration; and

(B) transfer from the General Post Fund to the Loan Guaranty Revolving Fund under chapter 37 of this title an amount (not to exceed the amount the Secretary paid for the property) representing the amount the Secretary considers could be obtained by sale of such property to a nonprofit organization or a State for use as a shelter for homeless veterans.

(3) In the case of any residential property obtained by the Secretary from the Department of Housing and Urban Development under this section, the amount paid by the Secretary to that Department for that property may not exceed the amount that the Secretary of Housing and Urban Development would charge for the sale of that property to a nonprofit organization or a State for use as a shelter for homeless persons. Funds for such charge shall be derived from the General Post Fund.

(f) The Secretary shall prescribe—

(1) a procedure for establishing reasonable payment rates for persons residing in transitional housing; and

(2) appropriate limits on the period for which such persons may reside in transitional housing.

(g) The Secretary may dispose of any property acquired for the purpose of this section. The proceeds of any such disposal shall be credited to the General Post Fund.

(h) Funds received by the Department under this section shall be deposited in the General Post Fund. The Secretary may distribute out of the fund such amounts as necessary for the acquisition, management, maintenance, and disposition of real property for the purpose of carrying out such program. The Secretary shall manage the operation of this section so as to ensure that expenditures under this subsection for any fiscal year shall not exceed by more than

$500,000 proceeds credited to the General Post Fund under this section. The operation of the program and funds received shall be separately accounted for, and shall be stated in the documents accompanying the President's budget for each fiscal year.

41 U.S.C. § § 701–707
Drug Free Workplace Act, Public Law 100–690, secs. 5152–5158
Drug free workplace requirements for Federal contractors and grantees

Title 41. Public Contracts

Chapter 10. Drug Free Workplace

§ 701. Drug-free workplace requirements for Federal contractors [1]

(a) Drug-free workplace requirement

(1) Requirement for persons other than individuals

No person, other than an individual, shall be considered a responsible source, under the meaning of such term as defined in section 403(8) of this title, for the purposes of being awarded a contract for the procurement of any property or services of a value greater than the simplified acquisition threshold (as defined in section 403(11) of this title) by any Federal agency, other than a contract for the procurement of commercial items (as defined in section 403(12) of this title), unless such person agrees to provide a drug-free workplace by—

(A) publishing a statement notifying employees that the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance is prohibited in the person's workplace and specifying the actions that will be taken against employees for violations of such prohibition;

(B) establishing a drug-free awareness program to inform employees about—

(i) the dangers of drug abuse in the workplace;

(ii) the person's policy of maintaining a drug-free workplace;

(iii) any available drug counseling, rehabilitation, and employee assistance programs; and

(iv) the penalties that may be imposed upon employees for drug abuse violations;

(C) making it a requirement that each employee to be engaged in the performance of such contract be given a copy of the statement required by subparagraph (A);

(D) notifying the employee in the statement required by subparagraph (A), that as a condition of employment on such contract, the employee will—

(i) abide by the terms of the statement; and

[1] Public Law 100–690, Title V, § 5152, Nov. 18, 1988, 102 Stat. 4304; Public Law 103–355, Title IV, § 4104(d), Title VIII, § 8301(f), Oct. 13, 1994, 108 Stat. 3342, 3397; Public Law 104–106, Div. D, Title XLIII, § § 4301(a)(3), 4321(i)(13), Feb. 10, 1996, 110 Stat. 656, 677.

(ii) notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than 5 days after such conviction;

(E) notifying the contracting agency within 10 days after receiving notice under subparagraph (D)(ii) from an employee or otherwise receiving actual notice of such conviction;

(F) imposing a sanction on, or requiring the satisfactory participation in a drug abuse assistance or rehabilitation program by, any employee who is so convicted, as required by section 703 of this title; and

(G) making a good faith effort to continue to maintain a drug-free workplace through implementation of subparagraphs (A), (B), (C), (D), (E), and (F).

(2) Requirement for individuals

No Federal agency shall enter into a contract with an individual unless such individual agrees that the individual will not engage in the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance in the performance of the contract.

(b) Suspension, termination, or debarment of the contractor

(1) Grounds for suspension, termination, or debarment

Each contract awarded by a Federal agency shall be subject to suspension of payments under the contract or termination of the contract, or both, and the contractor thereunder or the individual who entered the contract with the Federal agency, as applicable, shall be subject to suspension or debarment in accordance with the requirements of this section if the head of the agency determines that—

(A) the contractor violates the requirements of subparagraph (A), (B), (C), (D), (E), or (F) of subsection (a)(1) of this section; or

(B) such a number of employees of such contractor have been convicted of violations of criminal drug statutes for violations occurring in the workplace as to indicate that the contractor has failed to make a good faith effort to provide a drug-free workplace as required by subsection (a) of this section.

(2) Conduct of suspension, termination, and debarment proceedings

(A) If a contracting officer determines, in writing, that cause for suspension of payments, termination, or suspension or debarment exists, an appropriate action shall be initiated by a contracting officer of the agency, to be conducted by the agency concerned in accordance with the Federal Acquisition Regulation and applicable agency procedures.

(B) The Federal Acquisition Regulation shall be revised to include rules for conducting suspension and debarment proceedings under this subsection, including rules providing notice, opportunity to respond in writing or in person, and such

other procedures as may be necessary to provide a full and fair proceeding to a contractor or individual in such proceeding.

(3) Effect of debarment

Upon issuance of any final decision under this subsection requiring debarment of a contractor or individual, such contractor or individual shall be ineligible for award of any contract by any Federal agency, and for participation in any future procurement by any Federal agency, for a period specified in the decision, not to exceed 5 years.

§ 702. Drug-free workplace requirements for Federal grant recipients [2]

(a) Drug-free workplace requirement

(1) Persons other than individuals

No person, other than an individual, shall receive a grant from any Federal agency unless such person agrees to provide a drug-free workplace by—

(A) publishing a statement notifying employees that the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violations of such prohibition;

(B) establishing a drug-free awareness program to inform employees about—

(i) the dangers of drug abuse in the workplace;

(ii) the grantee's policy of maintaining a drug-free workplace;

(iii) any available drug counseling, rehabilitation, and employee assistance programs; and

(iv) the penalties that may be imposed upon employees for drug abuse violations;

(C) making it a requirement that each employee to be engaged in the performance of such grant be given a copy of the statement required by subparagraph (A);

(D) notifying the employee in the statement required by subparagraph (A), that as a condition of employment in such grant, the employee will—

(i) abide by the terms of the statement; and

(ii) notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than 5 days after such conviction;

(E) notifying the granting agency within 10 days after receiving notice of a conviction under subparagraph (D)(ii) from an employee or otherwise receiving actual notice of such conviction;

(F) imposing a sanction on, or requiring the satisfactory participation in a drug abuse assistance or rehabilitation program by, any employee who is so convicted, as required by section 703 of this title; and

[2] Public Law 100–690, Title V, § 5153, Nov. 18, 1988, 102 Stat. 4306; Public Law 105–85, Div. A, Title VIII, § 809, Nov. 18, 1997, 111 Stat. 1838.

(G) making a good faith effort to continue to maintain a drug-free workplace through implementation of subparagraphs (A), (B), (C), (D), (E), and (F).

(2) Individuals

No Federal agency shall make a grant to any individual unless such individual agrees as a condition of such grant that the individual will not engage in the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance in conducting any activity with such grant.

(b) Suspension, termination, or debarment of grantee

(1) Grounds for suspension, termination, or debarment

Each grant awarded by a Federal agency shall be subject to suspension of payments under the grant or termination of the grant, or both, and the grantee thereunder shall be subject to suspension or debarment, in accordance with the requirements of this section if the agency head of the granting agency or his official designee determines, in writing, that—

(A) the grantee violates the requirements of subparagraph (A), (B), (C), (D), (E), (F), or (G) of subsection (a)(1) of this section; or

(B) such a number of employees of such grantee have been convicted of violations of criminal drug statutes for violations occurring in the workplace as to indicate that the grantee has failed to make a good faith effort to provide a drug-free workplace as required by subsection (a)(1) of this section.

(2) Conduct of suspension, termination, and debarment proceedings

A suspension of payments, termination, or suspension or debarment proceeding subject to this subsection shall be conducted in accordance with applicable law, including Executive Order 12549 or any superseding Executive order and any regulations promulgated to implement such law or Executive order.

(3) Effect of debarment

Upon issuance of any final decision under this subsection requiring debarment of a grantee, such grantee shall be ineligible for award of any grant from any Federal agency and for participation in any future grant from any Federal agency for a period specified in the decision, not to exceed 5 years.

§ 703. Employee sanctions and remedies [3]

A grantee or contractor shall, within 30 days after receiving notice from an employee of a conviction pursuant to section 701(a)(1)(D)(ii) or 702(a)(1)(D)(ii) of this title—

(1) take appropriate personnel action against such employee up to and including termination; or

(2) require such employee to satisfactorily participate in a drug abuse assistance or rehabilitation program approved for

[3] Public Law 100–690, Title V, § 5154, Nov. 18, 1988, 102 Stat. 4307.

such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency.

§ 704. Waiver[4]

(a) In general

A termination, suspension of payments, or suspension or debarment under this chapter may be waived by the head of an agency with respect to a particular contract or grant if—

(1) in the case of a waiver with respect to a contract, the head of the agency determines under section 701(b)(1) of this title, after the issuance of a final determination under such section, that suspension of payments, or termination of the contract, or suspension or debarment of the contractor, or refusal to permit a person to be treated as a responsible source for a contract, as the case may be, would severely disrupt the operation of such agency to the detriment of the Federal Government or the general public; or

(2) in the case of a waiver with respect to a grant, the head of the agency determines that suspension of payments, termination of the grant, or suspension or debarment of the grantee would not be in the public interest.

(b) Exclusive authority

The authority of the head of an agency under this section to waive a termination, suspension, or debarment shall not be delegated.

§ 705. Regulations[5]

Not later than 90 days after November 18, 1988, the governmentwide regulations governing actions under this chapter shall be issued pursuant to the Office of Federal Procurement Policy Act (41 U.S.C. 401 et seq.).

§ 706. Definitions[6]

For purposes of this chapter—

(1) the term "drug-free workplace" means a site for the performance of work done in connection with a specific grant or contract described in section 701 or 702 of this title of an entity at which employees of such entity are prohibited from engaging in the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance in accordance with the requirements of this Act;

(2) the term "employee" means the employee of a grantee or contractor directly engaged in the performance of work pursuant to the provisions of the grant or contract described in section 701 or 702 of this title;

(3) the term "controlled substance" means a controlled substance in schedules I through V of section 812 of Title 21;

(4) the term "conviction" means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both,

[4] Public Law 100–690, Title V, § 5155, Nov. 18, 1988, 102 Stat. 4307.
[5] Public Law 100–690, Title V, § 5156, Nov. 18, 1988, 102 Stat. 4308.
[6] Public Law 100–690, Title V, § 5157, Nov. 18, 1988, 102 Stat. 4308.

by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

(5) the term "criminal drug statute" means a criminal statute involving manufacture, distribution, dispensation, use, or possession of any controlled substance;

(6) the term "grantee" means the department, division, or other unit of a person responsible for the performance under the grant;

(7) the term "contractor" means the department, division, or other unit of a person responsible for the performance under the contract; and

(8) the term "Federal agency" means an agency as that term is defined in section 552(f) of Title 5.

§ 707. Construction of chapter[7]

Nothing in this chapter shall be construed to require law enforcement agencies, if the head of the agency determines it would be inappropriate in connection with the agency's undercover operations, to comply with the provisions of this chapter.

[7] Public Law 100–690, Title V, § 5158, Nov. 18, 1988, 102 Stat. 4308.

42 U.S.C. § 1320a–7

Social Security Act, Public Law 74–271 (Act of August 14, 1935), sec. 1128

Exclusion of individuals convicted of certain controlled substance offenses from participation in Medicare and State health care programs

Title 42. The Public Health and Welfare

Chapter 7. Social Security

§ 1320a–7. Exclusion of certain individuals and entities from participation in Medicare and State health care programs [1]

(a) Mandatory exclusion

The Secretary shall exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a–7b(f) of this title):

(1) Conviction of program-related crimes

Any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under subchapter XVIII of this chapter or under any State health care program.

(2) Conviction relating to patient abuse

Any individual or entity that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service.

(3) Felony conviction relating to health care fraud

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health

[1] Aug. 14, 1935, c. 531, Title XI, § 1128, as added Dec. 5, 1980, Public Law 96–499, Title IX, § 913(a), 94 Stat. 2619, and amended Aug. 13, 1981, Public Law 97–35, Title XXI, § 2105(b), Title XXIII, § 2353(k), 95 Stat. 791, 873; July 18, 1984, Public Law 98–369, Div. B, Title III, § 2333(a), (b), 98 Stat. 1089; Oct. 21, 1986, Public Law 99–509, Title IX, § 9317(c), 100 Stat. 2008; Aug. 18, 1987, Public Law 100–93, § 2, 101 Stat. 680; Dec. 22, 1987, Public Law 100–203, Title IV, § 4118(e)(2), 101 Stat. 1330–155; Dec. 22, 1987, Public Law 100–203, Title IV, § 4118(e)(3) to (5), as added July 1, 1988, Public Law 100–360, Title IV, § 411(k)(10)(D), 102 Stat. 795; July 1, 1988, Public Law 100–360, Title IV, § 411(k)(10)(C), 102 Stat. 795; Dec. 19, 1989, Public Law 101–239, Title VI, § 6411(d)(1), 103 Stat. 2270; Nov. 5, 1990, Public Law 101–508, Title IV, § 4164(b)(3), 104 Stat. 1388–102; June 13, 1991, Public Law 102–54, § 13(q)(3)(A)(ii), 105 Stat. 279; Aug. 15, 1994, Public Law 103–296, Title I, § 108(b)(9), Title II, § 206(b)(2), 108 Stat. 1483, 1513; Aug. 21, 1996, Public Law 104–191, Title II, §§ 211 to 213, 110 Stat. 2003 to 2005; Aug. 5, 1997, Public Law 105–33, Title IV, §§ 4301, 4303(a), 4331(c), 4901(b)(2), 111 Stat. 382, 396, 570; Dec. 8, 2003, Public Law 108–173, Title IX, § 949, 117 Stat. 2426.

care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

(4) Felony conviction relating to controlled substance

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

(b) Permissive exclusion

The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a–7b(f) of this title):

(1) Conviction relating to fraud

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law—

(A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) in connection with the delivery of a health care item or service, or

(ii) with respect to any act or omission in a health care program (other than those specifically described in subsection (a)(1) of this section) operated by or financed in whole or in part by any Federal, State, or local government agency; or

(B) of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program (other than a health care program) operated by or financed in whole or in part by any Federal, State, or local government agency.

(2) Conviction relating to obstruction of an investigation

Any individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation into any criminal offense described in paragraph (1) or in subsection (a) of this section.

(3) Misdemeanor conviction relating to controlled substance

Any individual or entity that has been convicted, under Federal or State law, of a criminal offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

(4) License revocation or suspension

Any individual or entity—

(A) whose license to provide health care has been revoked or suspended by any State licensing authority, or who otherwise lost such a license or the right to apply for or renew such a license, for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity, or

(B) who surrendered such a license while a formal disciplinary proceeding was pending before such an authority and the proceeding concerned the individual's or entity's professional competence, professional performance, or financial integrity.

(5) Exclusion or suspension under Federal or State health care program

Any individual or entity which has been suspended or excluded from participation, or otherwise sanctioned, under—

(A) any Federal Program, including programs of the Department of Defense or the Department of Veterans Affairs, involving the provision of health care, or

(B) a State health care program,

for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity.

(6) Claims for excessive charges or unnecessary services and failure of certain organizations to furnish medically necessary services

Any individual or entity that the Secretary determines—

(A) has submitted or caused to be submitted bills or requests for payment (where such bills or requests are based on charges or cost) under subchapter XVIII of this chapter or a State health care program containing charges (or, in applicable cases, requests for payment of costs) for items or services furnished substantially in excess of such individual's or entity's usual charges (or, in applicable cases, substantially in excess of such individual's or entity's costs) for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs;

(B) has furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under subchapter XVIII of this chapter or under a State health care program) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care;

(C) is—

(i) a health maintenance organization (as defined in section 1396b(m) of this title) providing items and services under a State plan approved under subchapter XIX of this chapter, or

(ii) an entity furnishing services under a waiver approved under section 1396n(b)(1) of this title,

and has failed substantially to provide medically necessary items and services that are required (under law or the contract with the State under subchapter XIX of this chapter) to be provided to individuals covered under that plan or waiver, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals; or

(D) is an entity providing items and services as an eligible organization under a risk-sharing contract under section 1395mm of this title and has failed substantially to provide medically necessary items and services that are required (under law or such contract) to be provided to individuals covered under the risk-sharing contract, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals.

(7) Fraud, kickbacks, and other prohibited activities

Any individual or entity that the Secretary determines has committed an act which is described in section 1320a–7a, 1320a–7b, or 1320a–8 of this title.

(8) Entities controlled by a sanctioned individual

Any entity with respect to which the Secretary determines that a person—

(A)(i) who has a direct or indirect ownership or control interest of 5 percent or more in the entity or with an ownership or control interest (as defined in section 1320a–3(a)(3) of this title) in that entity,

(ii) who is an officer, director, agent, or managing employee (as defined in section 1320a–5(b) of this title) of that entity; or

(iii) who was described in clause (i) but is no longer so described because of a transfer of ownership or control interest, in anticipation of (or following) a conviction, assessment, or exclusion described in subparagraph (B) against the person, to an immediate family member (as defined in subsection (j)(1) of this section) or a member of the household of the person (as defined in subsection (j)(2) of this section) who continues to maintain an interest described in such clause—

is a person—

(B)(i) who has been convicted of any offense described in subsection (a) of this section or in paragraph (1), (2), or (3) of this subsection;

(ii) against whom a civil monetary penalty has been assessed under section 1320a–7a or 1320a–8 of this title; or

(iii) who has been excluded from participation under a program under subchapter XVIII of this chapter or under a State health care program.

(9) Failure to disclose required information

Any entity that did not fully and accurately make any disclosure required by section 1320a–3 of this title, section 1320a–3a of this title, or section 1320a–5 of this title.

(10) Failure to supply requested information on subcontractors and suppliers

Any disclosing entity (as defined in section 1320a–3(a)(2) of this title) that fails to supply (within such period as may be specified by the Secretary in regulations) upon request specifically addressed to the entity by the Secretary or by the State agency administering or supervising the administration of a State health care program—

(A) full and complete information as to the ownership of a subcontractor (as defined by the Secretary in regulations) with whom the entity has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000, or

(B) full and complete information as to any significant business transactions (as defined by the Secretary in regulations), occurring during the five-year period ending on the date of such request, between the entity and any wholly owned supplier or between the entity and any subcontractor.

(11) Failure to supply payment information

Any individual or entity furnishing items or services for which payment may be made under subchapter XVIII of this chapter or a State health care program that fails to provide such information as the Secretary or the appropriate State agency finds necessary to determine whether such payments are or were due and the amounts thereof, or has refused to permit such examination of its records by or on behalf of the Secretary or that agency as may be necessary to verify such information.

(12) Failure to grant immediate access

Any individual or entity that fails to grant immediate access, upon reasonable request (as defined by the Secretary in regulations) to any of the following:

(A) To the Secretary, or to the agency used by the Secretary, for the purpose specified in the first sentence of section 1395aa(a) of this title (relating to compliance with conditions of participation or payment).

(B) To the Secretary or the State agency, to perform the reviews and surveys required under State plans under paragraphs (26), (31), and (33) of section 1396a(a) of this title and under section 1396b(g) of this title.

(C) To the Inspector General of the Department of Health and Human Services, for the purpose of reviewing records, documents, and other data necessary to the performance of the statutory functions of the Inspector General.

(D) To a State medicaid fraud control unit (as defined in section 1396b(q) of this title), for the purpose of conducting activities described in that section.

(13) Failure to take corrective action

Any hospital that fails to comply substantially with a corrective action required under section 1395ww(f)(2)(B) of this title.

(14) Default on health education loan or scholarship obligations

Any individual who the Secretary determines is in default on repayments of scholarship obligations or loans in connection with health professions education made or secured, in whole or in part, by the Secretary and with respect to whom the Secretary has taken all reasonable steps available to the Secretary to secure repayment of such obligations or loans, except that (A) the Secretary shall not exclude pursuant to this paragraph a physician who is the sole community physician or sole source of essential specialized services in a community if a State requests that the physician not be excluded, and (B) the Secretary shall take into account, in determining whether to exclude any other physician pursuant to this paragraph, access of beneficiaries to physician services for which payment may be made under subchapter XVIII or XIX of this chapter.

(15) Individuals controlling a sanctioned entity

(A) Any individual—

(i) who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know (as defined in section 1320a–7a(i)(6)[2] of this title) of the action constituting the basis for the conviction or exclusion described in subparagraph (B); or

(ii) who is an officer or managing employee (as defined in section 1320a–5(b) of this title) of such an entity.

(B) For purposes of subparagraph (A), the term "sanctioned entity" means an entity—

(i) that has been convicted of any offense described in subsection (a) of this section or in paragraph (1), (2), or (3) of this subsection; or

(ii) that has been excluded from participation under a program under subchapter XVIII of this chapter or under a State health care program.

(c) Notice, effective date, and period of exclusion

(1) An exclusion under this section or under section 1320a–7a of this title shall be effective at such time and upon such reasonable notice to the public and to the individual or entity excluded as may be specified in regulations consistent with paragraph (2).

(2)(A) Except as provided in subparagraph (B), such an exclusion shall be effective with respect to services furnished to an individual on or after the effective date of the exclusion.

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[2] So in original. Probably should be section "1320a–7a(i)(7)".

(B) Unless the Secretary determines that the health and safety of individuals receiving services warrants the exclusion taking effect earlier, an exclusion shall not apply to payments made under subchapter XVIII of this chapter or under a State health care program for—

(i) inpatient institutional services furnished to an individual who was admitted to such institution before the date of the exclusion, or

(ii) home health services and hospice care furnished to an individual under a plan of care established before the date of the exclusion,

until the passage of 30 days after the effective date of the exclusion.

(3)(A) The Secretary shall specify, in the notice of exclusion under paragraph (1) and the written notice under section 1320a–7a of this title, the minimum period (or, in the case of an exclusion of an individual under subsection (b)(12) of this section or in the case described in subparagraph (G), the period) of the exclusion.

(B) Subject to subparagraph (G), in the case of an exclusion under subsection (a) of this section, the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1320–7b(f) of this title) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of subchapter XVIII of this chapter or enrolled under part B of subchapter VIII of this chapter, or both, the Secretary may, after consulting with the Inspector General of the Department of Health and Human Services, waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) of this section with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. The Secretary's decision whether to waive the exclusion shall not be reviewable.

(C) In the case of an exclusion of an individual under subsection (b)(12) of this section, the period of the exclusion shall be equal to the sum of—

(i) the length of the period in which the individual failed to grant the immediate access described in that subsection, and

(ii) an additional period, not to exceed 90 days, set by the Secretary.

(D) Subject to subparagraph (G), in the case of an exclusion of an individual or entity under paragraph (1), (2), or (3) of subsection (b) of this section, the period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances.

(E) In the case of an exclusion of an individual or entity under subsection (b)(4) or (b)(5) of this section, the period of the exclusion shall not be less than the period during which the individual's or entity's license to provide health care is revoked, suspended, or surrendered, or the individual or the entity is excluded or suspended from a Federal or State health care program.

(F) In the case of an exclusion of an individual or entity under subsection (b)(6)(B) of this section, the period of the exclusion shall be not less than 1 year.

(G) In the case of an exclusion of an individual under subsection (a) of this section based on a conviction occurring on or after August 5, 1997, if the individual has (before, on, or after August 5, 1997) been convicted—

(i) on one previous occasion of one or more offenses for which an exclusion may be effected under such subsection, the period of the exclusion shall be not less than 10 years, or

(ii) on 2 or more previous occasions of one or more offenses for which an exclusion may be effected under such subsection, the period of the exclusion shall be permanent.

(d) Notice to State agencies and exclusion under State health care programs

(1) Subject to paragraph (3), the Secretary shall exercise the authority under this section and section 1320a–7a of this title in a manner that results in an individual's or entity's exclusion from all the programs under subchapter XVIII of this chapter and all the State health care programs in which the individual or entity may otherwise participate.

(2) The Secretary shall promptly notify each appropriate State agency administering or supervising the administration of each State health care program (and, in the case of an exclusion effected pursuant to subsection (a) of this section and to which section 824(a)(5) of Title 21 may apply, the Attorney General)—

(A) of the fact and circumstances of each exclusion effected against an individual or entity under this section or section 1320a–7a of this title, and

(B) of the period (described in paragraph (3)) for which the State agency is directed to exclude the individual or entity from participation in the State health care program.

(3)(A) Except as provided in subparagraph (B), the period of the exclusion under a State health care program under paragraph (2) shall be the same as any period of exclusion under subchapter XVIII of this chapter.

(B)(i) The Secretary may waive an individual's or entity's exclusion under a State health care program under paragraph (2) if the Secretary receives and approves a request for the waiver with respect to the individual or entity from the State agency administering or supervising the administration of the program.

(ii) A State health care program may provide for a period of exclusion which is longer than the period of exclusion under subchapter XVIII of this chapter.

(e) Notice to State licensing agencies

The Secretary shall—

(1) promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation under this section or section 1320a–7a of this title, of the fact and circumstances of the exclusion,

(2) request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and

(3) request that the State or local agency or authority keep the Secretary and the Inspector General of the Department of Health and Human Services fully and currently informed with respect to any actions taken in response to the request.

(f) Notice, hearing, and judicial review

(1) Subject to paragraph (2), any individual or entity that is excluded (or directed to be excluded) from participation under this section is entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and section 405(l) of this title, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(2) Unless the Secretary determines that the health or safety of individuals receiving services warrants the exclusion taking effect earlier, any individual or entity that is the subject of an adverse determination under subsection (b)(7) of this section shall be entitled to a hearing by an administrative law judge (as provided under section 405(b) of this title) on the determination under subsection (b)(7) of this section before any exclusion based upon the determination takes effect.

(3) The provisions of section 405(h) of this title shall apply with respect to this section and sections 1320a–7a, 1320a–8, and 1320c–5 of this title to the same extent as it is applicable with respect to subchapter II of this chapter, except that, in so applying such section and section 405(l) of this title, any reference therein to the Commissioner of Social Security shall be considered a reference to the Secretary.

(g) Application for termination of exclusion

(1) An individual or entity excluded (or directed to be excluded) from participation under this section or section 1320a–7a of this title may apply to the Secretary, in the manner specified by the Secretary in regulations and at the end of the minimum period of exclusion provided under subsection (c)(3) of this section and at such other times as the Secretary may provide, for termination of the exclusion effected under this section or section 1320a–7a of this title.

(2) The Secretary may terminate the exclusion if the Secretary determines, on the basis of the conduct of the applicant which occurred after the date of the notice of exclusion or which was unknown to the Secretary at the time of the exclusion, that—

(A) there is no basis under subsection (a) or (b) of this section or section 1320a–7a(a) of this title for a continuation of the exclusion, and

(B) there are reasonable assurances that the types of actions which formed the basis for the original exclusion have not recurred and will not recur.

(3) The Secretary shall promptly notify each appropriate State agency administering or supervising the administration of each State health care program (and, in the case of an exclusion effected pursuant to subsection (a) of this section and to which section 824(a)(5) of Title 21 may apply, the Attorney General) of the fact and circumstances of each termination of exclusion made under this subsection.

(h) "State health care program" defined

For purposes of this section and sections 1320a–7a and 1320a–7b of this title, the term "State health care program" means—

(1) a State plan approved under subchapter XIX of this chapter,

(2) any program receiving funds under subchapter V of this chapter or from an allotment to a State under such subchapter,

(3) any program receiving funds under subchapter XX of this chapter or from an allotment to a State under such subchapter, or

(4) a State child health plan approved under subchapter XXI of this chapter.

(i) "Convicted" defined

For purposes of subsections (a) and (b) of this section, an individual or entity is considered to have been "convicted" of a criminal offense—

(1) when a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged;

(2) when there has been a finding of guilt against the individual or entity by a Federal, State, or local court;

(3) when a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court; or

(4) when the individual or entity has entered into participation in a first offender, deferred adjudication, or other arrangement or program where judgment of conviction has been withheld.

(j) Definition of immediate family member and member of household

For purposes of subsection (b)(8)(A)(iii) of this section:

(1) The term "immediate family member" means, with respect to a person—

(A) the husband or wife of the person;

(B) the natural or adoptive parent, child, or sibling of the person;

(C) the stepparent, stepchild, stepbrother, or stepsister of the person;

(D) the father-, mother-, daughter-, son-, brother-, or sister-in-law of the person;

(E) the grandparent or grandchild of the person; and

(F) the spouse of a grandparent or grandchild of the person.

(2) The term "member of the household" means, with respect to any person, any individual sharing a common abode as part of a single family unit with the person, including domestic employees and others who live together as a family unit, but not including a roomer or boarder.

42 U.S.C. § 1396n

Social Security Act, Public Law 74–271 (Act of August 14, 1935), sec. 1915

Waivers to permit inclusion in a State's medical assistance plan of children dependent at birth on heroin, cocaine, or phencyclidine

§ 1396n. Compliance with State plan and payment provisions [1]

(a) Activities deemed as compliance

A State shall not be deemed to be out of compliance with the requirements of paragraphs (1), (10), or (23) of section 1396a(a) of this title solely by reason of the fact that the State (or any political subdivision thereof)—

(1) has entered into—

(A) a contract with an organization which has agreed to provide care and services in addition to those offered under the State plan to individuals eligible for medical assistance who reside in the geographic area served by such organization and who elect to obtain such care and services from such organization, or by reason of the fact that the plan provides for payment for rural health clinic services only if those services are provided by a rural health clinic; or

(B) arrangements through a competitive bidding process or otherwise for the purchase of laboratory services referred to in section 1396d(a)(3) of this title or medical devices if the Secretary has found that—

(i) adequate services or devices will be available under such arrangements, and

(ii) any such laboratory services will be provided only through laboratories—

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[1] Aug. 14, 1935, c. 531, Title XIX, § 1915, as added and amended Aug. 13, 1981, Public Law 97–35, Title XXI, §§ 2175(b), 2176, 2177(a), 95 Stat. 809, 812, 813; Sept. 3, 1982, Public Law 97–248, Title I, § 137(b)(19)(A), (20) to (25), 96 Stat. 380; Jan. 12, 1983, Public Law 97–448, Title III, § 309(b)(17), 96 Stat. 2409; July 18, 1984, Public Law 98–369, Div. B, Title III, § 2373(b)(21), 98 Stat. 1112; Apr. 7, 1986, Public Law 99–272, Title IX, §§ 9502(a) to (e), (g) to (i), 9508(a), 100 Stat. 202 to 204, 210; Oct. 21, 1986, Public Law 99–509, Title IX, §§ 9320(h)(3), 9411(a) to (d), 100 Stat. 2016, 2061, 2062; Aug. 18, 1987, Public Law 100–93, § 8(h)(2), 101 Stat. 694; Dec. 22, 1987, Public Law 100–203, Title IV, §§ 4072(d), 4102(a)(1), (b)(2), § 4118(a)(1), (b), (i)(1), (k), (l)(1), (p)(10), 4211(h)(10), 101 Stat. 1330–117, 1330–143, 1330–146, 1330–154 to 1330–157, 1330–160, 1330–206; July 1, 1988, Public Law 100–360, Title II, § 204(d)(3), Title IV, § 411(k)(3), (10)(A), (H), (I), (17)(A), (l)(3)(G), 102 Stat. 729, 791, 794, 796, 799, 803; Oct. 13, 1988, Public Law 100–485, Title VI, § 608(d)(26)(M), (f)(2), 102 Stat. 2422, 2424; Nov. 10, 1988, Public Law 100–647, Title VIII, §§ 8432(a), (b), 8437(a), 102 Stat. 3804, 3806; Dec. 13, 1989, Public Law 101–234, Title II, § 201(a), 103 Stat. 1981; Dec. 19, 1989, Public Law 101–239, Title VI, §§ 6115(c), 6411(c)(2), 103 Stat. 2219, 2270; Nov. 5, 1990, Public Law 101–508, Title IV, §§ 4604(c), 4704(b)(3), 4741, 4742(a), (c)(1), (d)(1), 105 Stat. 1388–169, 1388–172, 1388–197, 1388–198; Oct. 7, 1991, Public Law 102–119, § 26(i)(2), 105 Stat. 607; Aug. 10, 1993, Public Law 103–66, Title XIII, § 13603(d), 107 Stat. 620; Aug. 5, 1997, Public Law 105–33, Title IV, §§ 4106(c), 4743(a), 111 Stat. 368, 524; Nov. 29, 1999, Public Law 106–113, Div. B, § 1000(a)(6) [Title VI, § 608(o)], 113 Stat. 1536, 1501A–397; Dec. 21, 2000, Public Law 106–554, § 1(a) (6) [Title VII, § 702(c)(2)], 114 Stat. 2763, 2763A–574; Jan. 15, 2002, Public Law 107–121, § 2(b)(3), 115 Stat. 2384; Dec. 3, 2004, Public Law 108–446, Title III, § 305(j)(2), 118 Stat. 2806.

(I) which meet the applicable requirements of section 1395x(e)(9) of this title or paragraphs (16) and (17) of section 1395x(s) of this title, and such additional requirements as the Secretary may require, and

(II) no more than 75 percent of whose charges for such services are for services provided to individuals who are entitled to benefits under this subchapter or under part A or part B of subchapter XVIII of this chapter; or

(2) restricts for a reasonable period of time the provider or providers from which an individual (eligible for medical assistance for items or services under the State plan) can receive such items or services, if—

(A) the State has found, after notice and opportunity for a hearing (in accordance with procedures established by the State), that the individual has utilized such items or services at a frequency or amount not medically necessary (as determined in accordance with utilization guidelines established by the State), and

(B) under such restriction, individuals eligible for medical assistance for such services have reasonable access (taking into account geographic location and reasonable travel time) to such services of adequate quality.

(b) Waivers to promote cost-effectiveness and efficiency

The Secretary, to the extent he finds it to be cost-effective and efficient and not inconsistent with the purposes of this subchapter, may waive such requirements of section 1396a of this title (other than subsection (s) of this section)[2] (other than sections 1396a(a)(15), 1396a(bb), and 1396a(a)(10)(A) of this title insofar as it requires provision of the care and services described in section 1396d(a)(2)(C) of this title) as may be necessary for a State—

(1) to implement a primary care case-management system or a specialty physician services arrangement which restricts the provider from (or through) whom an individual (eligible for medical assistance under this subchapter) can obtain medical care services (other than in emergency circumstances), if such restriction does not substantially impair access to such services of adequate quality where medically necessary,

(2) to allow a locality to act as a central broker in assisting individuals (eligible for medical assistance under this subchapter) in selecting among competing health care plans, if such restriction does not substantially impair access to services of adequate quality where medically necessary,

(3) to share (through provision of additional services) with recipients of medical assistance under the State plan cost savings resulting from use by the recipient of more cost-effective medical care, and

(4) to restrict the provider from (or through) whom an individual (eligible for medical assistance under this subchapter) can obtain services (other than in emergency circumstances) to

[2] So in original.

providers or practitioners who undertake to provide such services and who meet, accept, and comply with the reimbursement, quality, and utilization standards under the State plan, which standards shall be consistent with the requirements of section 1396r-4 of this title and are consistent with access, quality, and efficient and economic provision of covered care and services, if such restriction does not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services and if providers under such restriction are paid on a timely basis in the same manner as health care practitioners must be paid under section 1396a(a)(37)(A) of this title.

No waiver under this subsection may restrict the choice of the individual in receiving services under section 1396d(a)(4)(C) of this title.

(c) Waiver respecting medical assistance requirement in State plan: scope, etc.; "habilitation services" defined; imposition of certain regulatory limits prohibited; computation of expenditures for certain disabled patients; coordinated services; substitution of participants

(1) The Secretary may by waiver provide that a State plan approved under this subchapter may include as "medical assistance" under such plan payment for part or all of the cost of home or community-based services (other than room and board) approved by the Secretary which are provided pursuant to a written plan of care to individuals with respect to whom there has been a determination that but for the provision of such services the individuals would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan. For purposes of this subsection, the term "room and board" shall not include an amount established under a method determined by the State to reflect the portion of costs of rent and food attributable to an unrelated personal caregiver who is residing in the same household with an individual who, but for the assistance of such caregiver, would require admission to a hospital, nursing facility, or intermediate care facility for the mentally retarded.

(2) A waiver shall not be granted under this subsection unless the State provides assurances satisfactory to the Secretary that—

(A) necessary safeguards (including adequate standards for provider participation) have been taken to protect the health and welfare of individuals provided services under the waiver and to assure financial accountability for funds expended with respect to such services;

(B) the State will provide, with respect to individuals who—

(i) are entitled to medical assistance for inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded under the State plan,

(ii) may require such services, and

(iii) may be eligible for such home or community-based care under such waiver,

for an evaluation of the need for inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded;

(C) such individuals who are determined to be likely to require the level of care provided in a hospital, nursing facility, or intermediate care facility for the mentally retarded are informed of the feasible alternatives, if available under the waiver, at the choice of such individuals, to the provision of inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded;

(D) under such waiver the average per capita expenditure estimated by the State in any fiscal year for medical assistance provided with respect to such individuals does not exceed 100 percent of the average per capita expenditure that the State reasonably estimates would have been made in that fiscal year for expenditures under the State plan for such individuals if the waiver had not been granted; and

(E) the State will provide to the Secretary annually, consistent with a data collection plan designed by the Secretary, information on the impact of the waiver granted under this subsection on the type and amount of medical assistance provided under the State plan and on the health and welfare of recipients.

(3) A waiver granted under this subsection may include a waiver of the requirements of section 1396a(a)(1) of this title (relating to statewideness), section 1396a(a)(10)(B) of this title (relating to comparability), and section 1396a(a)(10)(C)(i)(III) of this title (relating to income and resource rules applicable in the community). A waiver under this subsection shall be for an initial term of three years and, upon the request of a State, shall be extended for additional five-year periods unless the Secretary determines that for the previous waiver period the assurances provided under paragraph (2) have not been met. A waiver may provide, with respect to post-eligibility treatment of income of all individuals receiving services under that waiver, that the maximum amount of the individual's income which may be disregarded for any month for the maintenance needs of the individual may be an amount greater than the maximum allowed for that purpose under regulations in effect on July 1, 1985.

(4) A waiver granted under this subsection may, consistent with paragraph (2)—

(A) limit the individuals provided benefits under such waiver to individuals with respect to whom the State has determined that there is a reasonable expectation that the amount of medical assistance provided with respect to the individual under such waiver will not exceed the amount of such medical assistance provided for such individual if the waiver did not apply, and

(B) provide medical assistance to individuals (to the extent consistent with written plans of care, which are subject to the approval of the State) for case management services, homemaker/home health aide services and personal care services, adult day health services, habilitation services, respite care,

and such other services requested by the State as the Secretary may approve and for day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services (whether or not furnished in a facility) for individuals with chronic mental illness.

Except as provided under paragraph (2)(D), the Secretary may not restrict the number of hours or days of respite care in any period which a State may provide under a waiver under this subsection.

(5) For purposes of paragraph (4)(B), the term ''habilitation services''—

(A) means services designed to assist individuals in acquiring, retaining, and improving the self-help, socialization, and adaptive skills necessary to reside successfully in home and community based settings; and

(B) includes (except as provided in subparagraph (C)) prevocational, educational, and supported employment services; but

(C) does not include—

(i) special education and related services (as such terms are defined in section 1401 of Title 20), which otherwise are available to the individual through a local educational agency; and

(ii) vocational rehabilitation services which otherwise are available to the individual through a program funded under section 730 of Title 29.

(6) The Secretary may not require, as a condition of approval of a waiver under this section under paragraph (2)(D), that the actual total expenditures for home and community-based services under the waiver (and a claim for Federal financial participation in expenditures for the services) cannot exceed the approved estimates for these services. The Secretary may not deny Federal financial payment with respect to services under such a waiver on the ground that, in order to comply with paragraph (2)(D), a State has failed to comply with such a requirement.

(7)(A) In making estimates under paragraph (2)(D) in the case of a waiver that applies only to individuals with a particular illness or condition who are inpatients in, or who would require the level of care provided in, hospitals, nursing facilities, or intermediate care facilities for the mentally retarded, the State may determine the average per capita expenditure that would have been made in a fiscal year for those individuals under the State plan separately from the expenditures for other individuals who are inpatients in, or who would require the level of care provided in, those respective facilities.

(B) In making estimates under paragraph (2)(D) in the case of a waiver that applies only to individuals with developmental disabilities who are inpatients in a nursing facility and whom the State has determined, on the basis of an evaluation under paragraph (2)(B), to need the level of services provided by an intermediate care facility for the mentally retarded, the State may determine the average per capita expenditures that would have been made in a fiscal year for those individuals under the State plan on the basis of the average per capita expenditures under the State plan for services to individuals who are inpatients in an intermediate care

facility for the mentally retarded, without regard to the availability of beds for such inpatients.

(C) In making estimates under paragraph (2)(D) in the case of a waiver to the extent that it applies to individuals with mental retardation or a related condition who are resident in an intermediate care facility for the mentally retarded the participation of which under the State plan is terminated, the State may determine the average per capita expenditures that would have been made in a fiscal year for those individuals without regard to any such termination.

(8) The State agency administering the plan under this subchapter may, whenever appropriate, enter into cooperative arrangements with the State agency responsible for administering the program for children with special health care needs under subchapter V of this chapter in order to assure improved access to coordinated services to meet the needs of such children.

(9) In the case of any waiver under this subsection which contains a limit on the number of individuals who shall receive home or community-based services, the State may substitute additional individuals to receive such services to replace any individuals who die or become ineligible for services under the State plan.

(10) The Secretary shall not limit to fewer than 200 the number of individuals in the State who may receive home and community-based services under a waiver under this subsection.

(d) Home and community-based services for elderly

(1) Subject to paragraph (2), the Secretary shall grant a waiver to provide that a State plan approved under this subchapter shall include as "medical assistance" under such plan payment for part or all of the cost of home or community-based services (other than room and board) which are provided pursuant to a written plan of care to individuals 65 years of age or older with respect to whom there has been a determination that but for the provision of such services the individuals would be likely to require the level of care provided in a skilled nursing facility or intermediate care facility the cost of which could be reimbursed under the State plan. For purposes of this subsection, the term "room and board" shall not include an amount established under a method determined by the State to reflect the portion of costs of rent and food attributable to an unrelated personal caregiver who is residing in the same household with an individual who, but for the assistance of such caregiver, would require admission to a hospital, nursing facility, or intermediate care facility for the mentally retarded.

(2) A waiver shall not be granted under this subsection unless the State provides assurances satisfactory to the Secretary that—

(A) necessary safeguards (including adequate standards for provider participation) have been taken to protect the health and welfare of individuals provided services under the waiver and to assure financial accountability for funds expended with respect to such services;

(B) with respect to individuals 65 years of age or older who—

(i) are entitled to medical assistance for skilled nursing or intermediate care facility services under the State plan,

(ii) may require such services, and

(iii) may be eligible for such home or community-based services under such waiver,

the State will provide for an evaluation of the need for such skilled nursing facility or intermediate care facility services; and

(C) such individuals who are determined to be likely to require the level of care provided in a skilled nursing facility or intermediate care facility are informed of the feasible alternatives to the provision of skilled nursing facility or intermediate care facility services, which such individuals may choose if available under the waiver.

Each State with a waiver under this subsection shall provide to the Secretary annually, consistent with a reasonable data collection plan designed by the Secretary, information on the impact of the waiver granted under this subsection on the type and amount of medical assistance provided under the State plan and on the health and welfare of recipients.

(3) A waiver granted under this subsection may include a waiver of the requirements of section 1396a(a)(1) of this title (relating to statewideness), section 1396a(a)(10)(B) of this title (relating to comparability), and section 1396a(a)(10)(C)(i)(III) of this title (relating to income and resource rules applicable in the community). Subject to a termination by the State (with notice to the Secretary) at any time, a waiver under this subsection shall be for an initial term of 3 years and, upon the request of a State, shall be extended for additional 5-year periods unless the Secretary determines that for the previous waiver period the assurances provided under paragraph (2) have not been met. A waiver may provide, with respect to post-eligibility treatment of income of all individuals receiving services under the waiver, that the maximum amount of the individual's income which may be disregarded for any month is equal to the amount that may be allowed for that purpose under a waiver under subsection (c) of this section.

(4) A waiver under this subsection may, consistent with paragraph (2), provide medical assistance to individuals for case management services, homemaker/home health aide services and personal care services, adult day health services, respite care, and other medical and social services that can contribute to the health and well-being of individuals and their ability to reside in a community-based care setting.

(5)(A) In the case of a State having a waiver approved under this subsection, notwithstanding any other provision of section 1396b of this title to the contrary, the total amount expended by the State for medical assistance with respect to skilled nursing facility services, intermediate care facility services, and home and community-based services under the State plan for individuals 65 years of age or older during a waiver year under this subsection may not exceed the projected amount determined under subparagraph (B).

(B) For purposes of subparagraph (A), the projected amount under this subparagraph is the sum of the following:

(i) The aggregate amount of the State's medical assistance under this subchapter for skilled nursing facility services and intermediate care facility services furnished to individuals who have attained the age of 65 for the base year increased by a

percentage which is equal to the lesser of 7 percent times the number of years (rounded to the nearest quarter of a year) beginning after the base year and ending at the end of the waiver year involved or the sum of—

(I) the percentage increase (based on an appropriate market-basket index representing the costs of elements of such services) between the beginning of the base year and the beginning of the waiver year involved, plus

(II) the percentage increase between the beginning of the base year and the beginning of the waiver year involved in the number of residents in the State who have attained the age of 65, plus

(III) 2 percent for each year (rounded to the nearest quarter of a year) beginning after the base year and ending at the end of the waiver year.

(ii) The aggregate amount of the State's medical assistance under this subchapter for home and community-based services for individuals who have attained the age of 65 for the base year increased by a percentage which is equal to the lesser of 7 percent times the number of years (rounded to the nearest quarter of a year) beginning after the base year and ending at the end of the waiver year involved or the sum of—

(I) the percentage increase (based on an appropriate market-basket index representing the costs of elements of such services) between the beginning of the base year and the beginning of the waiver year involved, plus

(II) the percentage increase between the beginning of the base year and the beginning of the waiver year involved in the number of residents in the State who have attained the age of 65, plus

(III) 2 percent for each year (rounded to the nearest quarter of a year) beginning after the base year and ending at the end of the waiver year.

(iii) The Secretary shall develop and promulgate by regulation (by not later than October 1, 1989)—

(I) a method, based on an index of appropriately weighted indicators of changes in the wages and prices of the mix of goods and services which comprise both skilled nursing facility services and intermediate care facility services (regardless of the source of payment for such services), for projecting the percentage increase for purposes of clause (i)(I);

(II) a method, based on an index of appropriately weighted indicators of changes in the wages and prices of the mix of goods and services which comprise home and community-based services (regardless of the source of payment for such services), for projecting the percentage increase for purposes of clause (ii)(I); and

(III) a method for projecting, on a State specific basis, the percentage increase in the number of residents in each State who are over 65 years of age for any period.

The Secretary shall develop (by not later than October 1, 1989) a method for projecting, on a State-specific basis, the percentage increase in the number of residents in each State who are

over 65 years of age for any period. Effective on and after the date the Secretary promulgates the regulation under clause (iii), any reference in this subparagraph to the "lesser of 7 percent" shall be deemed to be a reference to the "greater of 7 percent".

(iv) If there is enacted after December 22, 1987, an Act which amends this subchapter whose provisions become effective on or after such date and which results in an increase in the aggregate amount of medical assistance under this subchapter for nursing facility services and home and community-based services for individuals who have attained the age of 65 years, the Secretary, at the request of a State with a waiver under this subsection for a waiver year or years and in close consultation with the State, shall adjust the projected amount computed under this subparagraph for the waiver year or years to take into account such increase.

(C) In this paragraph:

(i) The term "home and community-based services" includes services described in sections 1396d(a)(7) and 1396d(a)(8) of this title, services described in subsection (c)(4)(B) of this section, services described in paragraph (4), and personal care services.

(ii)(I) Subject to subclause (II), the term "base year" means the most recent year (ending before December 22, 1987) for which actual final expenditures under this subchapter have been reported to, and accepted by, the Secretary.

(II) For purposes of subparagraph (C), in the case of a State that does not report expenditures on the basis of the age categories described in such subparagraph for a year ending before December 22, 1987, the term "base year" means fiscal year 1989.

(iii) The term "intermediate care facility services" does not include services furnished in an institution certified in accordance with section 1396d(d) of this title.

(6)(A) A determination by the Secretary to deny a request for a waiver (or extension of waiver) under this subsection shall be subject to review to the extent provided under section 1316(b) of this title.

(B) Notwithstanding any other provision of this chapter, if the Secretary denies a request of the State for an extension of a waiver under this subsection, any waiver under this subsection in effect on the date such request is made shall remain in effect for a period of not less than 90 days after the date on which the Secretary denies such request (or, if the State seeks review of such determination in accordance with subparagraph (A), the date on which a final determination is made with respect to such review).

(e) Waiver for children infected with AIDS or drug dependent at birth

(1)(A) Subject to paragraph (2), the Secretary shall grant a waiver to provide that a State plan approved under this subchapter shall include as "medical assistance" under such plan payment for part or all of the cost of nursing care, respite care, physicians' services, prescribed drugs, medical devices and supplies, transportation

services, and such other services requested by the State as the Secretary may approve which are provided pursuant to a written plan of care to a child described in subparagraph (B) with respect to whom there has been a determination that but for the provision of such services the infants would be likely to require the level of care provided in a hospital or nursing facility the cost of which could be reimbursed under the State plan.

(B) Children described in this subparagraph are individuals under 5 years of age who—

(i) at the time of birth were infected with (or tested positively for) the etiologic agent for acquired immune deficiency syndrome (AIDS),

(ii) have such syndrome, or

(iii) at the time of birth were dependent on heroin, cocaine, or phencyclidine,

and with respect to whom adoption or foster care assistance is (or will be) made available under part E of subchapter IV of this chapter.

(2) A waiver shall not be granted under this subsection unless the State provides assurances satisfactory to the Secretary that—

(A) necessary safeguards (including adequate standards for provider participation) have been taken to protect the health and welfare of individuals provided services under the waiver and to assure financial accountability for funds expended with respect to such services;

(B) under such waiver the average per capita expenditure estimated by the State in any fiscal year for medical assistance provided with respect to such individuals does not exceed 100 percent of the average per capita expenditure that the State reasonably estimates would have been made in that fiscal year for expenditures under the State plan for such individuals if the waiver had not been granted; and

(C) the State will provide to the Secretary annually, consistent with a data collection plan designed by the Secretary, information on the impact of the waiver granted under this subsection on the type and amount of medical assistance provided under the State plan and on the health and welfare of recipients.

(3) A waiver granted under this subsection may include a waiver of the requirements of section 1396a(a)(1) of this title (relating to statewideness) and section 1396a(a)(10)(B) of this title (relating to comparability). A waiver under this subsection shall be for an initial term of 3 years and, upon the request of a State, shall be extended for additional five-year periods unless the Secretary determines that for the previous waiver period the assurances provided under paragraph (2) have not been met.

(4) The provisions of paragraph (6) of subsection (d) of this section shall apply to this subsection in the same manner as it applies to subsection (d) of this section.

(f) Monitor of implementation of waivers; termination of waiver for noncompliance; time limitation for action on requests for plan approval, amendments, or waivers

(1) The Secretary shall monitor the implementation of waivers granted under this section to assure that the requirements for such waiver are being met and shall, after notice and opportunity for a hearing, terminate any such waiver where he finds noncompliance has occurred.

(2) A request to the Secretary from a State for approval of a proposed State plan or plan amendment or a waiver of a requirement of this subchapter submitted by the State pursuant to a provision of this subchapter shall be deemed granted unless the Secretary, within 90 days after the date of its submission to the Secretary, either denies such request in writing or informs the State agency in writing with respect to any additional information which is needed in order to make a final determination with respect to the request. After the date the Secretary receives such additional information, the request shall be deemed granted unless the Secretary, within 90 days of such date, denies such request.

(g) Optional targeted case management services

(1) A State may provide, as medical assistance, case management services under the plan without regard to the requirements of section 1396a(a)(1) of this title and section 1396a(a)(10)(B) of this title. The provision of case management services under this subsection shall not restrict the choice of the individual to receive medical assistance in violation of section 1396a(a)(23) of this title. A State may limit the provision of case management services under this subsection to individuals with acquired immune deficiency syndrome (AIDS), or with AIDS-related conditions, or with either, or to individuals described in section 1396a(z)(1)(A) of this title and a State may limit the provision of case management services under this subsection to individuals with chronic mental illness. The State may limit the case managers available with respect to case management services for eligible individuals with developmental disabilities or with chronic mental illness in order to ensure that the case managers for such individuals are capable of ensuring that such individuals receive needed services.

(2) For purposes of this subsection, the term "case management services" means services which will assist individuals eligible under the plan in gaining access to needed medical, social, educational, and other services.

(h) Period of waivers; continuations

No waiver under this section (other than a waiver under subsection (c), (d), or (e) of this section) may extend over a period of longer than two years unless the State requests continuation of such waiver, and such request shall be deemed granted unless the Secretary, within 90 days after the date of its submission to the Secretary, either denies such request in writing or informs the State agency in writing with respect to any additional information

which is needed in order to make a final determination with respect to the request. After the date the Secretary receives such additional information, the request shall be deemed granted unless the Secretary, within 90 days of such date, denies such request.

42 U.S.C. § 1437a

United States Housing Act, Public Law 75–412 (Act of September 1, 1937), sec. 3

Drug-related criminal activity means illegal manufacture, distribution, or possession of controlled substances

Chapter 8. Low-income Housing

§ 1437a. Rental payments [1]

(a) Families included; rent options; minimum amount; occupancy by police officers and over-income families

(1) Dwelling units assisted under this chapter shall be rented only to families who are low-income families at the time of their initial occupancy of such units. Reviews of family income shall be made at least annually. Except as provided in paragraph (2) and subject to the requirement under paragraph (3), a family shall pay as rent for a dwelling unit assisted under this chapter (other than a family assisted under section 1437f(*o*) or (y) of this title or paying rent under section 1437f(c)(3)(B) of this title) the highest of the following amounts, rounded to the nearest dollar:

(A) 30 per centum of the family's monthly adjusted income;

(B) 10 per centum of the family's monthly income; or

(C) if the family is receiving payments for welfare assistance from a public agency and a part of such payments, adjusted in accordance with the family's actual housing costs, is specifically designated by such agency to meet the family's housing costs, the portion of such payments which is so designated.

(2) RENTAL PAYMENTS FOR PUBLIC HOUSING FAMILIES

(A) AUTHORITY FOR FAMILY TO SELECT

(i) IN GENERAL

A family residing in a public housing dwelling shall pay as monthly rent for the unit the amount determined under

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[1] Sept. 1, 1937, c. 896, Title I, § 3, as added Aug. 22, 1974, Public Law 93–383, Title II, § 201(a), 88 Stat. 654, and amended Aug. 3, 1976, Public Law 94–375, § 2(f), 90 Stat. 1068; Oct. 31, 1978, Public Law 95–557, Title II, § 206(c), 92 Stat. 2091; Dec. 21, 1979, Public Law 96–153, Title II, § 202(a), 93 Stat. 1106; Aug. 13, 1981, Public Law 97–35, Title III, § 322(a), 95 Stat. 400; Nov. 30, 1983, Public Law 98–181, Title II, §§ 202, 206(a) to (c), 97 Stat. 1178, 1179; Oct. 17, 1984, Public Law 98–479, Title I, § 102(b)(1) to (3), 98 Stat. 2221; Feb. 5, 1988, Public Law 100–242, Title I, §§ 102(a), 111, 170(c), 101 Stat. 1821, 1823, 1867; redesignated Title I and amended June 29, 1988, Public Law 100–358, §§ 4, 5, 102 Stat. 680, 681; Dec. 15, 1989, Public Law 101–235, Title III, § 302, 103 Stat. 2043; Nov. 28, 1990, Public Law 101–625, Title V, §§ 515(b), 572, 573(a) to (d), 574, 104 Stat. 4199, 4236 to 4238; Oct. 28, 1992, Public Law 102–550, Title I, §§ 102, 103(a)(1), (2), 185(c)(4), Title VI, §§ 621, 622(c), 625(a)(1), 106 Stat. 3683, 3748, 3812, 3817, 3820; Apr. 11, 1994, Public Law 103–233, Title III, § 301, 108 Stat. 369; Jan. 26, 1996, Public Law 104–99, Title IV, § 402(b)(1), (c), 110 Stat. 40, 41; Oct. 26, 1996, Public Law 104–330, Title V, § 501(b)(1), 110 Stat. 4041; Oct. 21, 1998, Public Law 105–276, Title V, §§ 506, 507(a) to (c), 508(a) to (b)(1), (c)(1), (d)(1), 520(a), 523, 524(a), 546, 112 Stat. 2523 to 2529, 2561, 2562, 2565, 2567, 2604; Oct. 20, 1999, Public Law 106–74, Title II, § 214(a), 113 Stat. 1074; Oct. 30, 2000, Public Law 106–402, Title IV, § 401(b)(7), 114 Stat. 1738.

clause (i) or (ii) of subparagraph (B), subject to the requirement under paragraph (3) (relating to minimum rents). Each public housing agency shall provide for each family residing in a public housing dwelling unit owned, assisted, or operated by the agency to elect annually whether the rent paid by such family shall be determined under clause (i) or (ii) of subparagraph (B). A public housing agency may not at any time fail to provide both such rent options for any public housing dwelling unit owned, assisted, or operated by the agency.

(ii) AUTHORITY TO RETAIN FLAT AND CEILING RENTS

Notwithstanding clause (i) or any other provision of law, any public housing agency that is administering flat rents or ceiling rents pursuant to any authority referred to in section 519(d) of the Quality Housing and Work Responsibility Act of 1998 before the effective day of such act may continue to charge rent in accordance with such rent provisions after such effective date, except that the agency shall provide for families residing in public housing dwelling units owned or operated by the agency to elect annually whether to pay rent under such provisions or in accordance with one of the rent options referred to in subparagraph (A).

(B) ALLOWABLE RENT STRUCTURES

(i) FLAT RENTS

Except as otherwise provided under this clause, each public housing agency shall establish, for each dwelling unit in public housing owned or operated by the agency, a flat rental amount for the dwelling unit, which shall—

(I) be based on the rental value of the unit, as determined by the public housing agency; and

(II) be designed in accordance with subparagraph (D) so that the rent structures do not create a disincentive for continued residency in public housing by families who are attempting to become economically self-sufficient through employment or who have attained a level of self-sufficiency through their own efforts.

The rental amount for a dwelling unit shall be considered to comply with the requirements of this clause if such amount does not exceed the actual monthly costs to the public housing agency attributable to providing and operating the dwelling unit. The preceding sentence may not be construed to require establishment of rental amounts equal to or based on operating costs or to prevent public housing agencies from developing flat rents required under this clause in any other manner that may comply with this clause.

(ii) INCOME-BASED RENTS

(I) IN GENERAL

The monthly rental amount determined under this clause for a family shall be an amount, determined by the public housing agency, that does not exceed the greatest of the amounts (rounded to the nearest dollar)

determined under subparagraphs (A), (B), and (C) of paragraph (1). This clause may not be construed to require a public housing agency to charge a monthly rent in the maximum amount permitted under this clause.

(II) DISCRETION

Subject to the limitation on monthly rental amount under subclause (I), a public housing agency may, in its discretion, implement a rent structure under this clause requiring that a portion of the rent be deposited to an escrow or savings account, imposing ceiling rents, or adopting income exclusions (such as those set forth in subsection (b)(5)(B) of this section), or may establish another reasonable rent structure or amount.

(C) SWITCHING RENT DETERMINATION METHODS BECAUSE OF HARDSHIP CIRCUMSTANCES

Notwithstanding subparagraph (A), in the case of a family that has elected to pay rent in the amount determined under subparagraph (B)(i), a public housing agency shall immediately provide for the family to pay rent in the amount determined under subparagraph (B)(ii) during the period for which such election was made upon a determination that the family is unable to pay the amount determined under subparagraph (B)(i) because of financial hardship, including—

(i) situations in which the income of the family has decreased because of changed circumstances, loss of[2] reduction of employment, death in the family, and reduction in or loss of income or other assistance;

(ii) an increase, because of changed circumstances, in the family's expenses for medical costs, child care, transportation, education, or similar items; and

(iii) such other situations as may be determined by the agency.

(D) ENCOURAGEMENT OF SELF-SUFFICIENCY

The rental policy developed by each public housing agency shall encourage and reward employment and economic self-sufficiency.

(E) INCOME REVIEWS

Notwithstanding the second sentence of paragraph (1), in the case of families that are paying rent in the amount determined under subparagraph (B)(i), the agency shall review the income of such family not less than once every 3 years.

(3) MINIMUM RENTAL AMOUNT

(A) REQUIREMENT

Notwithstanding paragraph (1) of this subsection, the method for rent determination elected pursuant to paragraph (2)(A) of this subsection by a family residing in public housing, section 1437f(o)(2) of this title, or section 206(d) of the Housing and Urban-Rural Recovery Act of 1983 (including paragraph (5) of such section), the following entities shall require the following families to pay a minimum monthly rental amount (which amount shall

[2] So in original. Probably should be "or".

include any amount allowed for utilities) of not more than $50 per month, as follows:

(i) Each public housing agency shall require the payment of such minimum monthly rental amount, which amount shall be determined by the agency, by—

(I) each family residing in a dwelling unit in public housing by the agency;

(II) each family who is assisted under the certificate or moderate rehabilitation program under section 1437f of this title; and

(III) each family who is assisted under the voucher program under section 1437f of this title, and the agency shall reduce the monthly assistance payment on behalf of such family as may be necessary to ensure payment of such minimum monthly rental amount.

(ii) The Secretary shall require each family who is assisted under any other program for rental assistance under section 1437f of this title to pay such minimum monthly rental amount, which amount shall be determined by the Secretary.

(B) EXCEPTION FOR HARDSHIP CIRCUMSTANCES

(i) IN GENERAL

Notwithstanding subparagraph (A), a public housing agency (or the Secretary, in the case of a family described in subparagraph (A)(ii)) shall immediately grant an exemption from application of the minimum monthly rental under such subparagraph to any family unable to pay such amount because of financial hardship, which shall include situations in which (I) the family has lost eligibility for or is awaiting an eligibility determination for a Federal, State, or local assistance program, including a family that includes a member who is an alien lawfully admitted for permanent residence under the Immigration and Nationality Act [8 U.S.C. 1101 et seq.] who would be entitled to public benefits but for title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996; (II) the family would be evicted as a result of the imposition of the minimum rent requirement under subparagraph (A); (III) the income of the family has decreased because of changed circumstance, including loss of employment; (IV) a death in the family has occurred; and (V) other situations as may be determined by the agency (or the Secretary, in the case of a family described in subparagraph (A)(ii)).

(ii) WAITING PERIOD

If a resident requests a hardship exemption under this subparagraph and the public housing agency (or the Secretary, in the case of a family described in subparagraph (A)(ii)) reasonably determines the hardship to be of a temporary nature, an exemption shall not be granted during the 90-day period beginning upon the making of a request for the exemption. A resident may

not be evicted during such 90-day period for nonpayment of rent. In such a case, if the resident thereafter demonstrates that the financial hardship is of a long-term basis, the agency (or the Secretary) shall retroactively exempt the resident from the applicability of the minimum rent requirement for such 90-day period.

(4) OCCUPANCY BY POLICE OFFICERS

(A) IN GENERAL

Subject to subparagraph (B) and notwithstanding any other provision of law, a public housing agency may, in accordance with the public housing agency plan for the agency, allow a police officer who is not otherwise eligible for residence in public housing to reside in a public housing dwelling unit. The number and location of units occupied by police officers under this paragraph and the terms and conditions of their tenancies shall be determined by the public housing agency.

(B) INCREASED SECURITY

A public housing agency may take the actions authorized in subparagraph (A) only for the purpose of increasing security for the residents of a public housing project.

(C) DEFINITION

In this paragraph, the term "police officer" means any person determined by a public housing agency to be, during the period of residence of that person in public housing, employed on a full-time basis as a duly licensed professional police officer by a Federal, State, or local government or by any agency thereof (including a public housing agency having an accredited police force).

(5) OCCUPANCY BY OVER-INCOME FAMILIES IN CERTAIN PUBLIC HOUSING

(A) AUTHORITY

Notwithstanding any other provision of law, a public housing agency that owns or operates less than 250 units may, on a month-to-month basis, lease a dwelling unit in a public housing project to an over-income family in accordance with this paragraph, but only if there are no eligible families applying for housing assistance from the public housing agency for that month and the agency provides not less than 30-day public notice of the availability of such assistance.

(B) TERMS AND CONDITIONS

The number and location of dwelling units of a public housing agency occupied under this paragraph by over-income families, and the terms and conditions of those tenancies, shall be determined by the public housing agency, except that—

(i) notwithstanding paragraph (2), rent for a unit shall be in an amount that is not less than the costs to operate the unit;

(ii) if an eligible family applies for residence after an over-income family moves in to the last available unit,

the over-income family shall vacate the unit in accordance with notice of termination of tenancy provided by the agency, which shall be provided not less than 30 days before such termination; and

(iii) if a unit is vacant and there is no one on the waiting list, the public housing agency may allow an over-income family to gain immediate occupancy in the unit, while simultaneously providing reasonable public notice and outreach with regard to availability of the unit.

(C) DEFINITION

For purposes of this paragraph, the term "over-income family" means an individual or family that is not a low-income family at the time of initial occupancy.

(b) Definition of terms under this chapter

When used in this chapter:

(1) LOW-INCOME HOUSING

The term "low-income housing" means decent, safe, and sanitary dwellings assisted under this chapter. The term "public housing" means low-income housing, and all necessary appurtenances thereto, assisted under this chapter other than under section 1437f of this title. The term "public housing" includes dwelling units in a mixed finance project that are assisted by a public housing agency with capital or operating assistance. When used in reference to public housing, the term "low-income housing project" or "project" means (A) housing developed, acquired, or assisted by a public housing agency under this chapter, and (B) the improvement of any such housing.

(2) LOW-INCOME FAMILIES

The term "low-income families" means those families whose incomes do not exceed 80 per centum of the median income for the area, as determined by the Secretary with adjustments for smaller and larger families, except that the Secretary may establish income ceilings higher or lower than 80 per centum of the median for the area on the basis of the Secretary's findings that such variations are necessary because of prevailing levels of construction costs or unusually high or low family incomes. The term "very low-income families" means low-income families whose incomes do not exceed 50 per centum of the median family income for the area, as determined by the Secretary with adjustments for smaller and larger families, except that the Secretary may establish income ceilings higher or lower than 50 per centum of the median for the area on the basis of the Secretary's findings that such variations are necessary because of unusually high or low family incomes. Such ceilings shall be established in consultation with the Secretary of Agriculture for any rural area, as defined in section 1490 of this title, taking into account the subsidy characteristics and types of programs to which such ceilings apply. In determining median incomes (of persons, families, or households) for an area or establishing any ceilings or limits based on income under this chapter, the Secretary shall determine or establish area median incomes and income ceilings and limits for Westchester

and Rockland Counties, in the State of New York, as if each such county were an area not contained within the metropolitan statistical area in which it is located. In determining such area median incomes or establishing such income ceilings or limits for the portion of such metropolitan statistical area that does not include Westchester or Rockland Counties, the Secretary shall determine or establish area median incomes and income ceilings and limits as if such portion included Westchester and Rockland Counties. In determining areas that are designated as difficult development areas for purposes of the low-income housing tax credit, the Secretary shall include Westchester and Rockland Counties, New York, in the New York City metropolitan area.

(3) PERSONS AND FAMILIES

(A) SINGLE PERSONS

The term "families" includes families consisting of a single person in the case of (i) an elderly person, (ii) a disabled person, (iii) a displaced person, (iv) the remaining member of a tenant family, and (v) any other single persons. In no event may any single person under clause (v) of the first sentence be provided a housing unit assisted under this chapter of 2 or more bedrooms.

(B) FAMILIES

The term "families" includes families with children and, in the cases of elderly families, near-elderly families, and disabled families, means families whose heads (or their spouses), or whose sole members, are elderly, near-elderly, or persons with disabilities, respectively. The term includes, in the cases of elderly families, near-elderly families, and disabled families, 2 or more elderly persons, near-elderly persons, or persons with disabilities living together, and 1 or more such persons living with 1 or more persons determined under the public housing agency plan to be essential to their care or well-being.

(C) ABSENCE OF CHILDREN

The temporary absence of a child from the home due to placement in foster care shall not be considered in determining family composition and family size.

(D) ELDERLY PERSON

The term "elderly person" means a person who is at least 62 years of age.

(E) PERSON WITH DISABILITIES

The term "person with disabilities" means a person who—

(i) has a disability as defined in section 423 of this title,

(ii) is determined, pursuant to regulations issued by the Secretary, to have a physical, mental, or emotional impairment which (I) is expected to be of long-continued and indefinite duration, (II) substantially impedes his or her ability to live independently, and (III) is of such a nature that such ability could be improved by more suitable housing conditions, or

(iii) has a developmental disability as defined in section 15002 of this title.

Such term shall not exclude persons who have the disease of acquired immunodeficiency syndrome or any conditions arising from the etiologic agent for acquired immunodeficiency syndrome. Notwithstanding any other provision of law, no individual shall be considered a person with disabilities, for purposes of eligibility for low-income housing under this subchapter, solely on the basis of any drug or alcohol dependence. The Secretary shall consult with other appropriate Federal agencies to implement the preceding sentence.

(F) DISPLACED PERSON

The term "displaced person" means a person displaced by governmental action, or a person whose dwelling has been extensively damaged or destroyed as a result of a disaster declared or otherwise formally recognized pursuant to Federal disaster relief laws.

(G) NEAR-ELDERLY PERSON

The term "near-elderly person" means a person who is at least 50 years of age but below the age of 62.

(4) INCOME

The term "income" means income from all sources of each member of the household, as determined in accordance with criteria prescribed by the Secretary, in consultation with the Secretary of Agriculture, except that any amounts not actually received by the family and any amounts which would be eligible for exclusion under section 1382b(a)(7) of this title may not be considered as income under this paragraph.

(5) ADJUSTED INCOME

The term "adjusted income" means, with respect to a family, the amount (as determined by the public housing agency) of the income of the members of the family residing in a dwelling unit or the persons on a lease, after any income exclusions as follows:

(A) MANDATORY EXCLUSIONS

In determining adjusted income, a public housing agency shall exclude from the annual income of a family the following amounts:

(i) ELDERLY AND DISABLED FAMILIES

$400 for any elderly or disabled family.

(ii) MEDICAL EXPENSES

The amount by which 3 percent of the annual family income is exceeded by the sum of—

(I) unreimbursed medical expenses of any elderly family or disabled family;

(II) unreimbursed medical expenses of any family that is not covered under subclause (I), except that this subclause shall apply only to the extent approved in appropriation Acts; and

(III) unreimbursed reasonable attendant care and auxiliary apparatus expenses for each handicapped member of the family, to the extent necessary to enable any member of such family (including such handicapped member) to be employed.

(iii) CHILD CARE EXPENSES

Any reasonable child care expenses necessary to enable a member of the family to be employed or to further his or her education.

(iv) MINORS, STUDENTS, AND PERSONS WITH DISABILITIES

$480 for each member of the family residing in the household (other than the head of the household or his or her spouse) who is less than 18 years of age or is attending school or vocational training on a full-time basis, or who is 18 years of age or older and is a person with disabilities.

(v) CHILD SUPPORT PAYMENTS

Any payment made by a member of the family for the support and maintenance of any child who does not reside in the household, except that the amount excluded under this clause may not exceed $480 for each child for whom such payment is made; except that this clause shall apply only to the extent approved in appropriations Acts.

(vi) SPOUSAL SUPPORT EXPENSES

Any payment made by a member of the family for the support and maintenance of any spouse or former spouse who does not reside in the household, except that the amount excluded under this clause shall not exceed the lesser of (I) the amount that such family member has a legal obligation to pay, or (II) $550 for each individual for whom such payment is made; except that this clause shall apply only to the extent approved in appropriations Acts.

(vii) EARNED INCOME OF MINORS

The amount of any earned income of a member of the family who is not—

(I) 18 years of age or older; and

(II) the head of the household (or the spouse of the head of the household).

(B) PERMISSIVE EXCLUSIONS FOR PUBLIC HOUSING

In determining adjusted income, a public housing agency may, in the discretion of the agency, establish exclusions from the annual income of a family residing in a public housing dwelling unit. Such exclusions may include the following amounts:

(i) EXCESSIVE TRAVEL EXPENSES

Excessive travel expenses in an amount not to exceed $25 per family per week, for employment-or education-related travel.

(ii) EARNED INCOME

An amount of any earned income of the family, established at the discretion of the public housing agency, which may be based on—

(I) all earned income of the family,[3]

(II) the amount earned by particular members of the family;

(III) the amount earned by families having certain characteristics; or

(IV) the amount earned by families or members during certain periods or from certain sources.

(iii) OTHERS

Such other amounts for other purposes, as the public housing agency may establish.

(6) PUBLIC HOUSING AGENCY

(A) IN GENERAL

Except as provided in subparagraph (B), the term "public housing agency" means any State, county, municipality, or other governmental entity or public body (or agency or instrumentality thereof) which is authorized to engage in or assist in the development or operation of public housing.

(B) SECTION 8 PROGRAM

For purposes of the program for tenant-based assistance under section 1437f of this title, such term includes—

(i) a consortia of public housing agencies that the Secretary determines has the capacity and capability to administer a program for assistance under such section in an efficient manner;

(ii) any other public or private nonprofit entity that, upon the effective date under section 503(a) of the Quality Housing and Work Responsibility Act of 1998, was administering any program for tenant-based assistance under section 1437f of this title (as in effect before the effective date of such Act), pursuant to a contract with the Secretary or a public housing agency; and

(iii) with respect to any area in which no public housing agency has been organized or where the Secretary determines that a public housing agency is unwilling or unable to implement a program for tenant-based assistance[4] section 1437f of this title, or is not performing effectively—

(I) the Secretary or another public or private nonprofit entity that by contract agrees to receive assistance amounts under section 1437f of this title and enter into housing assistance payments contracts with owners and perform the other functions of public housing agency under section 1437f of this title; or

(II) notwithstanding any provision of State or local law, a public housing agency for another

[3] So in original. The comma probably should be a semicolon.
[4] So in original. Probably should be "assistance under".

area that contracts with the Secretary to administer a program for housing assistance under section 1437f of this title, without regard to any otherwise applicable limitations on its area of operation.

(7) STATE

The term "State" includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, the territories and possessions of the United States, and the Trust Territory of the Pacific Islands.

(8) SECRETARY

The term "Secretary" means the Secretary of Housing and Urban Development.

(9) DRUG-RELATED CRIMINAL ACTIVITY

The term "drug-related criminal activity" means the illegal manufacture, sale, distribution, use, or possession with intent to manufacture, sell, distribute, or use, of a controlled substance (as such term is defined in section 802 of Title 21).

(10) MIXED-FINANCE PROJECT

The term "mixed-finance project" means a public housing project that meets the requirements of section 1437z–7 of this title.

(11) PUBLIC HOUSING AGENCY PLAN

The term "public housing agency plan" means the plan of a public housing agency prepared in accordance with section 1437c–1 of this title.

(12) CAPITAL FUND

The term "Capital Fund" means the fund established under section 1437g(d) of this title.

(13) OPERATING FUND

The term "Operating Fund" means the fund established under section 1437g(e) of this title.

(c) Definition of terms used in reference to public housing

When used in reference to public housing:

(1) The term "development" means any or all undertakings necessary for planning, land acquisition, demolition, construction, or equipment, in connection with a low-income housing project. The term "development cost" comprises the costs incurred by a public housing agency in such undertakings and their necessary financing (including the payment of carrying charges), and in otherwise carrying out the development of such project, but does not include the costs associated with the demolition of or remediation of environmental hazards associated with public housing units that will not be replaced on the project site, or other extraordinary site costs as determined by the Secretary. Construction activity in connection with a low-income housing project may be confined to the reconstruction, remodeling, or repair of existing buildings.

(2) The term "operation" means any or all undertakings appropriate for management, operation, services, maintenance, security (including the cost of security personnel), or financing in connection with a low-income housing project. The term also

means the financing of tenant programs and services for families residing in low-income housing projects, particularly where there is maximum feasible participation of the tenants in the development and operation of such tenant programs and services. As used in this paragraph, the term "tenant programs and services" includes the development and maintenance of tenant organizations which participate in the management of low-income housing projects; the training of tenants to manage and operate such projects and the utilization of their services in project management and operation; counseling on household management, housekeeping, budgeting, money management, child care, and similar matters; advice as to resources for job training and placement, education, welfare, health, and other community services; services which are directly related to meeting tenant needs and providing a wholesome living environment; and referral to appropriate agencies in the community when necessary for the provision of such services. To the maximum extent available and appropriate, existing public and private agencies in the community shall be used for the provision of such services.

(3) The term "acquisition cost" means the amount prudently required to be expended by a public housing agency in acquiring property for a low-income housing project.

(4) The term "congregate housing" means low-rent housing with which there is connected a central dining facility where wholesome and economical meals can be served to occupants. Expenditures incurred by a public housing agency in the operation of a central dining facility in connection with congregate housing (other than the cost of providing food and service) shall be considered a cost of operation of the project.

(5) The terms "group home" and "independent living facility" have the meanings given such terms in section 8013(k) of this title.

(d) Disallowance of earned income from rent determinations

(1) In general

Notwithstanding any other provision of law, the rent payable under subsection (a) of this section by a family described in paragraph (3) of this subsection may not be increased as a result of the increased income due to such employment during the 12-month period beginning on the date on which the employment is commenced.

(2) Phase-in of rent increases

Upon the expiration of the 12-month period referred to in paragraph (1), the rent payable by a family described in paragraph (3) may be increased due to the continued employment of the family member described in paragraph (3)(B), except that during the 12-month period beginning upon such expiration the amount of the increase may not be greater than 50 percent of the amount of the total rent increase that would be applicable but for this paragraph.

(3) Eligible families

A family described in this paragraph is a family—

(A) that—

(i) occupies a dwelling unit in a public housing project; or

(ii) receives assistance under section 1437f of this title; and

(B)(i) whose income increases as a result of employment of a member of the family who was previously unemployed for 1 or more years;

(ii) whose earned income increases during the participation of a family member in any family self-sufficiency or other job training program; or

(iii) who is or was, within 6 months, assisted under any State program for temporary assistance for needy families funded under part A of title IV of the Social Security Act [42 U.S.C. 601 et seq.] and whose earned income increases.

(4) Applicability

This subsection and subsection (e) of this section shall apply beginning upon October 1, 1999, except that this subsection and subsection (e) of this section shall apply with respect to any family described in paragraph 3(A)(ii)[5] only to the extent provided in advance in appropriations Acts.

(e) Individual savings accounts

(1) In general

In lieu of a disallowance of earned income under subsection (d) of this section, upon the request of a family that qualifies under subsection (d) of this section, a public housing agency may establish an individual savings account in accordance with this subsection for that family.

(2) Deposits to account

The public housing agency shall deposit in any savings account established under this subsection an amount equal to the total amount that otherwise would be applied to the family's rent payment under subsection (a) of this section as a result of employment.

(3) Withdrawal from account

Amounts deposited in a savings account established under this subsection may only be withdrawn by the family for the purpose of—

(A) purchasing a home;

(B) paying education costs of family members;

(C) moving out of public or assisted housing; or

(D) paying any other expense authorized by the public housing agency for the purpose of promoting the economic self-sufficiency of residents of public and assisted housing.

[5] So in original. Probably should be "(3)(A)(ii)".

(f) Availability of income matching information

(1) Disclosure to PHA

A public housing agency, or the owner responsible for determining the participant's eligibility or level of benefits, shall require any family described in paragraph (2) who receives information regarding income, earnings, wages, or unemployment compensation from the Department of Housing and Urban Development pursuant to income verification procedures of the Department to disclose such information, upon receipt of the information, to the public housing agency that owns or operates the public housing dwelling unit in which such family resides or that provides the housing assistance under this chapter on behalf of such family, as applicable, or to the owner responsible for determining the participant's eligibility or level of benefits.

(2) Families covered

A family described in this paragraph is a family that resides in a dwelling unit—

(A) that is a public housing dwelling unit;

(B) for which tenant-based assistance is provided under section 1437f of this title, or

(C) for which project-based assistance is provided under section 1437f of this title, section 1437bb of this title, or section 811.

42 U.S.C. § 1437d

United States Housing Act, Public Law 75–412 (Act of September 1, 1937), sec. 6

Public housing applicants may be required to sign consent forms for the release of drug treatment information; leases must contain clauses for termination for drug-related activity

§ 1437d. Contract provisions and requirements; loans and annual contributions [1]

(a) Conditions; elevators

The Secretary may include in any contract for loans, contributions, sale, lease, mortgage, or any other agreement or instrument made pursuant to this chapter, such covenants, conditions, or provisions as he may deem necessary in order to insure the lower income character of the project involved, in a manner consistent with the public housing agency plan. Any such contract shall require that, except in the case of housing predominantly for elderly or disabled families, high-rise elevator projects shall not be provided for families with children unless the Secretary makes a determination that there is no practical alternative.

(b) Limitation on development costs

(1) Each contract for loans (other than preliminary loans) or contributions for the development, acquisition, or operation of public housing shall provide that the total development cost of the project on which the computation of any annual contributions under this chapter may be based may not exceed the amount determined under paragraph (2) (for the appropriate structure type) unless the Secretary provides otherwise, and in any case may not exceed 110

[1] Sept. 1, 1937, c. 896, Title I, § 6, as added Aug. 22, 1974, Public Law 93–383, Title II, § 201(a), 88 Stat. 659, and amended Dec. 21, 1979, Public Law 96–153, Title II, § 206(a), 93 Stat. 1108; Oct. 8, 1980, Public Law 96–399, Title II, §§ 201(c), (e), 202(c), 94 Stat. 1625, 1629; Aug. 13, 1981, Public Law 97–35, Title III, § 322(c), (d), 95 Stat. 402; Nov. 30, 1983, Public Law 98–181, Title II, §§ 201(c), 203(a), 204, 205, 214(b), 97 Stat. 1177–1179, 1185; Oct. 17, 1984, Public Law 98–479, Title I, § 102(b)(4), (5), Title II, § 204(b)(1), 98 Stat. 2221, 2223; Nov. 25, 1985, Public Law 99–160, Title I, § 101, 99 Stat. 910; Feb. 5, 1988, Public Law 100–242, Title I, §§ 112(b)(2), 116, 170(d), 101 Stat. 1824, 1826, 1867; redesignated Title I, June 29, 1988, Public Law 100–358, § 5, 102 Stat. 681, and amended Nov. 7, 1988, Public Law 100–628, Title X, §§ 1001(b), 1014(a)(1), 102 Stat. 3263, 3269; Nov. 18, 1988, Public Law 100–690, Title V, § 5101, 102 Stat. 4300; Nov. 9, 1989, Public Law 101–144, Title II, 103 Stat. 846; Nov. 28, 1990, Public Law 101–625, Title V, §§ 501, 502(a), (c)(1), 503(a), (b), 504–506, 572, 104 Stat. 4180, 4181, 4183–4185, 4236; Oct. 28, 1991, Public Law 102–139, Title II, 105 Stat. 756, 757; Oct. 28, 1992, Public Law 102–550, Title I, §§ 112, 113, Title VI, §§ 622(b), 625(a)(2), 682(a), 106 Stat. 3689, 3817, 3820, 3830; Apr. 11, 1994, Public Law 103–233, Title I, § 101(c)(1), Title III, § 303, 108 Stat. 357, 370; Sept. 28, 1994, Public Law 103–327, Title II, 108 Stat. 2315; Jan. 26, 1996, Public Law 104–99, Title IV, § 402(d)(1), (6)(A)(i), 110 Stat. 41, 42; Mar. 28, 1996, Public Law 104–120, § 9(a) to (c), 110 Stat. 836, 837; Aug. 22, 1996, Public Law 104–193, Title IX, § 903(a)(1), 110 Stat. 2348; Oct. 26, 1996, Public Law 104–330, Title V, § 501(b)(3), 110 Stat. 4042; Oct. 21, 1998, Public Law 105–276, Title V, §§ 511(d), 512(b), 514(a)(1), (2)(A), 519(b), 520(b), 521, 525, 529, 530, 564, 565(a), 575, 576(d)(1), 112 Stat. 2539, 2543, 2547, 2561, 2563, 2564, 2568 to 2570, 2627, 2628, 2634, 2640.

per centum of such amount unless the Secretary for good cause determines otherwise.

(2) For purposes of paragraph (1), the Secretary shall determine the total development cost by multiplying the construction cost guideline for the project (which shall be determined by averaging the current construction costs, as listed by not less than 2 nationally recognized residential construction cost indices, for publicly bid construction of a good and sound quality) by—

(A) in the case of elevator type structures, 1.6; and

(B) in the case of nonelevator type structures, 1.75.

(3) In calculating the total development cost of a project under paragraph (2), the Secretary shall consider only capital assistance provided by the Secretary to a public housing agency that are[2] authorized for use in connection with the development of public housing, and shall exclude all other amounts, including amounts provided under

(A) the HOME investment partnerships program authorized under title II of the Cranston-Gonzalez National Affordable Housing Act [42 U.S.C. 12721 et seq.]; or

(B) the community development block grants program under title I of the Housing and Community Development Act of 1974 [42 U.S.C. 5301 et seq.].

(4) The Secretary may restrict the amount of capital funds that a public housing agency may use to pay for housing construction costs. For purposes of this paragraph, housing construction costs include the actual hard costs for the construction of units, builders' overhead and profit, utilities from the street, and finish landscaping.

(c) Revision of maximum income limits; certification of compliance with requirements; notification of eligibility; informal hearing; compliance with procedures for sound management

Every contract for contributions shall provide that—

(1) the Secretary may require the public housing agency to review and revise its maximum income limits if the Secretary determines that changed conditions in the locality make such revision necessary in achieving the purposes of this chapter;

(2) the public housing agency shall determine, and so certify to the Secretary, that each family in the project was admitted in accordance with duly adopted regulations and approved income limits; and the public housing agency shall review the incomes of families living in the project no less frequently than annually;

(3) the public housing agency shall promptly notify (i) any applicant determined to be ineligible for admission to the project of the basis for such determination and provide the applicant upon request, within a reasonable time after the determination is made, with an opportunity for an informal hearing on such determination, and (ii) any applicant determined to be eligible for admission to the project of the approximate date of

[2] So in original. Probably should be "is".

occupancy insofar as such date can be reasonably determined; and

(4) the public housing agency shall comply with such procedures and requirements as the Secretary may prescribe to assure that sound management practices will be followed in the operation of the project, including requirements pertaining to—

(A) making dwelling units in public housing available for occupancy, which shall provide that the public housing agency may establish a system for making dwelling units available that provides preference for such occupancy to families having certain characteristics; each system of preferences established pursuant to this subparagraph shall be based upon local housing needs and priorities, as determined by the public housing agency using generally accepted data sources, including any information obtained pursuant to an opportunity for public comment as provided under section 1437c–1(f) of this title and under the requirements applicable to the comprehensive housing affordability strategy for the relevant jurisdiction;

(B) the establishment of satisfactory procedures designed to assure the prompt payment and collection of rents and the prompt processing of evictions in the case of nonpayment of rent;

(C) the establishment of effective tenant-management relationships designed to assure that satisfactory standards of tenant security and project maintenance are formulated and that the public housing agency (together with tenant councils where they exist) enforces those standards fully and effectively;

(D) the development by local housing authority managements of viable homeownership opportunity programs for low-income families capable of assuming the responsibilities of homeownership;

(E) for each agency that receives assistance under this subchapter, the establishment and maintenance of a system of accounting for rental collections and costs (including administrative, utility, maintenance, repair and other operating costs) for each project or operating cost center (as determined by the Secretary), which collections and costs shall be made available to the general public and submitted to the appropriate local public official (as determined by the Secretary); except that the Secretary may permit agencies owning or operating less than 500 units to comply with the requirements of this subparagraph by accounting on an agency-wide basis; and

(F) requiring the public housing agency to ensure and maintain compliance with subtitle C of title VI of the Housing and Community Development Act of 1992 [42 U.S.C. 13601 et seq.] and any regulations issued under such subtitle.

(d) Exemption from personal and real property taxes; payments in lieu of taxes; cash contribution or tax remission

Every contract for contributions with respect to a low-income housing project shall provide that no contributions by the Secretary shall be made available for such project unless such project (exclusive of any portion thereof which is not assisted by contributions under this chapter) is exempt from all real and personal property taxes levied or imposed by the State, city, county, or other political subdivision; and such contract shall require the public housing agency to make payments in lieu of taxes equal to 10 per centum of the sum of the shelter rents charged in such project, or such lesser amount as (i) is prescribed by State law, or (ii) is agreed to by the local governing body in its agreement for local cooperation with the public housing agency required under section 1437c(e)(2) of this title, or (iii) is due to failure of a local public body or bodies other than the public housing agency to perform any obligation under such agreement. If any such project is not exempt from all real and personal property taxes levied or imposed by the State, city, county, or other political subdivision, such contract shall provide, in lieu of the requirement for tax exemption and payments in lieu of taxes, that no contributions by the Secretary shall be made available for such project unless and until the State, city, county, or other political subdivision in which such project is situated shall contribute, in the form of cash or tax remission, the amount by which the taxes paid with respect to the project exceed 10 per centum of the shelter rents charged in such project.

(f)[3] Housing quality requirements

(1) In general

Each contract for contributions for a public housing agency shall require that the agency maintain its public housing in a condition that complies with standards which meet or exceed the housing quality standards established under paragraph (2).

(2) Federal standards

The Secretary shall establish housing quality standards under this paragraph that ensure that public housing dwelling units are safe and habitable. Such standards shall include requirements relating to habitability, including maintenance, health and sanitation factors, condition, and construction of dwellings, and shall, to the greatest extent practicable, be consistent with the standards established under section 1437f(o)(8)(B)(i) of this title. The Secretary may determine whether the laws, regulations, standards, or codes of any State or local jurisdiction meet or exceed these standards, for purposes of this subsection.

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[3] Subsection (e) was repealed by Public Law 105–276, Title V, § 529(2), Oct. 21, 1998, 112 Stat. 2569.

(3) Annual inspections

Each public housing agency that owns or operates public housing shall make an annual inspection of each public housing project to determine whether units in the project are maintained in accordance with the requirements under paragraph (1). The agency shall retain the results of such inspections and, upon the request of the Secretary, the Inspector General for the Department of Housing and Urban Development, or any auditor conducting an audit under section 1437c(h) of this title, shall make such results available.

(g) Substantial default; conveyance of title and delivery of possession; reconveyance and redelivery; payments for outstanding obligations

Every contract for contributions (including contracts which amend or supersede contracts previously made) may provide that—

(1) upon the occurrence of a substantial default in respect to the covenants or conditions to which the public housing agency is subject (as such substantial default shall be defined in such contract), the public housing agency shall be obligated at the option of the Secretary either to convey title in any case where, in the determination of the Secretary (which determination shall be final and conclusive), such conveyance of title is necessary to achieve the purposes of this chapter, or to deliver to the Secretary possession of the project, as then constituted, to which such contract relates; and

(2) the Secretary shall be obligated to reconvey or redeliver possession of the project as constituted at the time of reconveyance or redelivery, to such public housing agency or to its successor (if such public housing agency or a successor exists) upon such terms as shall be prescribed in such contract, and as soon as practicable (i) after the Secretary is satisfied that all defaults with respect to the project have been cured, and that the project will, in order to fulfill the purposes of this chapter, thereafter be operated in accordance with the terms of such contract; or (ii) after the termination of the obligation to make annual contributions available unless there are any obligations or covenants of the public housing agency to the Secretary which are then in default. Any prior conveyances and reconveyances or deliveries and redeliveries of possession shall not exhaust the right to require a conveyance or delivery of possession of the project to the Secretary pursuant to subparagraph (1) upon the subsequent occurrence of a substantial default.

Whenever such a contract for annual contributions includes provisions which the Secretary in such contract determines are in accordance with this subsection, and the portion of the annual contribution payable for debt service requirements pursuant to such contract has been pledged by the public housing agency as security for the payment of the principal and interest on any of its obligations, the Secretary (notwithstanding any other provisions of this

chapter) shall continue to make such annual contributions available for the project so long as any of such obligations remain outstanding, and may covenant in such contract that in any event such annual contributions shall in each year be at least equal to an amount which, together with such income or other funds as are actually available from the project for the purpose at the time such annual contribution is made, will suffice for the payment of all installments, falling due within the next succeeding twelve months, of principal and interest on the obligations for which the annual contributions provided for in the contract shall have been pledged as security. In no case shall such annual contributions be in excess of the maximum sum specified in the contract involved, nor for longer than the remainder of the maximum period fixed by the contract.

(h) New construction contracts

On or after October 1, 1983, the Secretary may enter into a contract involving new construction only if the public housing agency demonstrates to the satisfaction of the Secretary that the cost of new construction in the neighborhood where the public housing agency determines the housing is needed is less than the cost of acquisition or acquisition and rehabilitation in such neighborhood, including any reserve fund under subsection (i) of this section, would be.

(i) Reserve fund; major repairs

The Secretary may, upon application by a public housing agency in connection with the acquisition of housing for use as public housing, establish and set aside a reserve fund in an amount not to exceed 30 per centum of the acquisition cost which shall be available for use for major repairs to such housing.

(j) Performance indicators for public housing agencies

(1) The Secretary shall develop and publish in the Federal Register indicators to assess the management performance of public housing agencies and resident management corporations. The indicators shall be established by rule under section 553 of Title 5. Such indicators shall enable the Secretary to evaluate the performance of public housing agencies and resident management corporations in all major areas of management operations. The Secretary shall, in particular, use the following indicators for public housing agencies, to the extent practicable:

(A) The number and percentage of vacancies within an agency's inventory, including the progress that an agency has made within the previous 3 years to reduce such vacancies.

(B) The amount and percentage of funds provided to the public housing agency from the Capital Fund under section 1437g(d) of this title which remain unobligated by the public housing agency after 3 years.

(C) The percentage of rents uncollected.

(D) The utility consumption (with appropriate adjustments to reflect different regions and unit sizes).

(E) The average period of time that an agency requires to repair and turn-around vacant units.

(F) The proportion of maintenance work orders outstanding, including any progress that an agency has made during the preceding 3 years to reduce the period of time required to complete maintenance work orders.

(G) The percentage of units that an agency fails to inspect to ascertain maintenance or modernization needs within such period of time as the Secretary deems appropriate (with appropriate adjustments, if any, for large and small agencies).

(H) The extent to which the public housing agency—

(i) coordinates, promotes, or provides effective programs and activities to promote the economic self-sufficiency of public housing residents; and

(ii) provides public housing residents with opportunities for involvement in the administration of the public housing.

(I)[4] The extent to which the public housing agency—

(i) implements effective screening and eviction policies and other anticrime strategies; and

(ii) coordinates with local government officials and residents in the project and implementation of such strategies.

(J) The extent to which the public housing agency is providing acceptable basic housing conditions.

(K) Any other factors as the Secretary deems appropriate which shall not exceed the seven factors in the statute, plus an additional five.

(I)[5] The Secretary shall:

(1) administer the system of evaluating public housing agencies flexibly to ensure that such agencies are not penalized as result of circumstances beyond their control;

(2) reflect in the weights assigned to the various indicators the differences in the difficulty of managing individual projects that result from their physical condition and their neighborhood environment; and

(3) determine a public housing agency's status as "troubled with respect to the program under section 1437l of this title" based upon factors solely related to its ability to carry out that program.

(2)(A)(i) The Secretary shall, under the rulemaking procedures under section 553 of Title 5, establish procedures for designating troubled public housing agencies, which procedures shall include identification of serious and substantial failure to perform as measured by the performance indicators specified under paragraph (1) and such other factors as the Secretary may deem to be appropriate. Such procedures shall provide that an agency that fails on a widespread basis to provide acceptable basic housing conditions for its residents shall be designated as a troubled public housing agency. The Secretary may use a simplified set of indicators for public housing agencies with less than 250 public housing units. The Secretary shall also designate, by rule under section 553 of Title 5, agencies that are troubled with respect to the program for

[4] Another subparagraph (I) is set out after subparagraph (K).
[5] Another subparagraph (I) is set out before subparagraph (J).

assistance from the Capital Fund under section 1437g(d) of this title.

(ii) The Secretary may also, in consultation with national organizations representing public housing agencies and public officials (as the Secretary determines appropriate), identify and commend public housing agencies that meet the performance standards established under paragraph (1) in an exemplary manner.

(iii) The Secretary shall establish procedures for public housing agencies to appeal designation as a troubled agency (including designation as a troubled agency for purposes of the program for assistance from the Capital Fund under section 1437g(d) of this title), to petition for removal of such designation, and to appeal any refusal to remove such designation.

(B)(i) Upon designating a public housing agency with more than 250 units as troubled pursuant to subparagraph (A) and determining that an assessment under this subparagraph will not duplicate any comparable and recent review, the Secretary shall provide for an on-site, independent assessment of the management of the agency.

(ii) To the extent the Secretary deems appropriate (taking into account an agency's performance under the indicators specified under paragraph (1)), the assessment team shall also consider issues relating to the agency's resident population and physical inventory, including the extent to which (I) the agency's comprehensive plan prepared pursuant to section 1437l of this title adequately and appropriately addresses the rehabilitation needs of the agency's inventory, (II) residents of the agency are involved in and informed of significant management decisions, and (III) any projects in the agency's inventory are severely distressed and eligible for assistance pursuant to section 1437v of this title.

(iii) An independent assessment under this subparagraph shall be carried out by a team of knowledgeable individuals selected by the Secretary (referred to in this section as the ''assessment team'') with expertise in public housing and real estate management. In conducting an assessment, the assessment team shall consult with the residents and with public and private entities in the jurisdiction in which the public housing is located. The assessment team shall provide to the Secretary and the public housing agency a written report, which shall contain, at a minimum, recommendations for such management improvements as are necessary to eliminate or substantially remedy existing deficiencies.

(C) The Secretary shall seek to enter into an agreement with each troubled public housing agency, after reviewing the report submitted pursuant to subparagraph (B) (if applicable) and consulting with the agency's assessment team. Such agreement shall set forth—

(i) targets for improving performance as measured by the performance indicators specified under paragraph (1) and other requirements within a specified period of time;

(ii) strategies for meeting such targets, including a description of the technical assistance that the Secretary will make available to the agency; and

(iii) incentives or sanctions for effective implementation of such strategies, which may include any constraints on the use of funds that the Secretary determines are appropriate.

To the extent the Secretary deems appropriate (taking into account an agency's performance under the indicators specified under paragraph (1)), such agreement shall also set forth a plan for enhancing resident involvement in the management of the public housing agency. The Secretary and the public housing agency shall, to the maximum extent practicable, seek the assistance of local public and private entities in carrying out the agreement.

(D) The Secretary shall apply the provisions of this paragraph to resident management corporations as well as public housing agencies.

(3)(A) Notwithstanding any other provision of law or of any contract for contributions, upon the occurrence of events or conditions that constitute a substantial default by a public housing agency with respect to the covenants or conditions to which the public housing agency is subject or an agreement entered into under paragraph (2), the Secretary may—

(i) solicit competitive proposals from other public housing agencies and private housing management agents which (I) in the discretion of the Secretary, may be selected by existing public housing residents through administrative procedures established by the Secretary, and (II) if appropriate, shall provide for such agents to manage all, or part, of the housing administered by the public housing agency or all or part of the other programs of the agency;

(ii) petition for the appointment of a receiver (which may be another public housing agency or a private management corporation) of the public housing agency to any district court of the United States or to any court of the State in which the real property of the public housing agency is situated, that is authorized to appoint a receiver for the purposes and having the powers prescribed in this subsection;

(iii) solicit competitive proposals from other public housing agencies and private entities with experience in construction management in the eventuality that such agencies or firms may be needed to oversee implementation of assistance made available from the Capital Fund under section 1437g(d) of this title for the housing; and [6]

(iv) take possession of all or part of the public housing agency, including all or part of any project or program of the agency, including any project or program under any other provision of this subchapter; and

(v) require the agency to make other arrangements acceptable to the Secretary and in the best interests of the public housing residents and families assisted under section 1437f of this title for managing all, or part, of the public housing administered by the agency or of the programs of the agency.

Residents of a public housing agency designated as troubled pursuant to paragraph (2)(A) may petition the Secretary in writing to take 1 or more of the actions referred to in this subparagraph. The

[6] So in original. The word "and" probably should not appear.

Secretary shall respond to such petitions in a timely manner with a written description of the actions, if any, the Secretary plans to take and, where applicable, the reasons why such actions differ from the course proposed by the residents.

(B)(i) If a public housing agency is identified as troubled under this subsection, the Secretary shall notify the agency of the troubled status of the agency.

(ii)(I) Upon the expiration of the 1-year period beginning on the later of the date on which the agency receives initial notice from the Secretary of the troubled status of the agency under clause (i) and October 21, 1998, the agency shall improve its performance, as measured by the performance indicators established pursuant to paragraph (1), by at least 50 percent of the difference between the most recent performance measurement and the measurement necessary to remove that agency's designation as troubled.

(II) Upon the expiration of the 2-year period beginning on the later of the date on which the agency receives initial notice from the Secretary of the troubled status of the agency under clause (i) and October 21, 1998, the agency shall improve its performance, as measured by the performance indicators established pursuant to paragraph (1), such that the agency is no longer designated as troubled.

(III) In the event that a public housing agency designated as troubled under this subsection fails to comply with the requirements set forth in subclause (I) or (II), the Secretary shall

(aa) in the case of a troubled public housing agency with 1,250 or more units, petition for the appointment of a receiver pursuant to subparagraph (A)(ii); or

(bb) in the case of a troubled public housing agency with fewer than 1,250 units, either petition for the appointment of a receiver pursuant to subparagraph (A)(ii), or take possession of the public housing agency (including all or part of any project or program of the agency) pursuant to subparagraph (A)(iv) and appoint, on a competitive or noncompetitive basis, an individual or entity as an administrative receiver to assume the responsibilities of the Secretary for the administration of all or part of the public housing agency (including all or part of any project or program of the agency).

This subparagraph shall not be construed to limit the courses of action available to the Secretary under subparagraph (A).

(IV) During the period between the date on which a petition is filed under subclause (III)(aa) and the date on which a receiver assumes responsibility for the management of the public housing agency under such subclause, the Secretary may take possession of the public housing agency (including all or part of any project or program of the agency) pursuant to subparagraph (A)(iv) and may appoint, on a competitive or noncompetitive basis, an individual or entity as an administrative receiver to assume the responsibilities of the Secretary for the administration of all or part of the public housing agency (including all or part of any project or program of the agency).

(C) If a receiver is appointed pursuant to subparagraph (A)(ii), in addition to the powers accorded by the court appointing the receiver, the receiver

(i) may abrogate any contract to which the United States or an agency of the United States is not a party that, in the receiver's written determination (which shall include the basis for such determination), substantially impedes correction of the substantial default, but only after the receiver determines that reasonable efforts to renegotiate such contract have failed;

(ii) may demolish and dispose of all or part of the assets of the public housing agency (including all or part of any project of the agency) in accordance with section 1437p of this title, including disposition by transfer of properties to resident-supported nonprofit entities;

(iii) if determined to be appropriate by the Secretary, may seek the establishment, as permitted by applicable State and local law, of 1 or more new public housing agencies;

(iv) if determined to be appropriate by the Secretary, may seek consolidation of all or part of the agency (including all or part of any project or program of the agency), as permitted by applicable State and local laws, into other well-managed public housing agencies with the consent of such well-managed agencies; and

(v) shall not be required to comply with any State or local law relating to civil service requirements, employee rights (except civil rights), procurement, or financial or administrative controls that, in the receiver's written determination (which shall include the basis for such determination), substantially impedes correction of the substantial default.

(D)(i) If, pursuant to subparagraph (A)(iv), the Secretary takes possession of all or part of the public housing agency, including all or part of any project or program of the agency, the Secretary

(I) may abrogate any contract to which the United States or an agency of the United States is not a party that, in the written determination of the Secretary (which shall include the basis for such determination), substantially impedes correction of the substantial default, but only after the Secretary determines that reasonable efforts to renegotiate such contract have failed;

(II) may demolish and dispose of all or part of the assets of the public housing agency (including all or part of any project of the agency) in accordance with section 1437p of this title, including disposition by transfer of properties to resident-supported nonprofit entities;

(III) may seek the establishment, as permitted by applicable State and local law, of 1 or more new public housing agencies;

(IV) may seek consolidation of all or part of the agency (including all or part of any project or program of the agency), as permitted by applicable State and local laws, into other well-managed public housing agencies with the consent of such well-managed agencies;

(V) shall not be required to comply with any State or local law relating to civil service requirements, employee rights (except civil rights), procurement, or financial or administrative controls that, in the Secretary's written determination (which shall include the basis for such determination), substantially impedes correction of the substantial default; and

(VI) shall, without any action by a district court of the United States, have such additional authority as a district court of the United States would have the authority to confer upon a receiver to achieve the purposes of the receivership.

(ii) If, pursuant to subparagraph (B)(ii)(III)(bb), the Secretary appoints an administrative receiver to assume the responsibilities of the Secretary for the administration of all or part of the public housing agency (including all or part of any project or program of the agency), the Secretary may delegate to the administrative receiver any or all of the powers given the Secretary by this subparagraph, as the Secretary determines to be appropriate and subject to clause (iii).

(iii) An administrative receiver may not take an action described in subclause (III) or (IV) of clause (i) unless the Secretary first approves an application by the administrative receiver to authorize such action.

(E) The Secretary may make available to receivers and other entities selected or appointed pursuant to this paragraph such assistance as the Secretary determines in the discretion of the Secretary is necessary and available to remedy the substantial deterioration of living conditions in individual public housing projects or other related emergencies that endanger the health, safety, and welfare of public housing residents or families assisted under section 1437f of this title. A decision made by the Secretary under this paragraph shall not be subject to review in any court of the United States, or in any court of any State, territory, or possession of the United States.

(F) In any proceeding under subparagraph (A)(ii), upon a determination that a substantial default has occurred and without regard to the availability of alternative remedies, the court shall appoint a receiver to conduct the affairs of all or part of the public housing agency in a manner consistent with this chapter and in accordance with such further terms and conditions as the court may provide. The receiver appointed may be another public housing agency, a private management corporation, or any other person or appropriate entity. The court shall have power to grant appropriate temporary or preliminary relief pending final disposition of the petition by the Secretary.

(G) The appointment of a receiver pursuant to this paragraph may be terminated, upon the petition of any party, when the court determines that all defaults have been cured or the public housing agency is capable again of discharging its duties.

(H) If the Secretary (or an administrative receiver appointed by the Secretary) takes possession of a public housing agency (including all or part of any project or program of the agency), or if a receiver is appointed by a court, the Secretary or receiver shall be deemed to be acting not in the official capacity of that person or entity, but rather in the capacity of the public housing agency, and any liability incurred, regardless of whether the incident giving rise to that liability occurred while the Secretary or receiver was in possession of all or part of the public housing agency (including all or part of any project or program of the agency), shall be the liability of the public housing agency.

(4) SANCTIONS FOR IMPROPER USE OF AMOUNTS

(A) IN GENERAL

In addition to any other actions authorized under this chapter, if the Secretary finds that a public housing agency receiving assistance amounts under section 1437g of this title for public housing has failed to comply substantially with any provision of this chapter relating to the public housing program, the Secretary may—

(i) terminate assistance payments under this[7] section 1437g of this title to the agency;

(ii) withhold from the agency amounts from the total allocations for the agency pursuant to section 1437g of this title;

(iii) reduce the amount of future assistance payments under section 1437g of this title to the agency by an amount equal to the amount of such payments that were not expended in accordance with this chapter;

(iv) limit the availability of assistance amounts provided to the agency under section 1437g of this title to programs, projects, or activities not affected by such failure to comply;

(v) withhold from the agency amounts allocated for the agency under section 1437f of this title; or

(vi) order other corrective action with respect to the agency.

(B) TERMINATION OF COMPLIANCE ACTION

If the Secretary takes action under subparagraph (A) with respect to a public housing agency, the Secretary shall—

(i) in the case of action under subparagraph (A)(i), resume payments of assistance amounts under section 1437g of this title to the agency in the full amount of the total allocations under section 1437g of this title for the agency at the time that the Secretary first determines that the agency will comply with the provisions of this chapter relating to the public housing program;

(ii) in the case of action under clause (ii) or (v) of subparagraph (A), make withheld amounts available as the Secretary considers appropriate to ensure that the agency complies with the provisions of this chapter relating to such program;

(iii) in the case of action under subparagraph (A)(iv), release such restrictions at the time that the Secretary first determines that the agency will comply with the provisions of this chapter relating to such program; or

(iv) in the case of action under subparagraph (vi), cease such action at the time that the Secretary first determines that the agency will comply with the provisions of this chapter relating to such program.

(5) The Secretary shall submit to the Congress annually, as a part of the report of the Secretary under section 3536 of this title, a report that—

(A) identifies the public housing agencies that have been designated as troubled under paragraph (2);

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[7] So in original. The word "this" probably should not appear.

(B) describes the grounds on which such public housing agencies were designated as troubled and continue to be so designated;

(C) describes the agreements that have been entered into with such agencies under such paragraph;

(D) describes the status of progress under such agreements;

(E) describes any action that has been taken in accordance with paragraph (3), including an accounting of the authorized funds that have been expended to support such actions; and

(F) describes the status of any public housing agency designated as troubled with respect to the program for assistance from the Capital Fund under section 1437g(d) of this title and specifies the amount of assistance the agency received under such program.

(6)(A) To the extent that the Secretary determines such action to be necessary in order to ensure the accuracy of any certification made under this section, the Secretary shall require an independent auditor to review documentation or other information maintained by a public housing agency pursuant to this section to substantiate each certification submitted by the agency or corporation relating to the performance of that agency or corporation.

(B) The Secretary may withhold, from assistance otherwise payable to the agency or corporation under section 1437g of this title, amounts sufficient to pay for the reasonable costs of any review under this paragraph.

(7) The Secretary shall apply the provisions of this subsection to resident management corporations in the same manner as applied to public housing agencies.

(k) Administrative grievance procedure regulations: grounds of adverse action, hearing, examination of documents, representation, evidence, decision; judicial hearing; eviction and termination procedures

The Secretary shall by regulation require each public housing agency receiving assistance under this chapter to establish and implement an administrative grievance procedure under which tenants will—

(1) be advised of the specific grounds of any proposed adverse public housing agency action;

(2) have an opportunity for a hearing before an impartial party upon timely request within any period applicable under subsection (*l*) of this section;

(3) have an opportunity to examine any documents or records or regulations related to the proposed action;

(4) be entitled to be represented by another person of their choice at any hearing;

(5) be entitled to ask questions of witnesses and have others make statements on their behalf; and

(6) be entitled to receive a written decision by the public housing agency on the proposed action.

For any grievance concerning an eviction or termination of tenancy that involves any activity that threatens the health, safety, or right to peaceful enjoyment of the premises of other tenants or employees of the public housing agency or any violent or drug-related

criminal activity on or off such premises, or any activity resulting in a felony conviction, the agency may (A) establish an expedited grievance procedure as the Secretary shall provide by rule under section 553 of Title 5, or (B) exclude from its grievance procedure any such grievance, in any jurisdiction which requires that prior to eviction, a tenant be given a hearing in court which the Secretary determines provides the basic elements of due process (which the Secretary shall establish by rule under section 553 of Title 5). Such elements of due process shall not include a requirement that the tenant be provided an opportunity to examine relevant documents within the possession of the public housing agency. The agency shall provide to the tenant a reasonable opportunity, prior to hearing or trial, to examine any relevant documents, records, or regulations directly related to the eviction or termination.

(l) Leases; terms and conditions; maintenance; termination

Each public housing agency shall utilize leases which—

(1) have a term of 12 months and shall be automatically renewed for all purposes except for noncompliance with the requirements under section 1437j(c) of this title (relating to community service requirements); except that nothing in this subchapter shall prevent a resident from seeking timely redress in court for failure to renew based on such noncompliance;

(2) do not contain unreasonable terms and conditions;

(3) obligate the public housing agency to maintain the project in a decent, safe, and sanitary condition;

(4) require the public housing agency to give adequate written notice of termination of the lease which shall not be less than—

(A) a reasonable period of time, but not to exceed 30 days—

(i) if the health or safety of other tenants, public housing agency employees, or persons residing in the immediate vicinity of the premises is threatened; or

(ii) in the event of any drug-related or violent criminal activity or any felony conviction;

(B) 14 days in the case of nonpayment of rent; and

(C) 30 days in any other case, except that if a State or local law provides for a shorter period of time, such shorter period shall apply;

(5) require that the public housing agency may not terminate the tenancy except for serious or repeated violation of the terms or conditions of the lease or for other good cause;

(6) provide that any criminal activity that threatens the health, safety, or right to peaceful enjoyment of the premises by other tenants or any drug-related criminal activity on or off such premises, engaged in by a public housing tenant, any member of the tenant's household, or any guest or other person under the tenant's control, shall be cause for termination of tenancy.

(7)[8] specify that with respect to any notice of eviction or termination, notwithstanding any State law, a public housing tenant shall be informed of the opportunity, prior to any hearing or trial, to examine any relevant documents, records, or regulations directly related to the eviction or termination;

(7)[9] provide that any occupancy in violation of section 13661(b) of this title (relating to ineligibility of illegal drug users and alcohol abusers) or the furnishing of any false or misleading information pursuant to section 13662 of this title (relating to termination of tenancy and assistance for illegal drug users and alcohol abusers) shall be cause for termination of tenancy;

(9) provide that it shall be cause for immediate termination of the tenancy of a public housing tenant if such tenant—

(A) is fleeing to avoid prosecution, or custody or confinement after conviction, under the laws of the place from which the individual flees, for a crime, or attempt to commit a crime, which is a felony under the laws of the place from which the individual flees, or which, in the case of the State of New Jersey, is a high misdemeanor under the laws of such State; or

(2)[10] is violating a condition of probation or parole imposed under Federal or State law.

For purposes of paragraph (5), the term "drug-related criminal activity" means the illegal manufacture, sale, distribution, use, or possession with intent to manufacture, sell, distribute, or use, of a controlled substance (as defined in section 802 of Title 21).

(m) Reporting requirements; limitation

The Secretary shall not impose any unnecessarily duplicative or burdensome reporting requirements on tenants or public housing agencies assisted under this chapter.

(n) Notice to post office regarding eviction for criminal activity

When a public housing agency evicts an individual or family from a dwelling unit for engaging in criminal activity, including drug-related criminal activity, the public housing agency shall notify the local post office serving that dwelling unit that such individual or family is no longer residing in the dwelling unit.

(o) Public housing assistance for foster care children

In providing housing in low-income housing projects, each public housing agency may coordinate with any local public agencies involved in providing for the welfare of children to make available dwelling units to—

(1) families identified by the agencies as having a lack of adequate housing that is a primary factor—

(A) in the imminent placement of a child in foster care; or

[8] So in original. Two paragraphs (7) were enacted.
[9] So in original. Two paragraphs (7) were enacted.
[10] So in original. Designation "(B)" was probably intended.

(B) in preventing the discharge of a child from foster care and reunification with his or her family; and

(2) youth, upon discharge from foster care, in cases in which return to the family or extended family or adoption is not available.

(q)[11] Availability of records

(1) In general

(A) Provision of information

Notwithstanding any other provision of law, except as provided in subparagraph (C), the National Crime Information Center, police departments, and other law enforcement agencies shall, upon request, provide information to public housing agencies regarding the criminal conviction records of adult applicants for, or tenants of, covered housing assistance for purposes of applicant screening, lease enforcement, and eviction.

(B) Requests by owners of project-based section 8 [42 U.S.C. 1437f] housing

A public housing agency may make a request under subparagraph (A) for information regarding applicants for, or tenants of, housing that is provided project-based assistance under section 1437f of this title only if the housing is located within the jurisdiction of the agency and the owner of such housing has requested that the agency obtain such information on behalf of the owner. Upon such a request by the owner, the agency shall make a request under subparagraph (A) for the information. The agency may not make such information available to the owner but shall perform determinations for the owner regarding screening, lease enforcement, and eviction based on criteria supplied by the owner.

(C) Exception

A law enforcement agency described in subparagraph (A) shall provide information under this paragraph relating to any criminal conviction of a juvenile only to the extent that the release of such information is authorized under the law of the applicable State, tribe, or locality.

(2) Opportunity to dispute

Before an adverse action is taken with regard to assistance under this subchapter on the basis of a criminal record, the public housing agency shall provide the tenant or applicant with a copy of the criminal record and an opportunity to dispute the accuracy and relevance of that record.

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[11] Subsection (p) was repealed by Public Law 105–276, Title V, § 519(b), Oct. 21, 1998, 112 Stat. 2561.

(3) Fees

A public housing agency may be charged a reasonable fee for information provided under paragraph (1). In the case of a public housing agency obtaining information pursuant to paragraph (1)(B) for another owner of housing, the agency may pass such fee on to the owner initiating the request and may charge additional reasonable fees for making the request on behalf of the owner and taking other actions for owners under this subsection.

(4) Records management

Each public housing agency shall establish and implement a system of records management that ensures that any criminal record received by the public housing agency is—

(A) maintained confidentially;

(B) not misused or improperly disseminated; and

(C) destroyed, once the purpose for which the record was requested has been accomplished.

(5) Confidentiality

A public housing agency receiving information under this subsection may use such information only for the purposes provided in this subsection and such information may not be disclosed to any person who is not an officer, employee, or authorized representative of the agency and who has a job-related need to have access to the information in connection with admission of applicants, eviction of tenants, or termination of assistance. For judicial eviction proceedings, disclosures may be made to the extent necessary. The Secretary shall, by regulation, establish procedures necessary to ensure that information provided under this subsection to a public housing agency is used, and confidentiality of such information is maintained, as required under this subsection. The Secretary shall establish standards for confidentiality of information obtained under this subsection by public housing agencies on behalf of owners.

(6) Penalty

Any person who knowingly and willfully requests or obtains any information concerning an applicant for, or tenant of, covered housing assistance pursuant to the authority under this subsection under false pretenses, or any person who knowingly and willfully discloses any such information in any manner to any individual not entitled under any law to receive it, shall be guilty of a misdemeanor and fined not more than $5,000. The term "person" as used in this paragraph include[12] an officer, employee, or authorized representative of any public housing agency.

(7) Civil action

Any applicant for, or tenant of, covered housing assistance affected by (A) a negligent or knowing disclosure of information referred to in this subsection about such person by an officer,

[12] So in original. Probably should be "includes".

employee, or authorized representative of any public housing agency, which disclosure is not authorized by this subsection, or (B) any other negligent or knowing action that is inconsistent with this subsection, may bring a civil action for damages and such other relief as may be appropriate against any public housing agency responsible for such unauthorized action. The district court of the United States in the district in which the affected applicant or tenant resides, in which such unauthorized action occurred, or in which the officer, employee, or representative alleged to be responsible for any such unauthorized action resides, shall have jurisdiction in such matters. Appropriate relief that may be ordered by such district courts shall include reasonable attorney's fees and other litigation costs.

(8) Definitions

For purposes of this subsection, the following definitions shall apply:

(A) Adult

The term "adult" means a person who is 18 years of age or older, or who has been convicted of a crime as an adult under any Federal, State, or tribal law.

(B) Covered housing assistance

The term "covered housing assistance" means—

(i) a dwelling unit in public housing;

(ii) a dwelling unit in housing that is provided project-based assistance under section 1437f of this title, including new construction and substantial rehabilitation projects; and

(iii) tenant-based assistance under section 1437f of this title.

(C) Owner

The term "owner" means, with respect to covered housing assistance described in subparagraph (B)(ii), the entity or private person (including a cooperative or public housing agency) that has the legal right to lease or sublease dwelling units in the housing assisted.

(r) Site-based waiting lists

(1) Authority

A public housing agency may establish procedures for maintaining waiting lists for admissions to public housing projects of the agency, which may include (notwithstanding any other law, regulation, handbook, or notice to the contrary) a system of site-based waiting lists under which applicants may apply directly at or otherwise designate the project or projects in which they seek to reside. All such procedures shall comply with all provisions of title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000d et seq.], the Fair Housing Act [42 U.S.C. 3601 et seq.], and other applicable civil rights laws.

(2) Notice

Any system described in paragraph (1) shall provide for the full disclosure by the public housing agency to each applicant of any option available to the applicant in the selection of the project in which to reside.

(s) Authority to require access to criminal records

A public housing agency may require, as a condition of providing admission to the public housing program or assisted housing program under the jurisdiction of the public housing agency, that each adult member of the household provide a signed, written authorization for the public housing agency to obtain records described in subsection (q)(1) of this section regarding such member of the household from the National Crime Information Center, police departments, and other law enforcement agencies.

(t) Obtaining information from drug abuse treatment facilities

(1) Authority

Notwithstanding any other provision of law other than the Public Health Service Act (42 U.S.C. 201 et seq.), a public housing agency may require each person who applies for admission to public housing to sign one or more forms of written consent authorizing the agency to receive information from a drug abuse treatment facility that is solely related to whether the applicant is currently engaging in the illegal use of a controlled substance.

(2) Confidentiality of applicant's records

(A) Limitation on information requested

In a form of written consent, a public housing agency may request only whether the drug abuse treatment facility has reasonable cause to believe that the applicant is currently engaging in the illegal use of a controlled substance.

(B) Records management

Each public housing agency that receives information under this subsection from a drug abuse treatment facility shall establish and implement a system of records management that ensures that any information received by the public housing agency under this subsection—

(i) is maintained confidentially in accordance with section 543 of the Public Health Service Act [42 U.S.C. 290dd–2];

(ii) is not misused or improperly disseminated; and

(iii) is destroyed, as applicable—

(I) not later than 5 business days after the date on which the public housing agency gives final approval for an application for admission; or

(II) if the public housing agency denies the application for admission, in a timely manner after

the date on which the statute of limitations for the commencement of a civil action from the applicant based upon that denial of admission has expired.

(C) Expiration of written consent

In addition to the requirements of subparagraph (B), an applicant's signed written consent shall expire automatically after the public housing agency has made a final decision to either approve or deny the applicant's application for admittance to public housing.

(3) Prohibition of discriminatory treatment of applicants

(A) Forms signed

A public housing agency may only require an applicant for admission to public housing to sign one or more forms of written consent under this subsection if the public housing agency requires all such applicants to sign the same form or forms of written consent.

(B) Circumstances of inquiry

A public housing agency may only make an inquiry to a drug abuse treatment facility under this subsection if—

(i) the public housing agency makes the same inquiry with respect to all applicants; or

(ii) the public housing agency only makes the same inquiry with respect to each and every applicant with respect to whom—

(I) the public housing agency receives information from the criminal record of the applicant that indicates evidence of a prior arrest or conviction; or

(II) the public housing agency receives information from the records of prior tenancy of the applicant that demonstrates that the applicant—

(aa) engaged in the destruction of property;

(bb) engaged in violent activity against another person; or

(cc) interfered with the right of peaceful enjoyment of the premises of another tenant.

(4) Fee permitted

A drug abuse treatment facility may charge a public housing agency a reasonable fee for information provided under this subsection.

(5) Disclosure permitted by treatment facilities

A drug abuse treatment facility shall not be liable for damages based on any information required to be disclosed pursuant to this subsection if such disclosure is consistent with section 543 of the Public Health Service Act (42 U.S.C. 290dd–2).

(6) Option to not request information

A public housing agency shall not be liable for damages based on its decision not to require each person who applies for admission to public housing to sign one or more forms of written consent authorizing the public housing agency to receive information from a drug abuse treatment facility under this subsection.

(7) Definitions

For purposes of this subsection, the following definitions shall apply:

(A) Drug abuse treatment facility

The term "drug abuse treatment facility" means an entity that—

(i) is—

(I) an identified unit within a general medical care facility; or

(II) an entity other than a general medical care facility; and

(ii) holds itself out as providing, and provides, diagnosis, treatment, or referral for treatment with respect to the illegal use of a controlled substance.

(B) Controlled substance

The term "controlled substance" has the meaning given the term in section 802 of Title 21.

(C) Currently engaging in the illegal use of a controlled substance

The term "currently engaging in the illegal use of a controlled substance" means the illegal use of a controlled substance that occurred recently enough to justify a reasonable belief that an applicant's illegal use of a controlled substance is current or that continuing illegal use of a controlled substance by the applicant is a real and ongoing problem.

(8) Effective date

This subsection shall take effect on October 21, 1998, and without the necessity of guidance from, or any regulation issued by, the Secretary.

42 U.S.C. § 1437f

United States Housing Act, Public Law 75–412 (Act of September 1, 1937), sec. 8

Drug-related criminal activity constitutes grounds for termination of public housing leases

§ 1437f. Low-income housing assistance [1]

(a) Authorization for assistance payments

For the purpose of aiding low-income families in obtaining a decent place to live and of promoting economically mixed housing, assistance payments may be made with respect to existing housing in accordance with the provisions of this section.

(b) Other existing housing programs

(1) IN GENERAL

The Secretary is authorized to enter into annual contributions contracts with public housing agencies pursuant to which such agencies may enter into contracts to make assistance payments to owners of existing dwelling units in accordance with

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[1] Sept. 1, 1937, c. 896, Title I, § 8, as added Aug. 22, 1974, Public Law 93–383, Title II, § 201(a), 88 Stat. 662, and amended Aug. 3, 1976, Public Law 94–375, § 2(d), (e), (g), 90 Stat. 1068; Apr. 30, 1977, Public Law 95–24, Title I, § 101(c), 91 Stat. 55; Oct. 12, 1977, Public Law 95–128, Title II, § 201(c) to (e), 91 Stat. 1128; Oct. 31, 1978, Public Law 95–557, Title II, § 206(d)(1), (e), (f), 92 Stat. 2091, 2092; Dec. 21, 1979, Public Law 96–153, Title II, §§ 202(b), 206(b), 210, 211(b), 93 Stat. 1106, 1108 to 1110; Oct. 8, 1980, Public Law 96–399, Title II, § 203, Title III, § 308(c)(3), 94 Stat. 1629, 1641; Aug. 13, 1981, Public Law 97–35, Title III, §§ 322(e), 324 to 326(a), (e)(1), 329H(a), 95 Stat. 402, 405 to 407, 410; Nov. 30, 1983, Public Law 98–181, Title II, §§ 203(b)(1), (2), 207 to 209(a), 210, 211, 97 Stat. 1178, 1181 to 1183; Oct. 17, 1984, Public Law 98–479, Title I, § 102(b)(6) to (10), 98 Stat. 2221, 2222; Feb. 5, 1988, Public Law 100–242, Title I, §§ 141 to 149, Title II, §§ 203, 262, 101 Stat. 1849 to 1853, 1878, 1890; renumbered Title I, June 29, 1988, Public Law 100–358, § 5, 102 Stat. 681, and amended Nov. 7, 1988, Public Law 100–628, Title X, §§ 1004(a), 1005(b)(1), (c), 1006, 1014(b), (c), 1029, 102 Stat. 3264, 3265, 3269, 3272; Dec. 15, 1989, Public Law 101–235, Title I, § 127, Title VIII, § 801(c), (g), 103 Stat. 2025, 2058, 2059; Nov. 28, 1990, Public Law 101–625, Title II, § 289(b), Title IV, § 413, Title V, §§ 541 to 545(a), 545(2) [b], 546 to 549, 550(a), (c), 551 to 553, 572, Title VI, §§ 603, 613(a), 104 Stat. 4128, 4160, 4216 to 4224, 4236, 4277, 4280; Oct. 28, 1991, Public Law 102–139, Title II, 105 Stat. 756; Oct. 28, 1992, Public Law 102–550, Title I, §§ 141 to 148, 185(a), Title VI, §§ 623(b), 660, 674, 675, 682(b), Title X, § 1012(g), 106 Stat. 3713 to 3715, 3745, 3819, 3825, 3827, 3828, 3830, 3905; Apr. 11, 1994, Public Law 103–233, Title I, § 101(c)(2), (3), (d), 108 Stat. 357; Sept. 28, 1994, Public Law 103–327, Title II, 108 Stat. 2315; July 27, 1995, Public Law 104–19, Title I, § 1003, 109 Stat. 236; Jan. 26, 1996, Public Law 104–99, Title IV, §§ 402(d)(2), (3), (6)(A)(iii), (iv), 405(c), 110 Stat. 41, 42, 44; Apr. 26, 1996, Public Law 104–134, Title I, § 101(e) [Title II, §§ 203(a) to (c), 208], 110 Stat. 1321–281, 1321–284; renumbered Title I, May 2, 1996, Public Law 104–140, § 1(a), 110 Stat. 1327, and amended Aug. 22, 1996, Public Law 104–193, Title IX, § 903(a)(2), 110 Stat. 2348; Sept. 26, 1996, Public Law 104–204, Title II, § 201(g), 110 Stat. 2893; June 12, 1997, Public Law 105–18, Title II, § 10002, 111 Stat. 201; Aug. 5, 1997, Public Law 105–33, Title II, §§ 2003, 2004, 111 Stat. 257; Oct. 27, 1997, Public Law 105–65, Title II, §§ 201(c), 205, Title V, § 523(a), (c), 111 Stat. 1364, 1365, 1406, 1407; Oct. 21, 1998, Public Law 105–276, Title II, § 209(a), Title V, §§ 514(b)(1), 545(a), (b), 547 to 549(a)(1), (2), (b), 550(a), 552 to 555(a), 556(a), 565(c), 112 Stat. 2485, 2547, 2596, 2604 to 2611, 2613, 2631; Oct. 20, 1999, Public Law 106–74, Title II, § 223, Title V, §§ 523(a), 531(d), 535, 538(a), 113 Stat. 1076, 1104, 1116, 1121, 1122; July 13, 2000, Public Law 106–246, Div. B, Title II, § 2801, 114 Stat. 569; Oct. 27, 2000, Public Law 106–377, § 1(a) (1) [Title II, §§ 205, 228, 232(a), 234], 114 Stat. 1441, 1441A–24, 1441A–30, 1441A–31, 1441A–35; Dec. 27, 2000, Public Law 106–569, Title III, § 301(a), Title IX, §§ 902(a), 903(a), 114 Stat. 2952, 3026; Public Law 107–95, § 12, Dec. 21, 2001, 115 Stat. 921; Public Law 107–116, Title VI, § 632, Jan. 10, 2002, 115 Stat. 2227.

this section. In areas where no public housing agency has been organized or where the Secretary determines that a public housing agency is unable to implement the provisions of this section, the Secretary is authorized to enter into such contracts and to perform the other functions assigned to a public housing agency by this section.

(2) The Secretary is authorized to enter into annual contributions contracts with public housing agencies for the purpose of replacing public housing transferred in accordance with subchapter II–A of this chapter. Each contract entered into under this subsection shall be for a term of not more than 60 months.

(c) Contents and purposes of contracts for assistance payments; amount and scope of monthly assistance payments

(1) An assistance contract entered into pursuant to this section shall establish the maximum monthly rent (including utilities and all maintenance and management charges) which the owner is entitled to receive for each dwelling unit with respect to which such assistance payments are to be made. The maximum monthly rent shall not exceed by more than 10 per centum the fair market rental established by the Secretary periodically but not less than annually for existing or newly constructed rental dwelling units of various sizes and types in the market area suitable for occupancy by persons assisted under this section, except that the maximum monthly rent may exceed the fair market rental (A) by more than 10 but not more than 20 per centum where the Secretary determines that special circumstances warrant such higher maximum rent or that such higher rent is necessary to the implementation of a housing strategy as defined in section 12705 of this title, or (B) by such higher amount as may be requested by a tenant and approved by the public housing agency in accordance with paragraph (3)(B). In the case of newly constructed and substantially rehabilitated units, the exception in the preceding sentence shall not apply to more than 20 per centum of the total amount of authority to enter into annual contributions contracts for such units which is allocated to an area and obligated with respect to any fiscal year beginning on or after October 1, 1980. Proposed fair market rentals for an area shall be published in the Federal Register with reasonable time for public comment, and shall become effective upon the date of publication in final form in the Federal Register. Each fair market rental in effect under this subsection shall be adjusted to be effective on October 1 of each year to reflect changes, based on the most recent available data trended so the rentals will be current for the year to which they apply, of rents for existing or newly constructed rental dwelling units, as the case may be, of various sizes and types in the market area suitable for occupancy by persons assisted under this section. Notwithstanding any other provision of this section, after October 12, 1977, the Secretary shall prohibit high-rise elevator projects for families with children unless there is no practical alternative. The Secretary shall establish separate fair market rentals under this paragraph for Westchester County in the State

of New York. The Secretary shall also establish separate fair market rentals under this paragraph for Monroe County in the Commonwealth of Pennsylvania. In establishing fair market rentals for the remaining portion of the market area in which Monroe County is located, the Secretary shall establish the fair market rentals as if such portion included Monroe County. If units assisted under this section are exempt from local rent control while they are so assisted or otherwise, the maximum monthly rent for such units shall be reasonable in comparison with other units in the market area that are exempt from local rent control.

(2)(A) The assistance contract shall provide for adjustment annually or more frequently in the maximum monthly rents for units covered by the contract to reflect changes in the fair market rentals established in the housing area for similar types and sizes of dwelling units or, if the Secretary determines, on the basis of a reasonable formula. However, where the maximum monthly rent, for a unit in a new construction, substantial rehabilitation, or moderate rehabilitation project, to be adjusted using an annual adjustment factor exceeds the fair market rental for an existing dwelling unit in the market area, the Secretary shall adjust the rent only to the extent that the owner demonstrates that the adjusted rent would not exceed the rent for an unassisted unit of similar quality, type, and age in the same market area, as determined by the Secretary. The immediately foregoing sentence shall be effective only during fiscal year 1995, fiscal year 1996 prior to April 26, 1996, and fiscal years 1997 and 1998, and during fiscal year 1999 and thereafter. Except for assistance under the certificate program, for any unit occupied by the same family at the time of the last annual rental adjustment, where the assistance contract provides for the adjustment of the maximum monthly rent by applying an annual adjustment factor and where the rent for a unit is otherwise eligible for an adjustment based on the full amount of the factor, 0.01 shall be subtracted from the amount of the factor, except that the factor shall not be reduced to less than 1.0. In the case of assistance under the certificate program, 0.01 shall be subtracted from the amount of the annual adjustment factor (except that the factor shall not be reduced to less than 1.0), and the adjusted rent shall not exceed the rent for a comparable unassisted unit of similar quality, type, and age in the market area. The immediately foregoing two sentences shall be effective only during fiscal year 1995, fiscal year 1996 prior to April 26, 1996, and fiscal years 1997 and 1998, and during fiscal year 1999 and thereafter. In establishing annual adjustment factors for units in new construction and substantial rehabilitation projects, the Secretary shall take into account the fact that debt service is a fixed expense. The immediately foregoing sentence shall be effective only during fiscal year 1998.

(B) The contract shall further provide for the Secretary to make additional adjustments in the maximum monthly rent for units under contract to the extent he determines such adjustments are necessary to reflect increases in the actual and necessary expenses of owning and maintaining the units which have resulted from substantial general increases in real property taxes, utility rates, or

similar costs which are not adequately compensated for by the adjustment in the maximum monthly rent authorized by subparagraph (A). The Secretary shall make additional adjustments in the maximum monthly rent for units under contract (subject to the availability of appropriations for contract amendments) to the extent the Secretary determines such adjustments are necessary to reflect increases in the actual and necessary expenses of owning and maintaining the units that have resulted from the expiration of a real property tax exemption. Where the Secretary determines that a project assisted under this section is located in a community where drug-related criminal activity is generally prevalent and the project's operating, maintenance, and capital repair expenses have been substantially increased primarily as a result of the prevalence of such drug-related activity, the Secretary may (at the discretion of the Secretary and subject to the availability of appropriations for contract amendments for this purpose), on a project by project basis, provide adjustments to the maximum monthly rents, to a level no greater than 120 percent of the project rents, to cover the costs of maintenance, security, capital repairs, and reserves required for the owner to carry out a strategy acceptable to the Secretary for addressing the problem of drug-related criminal activity. Any rent comparability standard required under this paragraph may be waived by the Secretary to so implement the preceding sentence. The Secretary may (at the discretion of the Secretary and subject to the availability of appropriations for contract amendments), on a project by project basis for projects receiving project-based assistance, provide adjustments to the maximum monthly rents to cover the costs of evaluating and reducing lead-based paint hazards, as defined in section 4851b of this title.

(C) Adjustments in the maximum rents under subparagraphs (A) and (B) shall not result in material differences between the rents charged for assisted units and unassisted units of similar quality, type, and age in the same market area, as determined by the Secretary. In implementing the limitation established under the preceding sentence, the Secretary shall establish regulations for conducting comparability studies for projects where the Secretary has reason to believe that the application of the formula adjustments under subparagraph (A) would result in such material differences. The Secretary shall conduct such studies upon the request of any owner of any project, or as the Secretary determines to be appropriate by establishing, to the extent practicable, a modified annual adjustment factor for such market area, as the Secretary shall designate, that is geographically smaller than the applicable housing area used for the establishment of the annual adjustment factor under subparagraph (A). The Secretary shall establish such modified annual adjustment factor on the basis of the results of a study conducted by the Secretary of the rents charged, and any change in such rents over the previous year, for assisted units and unassisted units of similar quality, type, and age in the smaller market area. Where the Secretary determines that such modified annual adjustment factor cannot be established or that such factor when applied to a particular project would result in material differences between the rents charged for assisted units and unassisted units

of similar quality, type, and age in the same market area, the Secretary may apply an alternative methodology for conducting comparability studies in order to establish rents that are not materially different from rents charged for comparable unassisted units. If the Secretary or appropriate State agency does not complete and submit to the project owner a comparability study not later than 60 days before the anniversary date of the assistance contract under this section, the automatic annual adjustment factor shall be applied. The Secretary may not reduce the contract rents in effect on or after April 15, 1987, for newly constructed, substantially rehabilitated, or moderately rehabilitated projects assisted under this section (including projects assisted under this section as in effect prior to November 30, 1983), unless the project has been refinanced in a manner that reduces the periodic payments of the owner. Any maximum monthly rent that has been reduced by the Secretary after April 14, 1987, and prior to November 7, 1988, shall be restored to the maximum monthly rent in effect on April 15, 1987. For any project which has had its maximum monthly rents reduced after April 14, 1987, the Secretary shall make assistance payments (from amounts reserved for the original contract) to the owner of such project in an amount equal to the difference between the maximum monthly rents in effect on April 15, 1987, and the reduced maximum monthly rents, multiplied by the number of months that the reduced maximum monthly rents were in effect.

(3) The amount of the monthly assistance payment with respect to any dwelling unit shall be the difference between the maximum monthly rent which the contract provides that the owner is to receive for the unit and the rent the family is required to pay under section 1437a(a) of this title. Reviews of family income shall be made no less frequently than annually.

(4) The assistance contract shall provide that assistance payments may be made only with respect to a dwelling unit under lease for occupancy by a family determined to be a lower income family at the time it initially occupied such dwelling unit, except that such payments may be made with respect to unoccupied units for a period not exceeding sixty days (A) in the event that a family vacates a dwelling unit before the expiration date of the lease for occupancy or (B) where a good faith effort is being made to fill an unoccupied unit, and, subject to the provisions of the following sentence, such payments may be made, in the case of a newly constructed or substantially rehabilitated project, after such sixty-day period in an amount equal to the debt service attributable to such an unoccupied dwelling unit for a period not to exceed one year, if a good faith effort is being made to fill the unit and the unit provides decent, safe, and sanitary housing. No such payment may be made after such sixty-day period if the Secretary determines that the dwelling unit is in a project which provides the owner with revenues exceeding the costs incurred by such owner with respect to such project.

(5) The Secretary shall take such steps as may be necessary, including the making of contracts for assistance payments in amounts in excess of the amounts required at the time of the initial renting of dwelling units, the reservation of annual contributions authority for the purpose of amending housing assistance contracts,

or the allocation of a portion of new authorizations for the purpose of amending housing assistance contracts, to assure that assistance payments are increased on a timely basis to cover increases in maximum monthly rents or decreases in family incomes.

(8)(A)[2] Not less than one year before termination of any contract under which assistance payments are received under this section, other than a contract for tenant-based assistance under this section, an owner shall provide written notice to the Secretary and the tenants involved of the proposed termination. The notice shall also include a statement that, if the Congress makes funds available, the owner and the Secretary may agree to a renewal of the contract, thus avoiding termination, and that in the event of termination the Department of Housing and Urban Development will provide tenant-based rental assistance to all eligible residents, enabling them to choose the place they wish to rent, which is likely to include the dwelling unit in which they currently reside. Any contract covered by this paragraph that is renewed may be renewed for a period of up to 1 year or any number or years, with payments subject to the availability of appropriations for any year.

(B) In the event the owner does not provide the notice required, the owner may not evict the tenants or increase the tenants' rent payment until such time as the owner has provided the notice and 1 year has elapsed. The Secretary may allow the owner to renew the terminating contract for a period of time sufficient to give tenants 1 year of advance notice under such terms and conditions as the Secretary may require.

(C) Any notice under this paragraph shall also comply with any additional requirements established by the Secretary.

(D) For purposes of this paragraph, the term "termination" means the expiration of the assistance contract or an owner's refusal to renew the assistance contract, and such term shall include termination of the contract for business reasons.

(d) Required provisions and duration of contracts for assistance payments; waiver of limitation

(1) Contracts to make assistance payments entered into by a public housing agency with an owner of existing housing units shall provide (with respect to any unit) that—

(A) the selection of tenants shall be the function of the owner, subject to the annual contributions contract between the Secretary and the agency, except that with respect to the certificate and moderate rehabilitation programs only, for the purpose of selecting families to be assisted, the public housing agency may establish local preferences, consistent with the public housing agency plan submitted under section 1437c–1 of this title by the public housing agency;

(B)(i) the lease between the tenant and the owner shall be for at least one year or the term of such contract, whichever is shorter, and shall contain other terms and conditions specified by the Secretary;

[2] Paragraph (6) was redesignated as paragraph (5). Paragraph (7) was repealed by Public Law 105–276, Title V, § 550(a)(3)(C), Oct. 21, 1998, 112 Stat. 2609.

(ii) during the term of the lease, the owner shall not terminate the tenancy except for serious or repeated violation of the terms and conditions of the lease, for violation of applicable Federal, State, or local law, or for other good cause;

(iii) during the term of the lease, any criminal activity that threatens the health, safety, or right to peaceful enjoyment of the premises by other tenants, any criminal activity that threatens the health, safety, or right to peaceful enjoyment of their residences by persons residing in the immediate vicinity of the premises, or any drug-related criminal activity on or near such premises, engaged in by a tenant of any unit, any member of the tenant's household, or any guest or other person under the tenant's control, shall be cause for termination of tenancy;

(iv) any termination of tenancy shall be preceded by the owner's provision of written notice to the tenant specifying the grounds for such action; and

(v) it shall be cause for termination of the tenancy of a tenant if such tenant—

(I) is fleeing to avoid prosecution, or custody or confinement after conviction, under the laws of the place from which the individual flees, for a crime, or attempt to commit a crime, which is a felony under the laws of the place from which the individual flees, or which, in the case of the State of New Jersey, is a high misdemeanor under the laws of such State; or

(II) is violating a condition of probation or parole imposed under Federal or State law;

(C) maintenance and replacement (including redecoration) shall be in accordance with the standard practice for the building concerned as established by the owner and agreed to by the agency; and

(D) the agency and the owner shall carry out such other appropriate terms and conditions as may be mutually agreed to by them.

(2)(A) Each contract for an existing structure entered into under this section shall be for a term of not less than one month nor more than one hundred and eighty months. The Secretary shall permit public housing agencies to enter into contracts for assistance payments of less than 12 months duration in order to avoid disruption in assistance to eligible families if the annual contributions contract is within 1 year of its expiration date.

(B)(i) In determining the amount of assistance provided under an assistance contract for project-based assistance under this paragraph or a contract for assistance for housing constructed or substantially rehabilitated pursuant to assistance provided under subsection (b)(2) of this section (as such subsection existed immediately before October 1, 1983), the Secretary may consider and annually adjust, with respect to such project, for the cost of employing or otherwise retaining the services of one or more service coordinators under section 661[3] to 3901 of the Housing and Community Development Act of 1992 [42 U.S.C. 13631] to coordinate the provision

[3] So in original. Probably should be "671".

of any services within the project for residents of the project who are elderly or disabled families.

(ii) The budget authority available under section 1437c(c) of this title for assistance under this section is authorized to be increased by $15,000,000 on or after October 1, 1992, and by $15,000,000 on or after October 1, 1993. Amounts made available under this subparagraph shall be used to provide additional amounts under annual contributions contracts for assistance under this section which shall be made available through assistance contracts only for the purpose of providing service coordinators under clause (i) for projects receiving project-based assistance under this paragraph and to provide additional amounts under contracts for assistance for projects constructed or substantially rehabilitated pursuant to assistance provided under subsection (b)(2) of this section (as such subsection existed immediately before October 1, 1983) only for such purpose.

(C) An assistance contract for project-based assistance under this paragraph shall provide that the owner shall ensure and maintain compliance with subtitle C of Title VI of the Housing and Community Development Act of 1992 [42 U.S.C. 13601 et seq.] and any regulations issued under such subtitle.

(D) An owner of a covered section 8 housing project (as such term is defined in section 659 of the Housing and Community Development Act of 1992 [42 U.S.C. 13619]) may give preference for occupancy of dwelling units in the project, and reserve units for occupancy, in accordance with subtitle D of Title VI of the Housing and Community Development Act of 1992 [42 U.S.C. 13611 et seq.].

(3) Notwithstanding any other provision of law, with the approval of the Secretary the public housing agency administering a contract under this section with respect to existing housing units may exercise all management and maintenance responsibilities with respect to those units pursuant to a contract between such agency and the owner of such units.

(4) A public housing agency that serves more than one unit of general local government may, at the discretion of the agency, in allocating assistance under this section, give priority to disabled families that are not elderly families.

(5) CALCULATION OF LIMIT.—Any contract entered into under section 514 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 shall be excluded in computing the limit on project-based assistance under this subsection.

(6) TREATMENT OF COMMON AREAS.—The Secretary may not provide any assistance amounts pursuant to an existing contract for project-based assistance under this section for a housing project and may not enter into a new or renewal contract for such assistance for a project unless the owner of the project provides consent, to such local law enforcement agencies as the Secretary determines appropriate, for law enforcement officers of such agencies to enter common areas of the project at any time and without advance notice upon a determination of probable cause by such officers that criminal activity is taking place in such areas.

(e) Restrictions on contracts for assistance payments

(1) Nothing in this chapter shall be deemed to prohibit an owner from pledging, or offering as security for any loan or obligation, a contract for assistance payments entered into pursuant to this section: *Provided,* That such security is in connection with a project constructed or rehabilitated pursuant to authority granted in this section, and the terms of the financing or any refinancing have been approved by the Secretary.[4]

(f) Definitions

As used in this section—

(1) the term "owner" means any private person or entity, including a cooperative, an agency of the Federal Government, or a public housing agency, having the legal right to lease or sublease dwelling units;

(2) the terms "rent" or "rental" mean, with respect to members of a cooperative, the charges under the occupancy agreements between such members and the cooperative;

(3) the term "debt service" means the required payments for principal and interest made with respect to a mortgage secured by housing assisted under this chapter;

(4) the term "participating jurisdiction" means a State or unit of general local government designated by the Secretary to be a participating jurisdiction under title II of the Cranston-Gonzalez National Affordable Housing Act [42 U.S.C. 12721 et seq.];

(5) the term "drug-related criminal activity" means the illegal manufacture, sale, distribution, use, or possession with intent to manufacture, sell, distribute, or use, of a controlled substance (as defined in section 802 of Title 21);

(6) the term "project-based assistance" means rental assistance under subsection (b) of this section that is attached to the structure pursuant to subsection (d)(2) or (o)(13) of this section; and

(7) the term "tenant-based assistance" means rental assistance under subsection (o) of this section that is not project-based assistance and that provides for the eligible family to select suitable housing and to move to other suitable housing.

(g) Regulations applicable for implementation of assistance payments

Notwithstanding any other provision of this chapter, assistance payments under this section may be provided, in accordance with regulations prescribed by the Secretary, with respect to some or all of the units in any project approved pursuant to section 1701q of Title 12.

(h) Nonapplicability of inconsistent provisions to contracts for assistance payments

Sections 1437c(e) and 1437d of this title (except as provided in section 1437d(j)(3) of this title), and any other provisions of this

[4] Paragraph (2) was repealed by Public Law 101–625, Title II, § 289(b), Nov. 28, 1990, 104 Stat. 4128.

chapter which are inconsistent with the provisions of this section shall not apply to contracts for assistance entered into under this section.

(i) Receipt of assistance by public housing agency under other law not to be considered

The Secretary may not consider the receipt by a public housing agency of assistance under section 811(b)(1) of the Cranston-Gonzalez National Affordable Housing Act [42 U.S.C. 8013(b)(1)], or the amount received, in approving assistance for the agency under this section or determining the amount of such assistance to be provided.

(k)[5] Verification of income

The Secretary shall establish procedures which are appropriate and necessary to assure that income data provided to public housing agencies and owners by families applying for or receiving assistance under this section is complete and accurate. In establishing such procedures, the Secretary shall randomly, regularly, and periodically select a sample of families to authorize the Secretary to obtain information on these families for the purpose of income verification, or to allow those families to provide such information themselves. Such information may include, but is not limited to, data concerning unemployment compensation and Federal income taxation and data relating to benefits made available under the Social Security Act [42 U.S.C. 301 et seq.], the Food Stamp Act of 1977 [7 U.S.C. 2011 et seq.], or Title 38. Any such information received pursuant to this subsection shall remain confidential and shall be used only for the purpose of verifying incomes in order to determine eligibility of families for benefits (and the amount of such benefits, if any) under this section.

(o)[6] Voucher program

(1) Authority

(A) In general

The Secretary may provide assistance to public housing agencies for tenant-based assistance using a payment standard established in accordance with subparagraph (B). The payment standard shall be used to determine the monthly assistance that may be paid for any family, as provided in paragraph (2).

(B) Establishment of payment standard

Except as provided under subparagraph (D), the payment standard for each size of dwelling unit in a market area shall not exceed 110 percent of the fair market rental established under subsection (c) of this section for the same size of dwelling unit in the same market area and

[5] Subsection (j) was repealed by Public Law 105–276, Title V, § 550(a)(6), Oct. 21, 1998, 112 Stat. 2609.

[6] Subsections (l) and (m) were repealed by Public Law 98–181, Title II, § 209(a)(5), Nov. 30, 1983, 97 Stat. 1183. Subsection (n) was repealed by Public Law 105–276, Title V, § 550(a)(7), Oct. 21, 1998, 112 Stat. 2609.

shall be not less than 90 percent of that fair market rental.

(C) Set-aside

The Secretary may set aside not more than 5 percent of the budget authority made available for assistance under this subsection as an adjustment pool. The Secretary shall use amounts in the adjustment pool to make adjusted payments to public housing agencies under subparagraph (A), to ensure continued affordability, if the Secretary determines that additional assistance for such purpose is necessary, based on documentation submitted by a public housing agency.

(D) Approval

The Secretary may require a public housing agency to submit the payment standard of the public housing agency to the Secretary for approval, if the payment standard is less than 90 percent of the fair market rental or exceeds 110 percent of the fair market rental.

(E) Review

The Secretary—

(i) shall monitor rent burdens and review any payment standard that results in a significant percentage of the families occupying units of any size paying more than 30 percent of adjusted income for rent; and

(ii) may require a public housing agency to modify the payment standard of the public housing agency based on the results of that review.

(2) Amount of monthly assistance payment

Subject to the requirement under section 1437a(a)(3) of this title (relating to minimum rental amount), the monthly assistance payment for a family receiving assistance under this subsection shall be determined as follows:

(A) Tenant-based assistance; rent not exceeding payment standard

For a family receiving tenant-based assistance, if the rent for the family (including the amount allowed for tenant-paid utilities) does not exceed the applicable payment standard established under paragraph (1), the monthly assistance payment for the family shall be equal to the amount by which the rent (including the amount allowed for tenant-paid utilities) exceeds the greatest of the following amounts, rounded to the nearest dollar:

(i) 30 percent of the monthly adjusted income of the family.

(ii) 10 percent of the monthly income of the family.

(iii) If the family is receiving payments for welfare assistance from a public agency and a part of those payments, adjusted in accordance with the actual housing costs of the family, is specifically designated

by that agency to meet the housing costs of the family, the portion of those payments that is so designated.

(B) Tenant-based assistance; rent exceeding payment standard

For a family receiving tenant-based assistance, if the rent for the family (including the amount allowed for tenant-paid utilities) exceeds the applicable payment standard established under paragraph (1), the monthly assistance payment for the family shall be equal to the amount by which the applicable payment standard exceeds the greatest of amounts under clauses (i), (ii), and (iii) of subparagraph (A).

(C) Families receiving project-based assistance

For a family receiving project-based assistance, the rent that the family is required to pay shall be determined in accordance with section 1437a(a)(1) of this title, and the amount of the housing assistance payment shall be determined in accordance with subsection (c)(3) of this section.

(3) 40 percent limit

At the time a family initially receives tenant-based assistance under this section with respect to any dwelling unit, the total amount that a family may be required to pay for rent may not exceed 40 percent of the monthly adjusted income of the family.

(4) Eligible families

To be eligible to receive assistance under this subsection, a family shall, at the time a family initially receives assistance under this subsection, be a low-income family that is—

(A) a very low-income family;

(B) a family previously assisted under this subchapter;

(C) a low-income family that meets eligibility criteria specified by the public housing agency;

(D) a family that qualifies to receive a voucher in connection with a homeownership program approved under title IV of the Cranston-Gonzalez National Affordable Housing Act; or

(E) a family that qualifies to receive a voucher under section 223 or 226 of the Low-Income Housing Preservation and Resident Homeownership Act of 1990 [12 U.S.C. 4113 or 4116].

(5) Annual review of family income

(A) In general

Reviews of family incomes for purposes of this section shall be subject to the provisions of section 3544 of this title and shall be conducted upon the initial provision of housing assistance for the family and thereafter not less than annually.

(B) Procedures

Each public housing agency administering assistance under this subsection shall establish procedures that are appropriate and necessary to ensure that income data provided to the agency and owners by families applying for or receiving assistance from the agency is complete and accurate. Each public housing agency shall, not less frequently than annually, conduct a review of the family income of each family receiving assistance under this subsection.

(6) Selection of families and disapproval of owners

(A) Preferences

(i) Authority to establish

Each public housing agency may establish a system for making tenant-based assistance under this subsection available on behalf of eligible families that provides preference for such assistance to eligible families having certain characteristics, which may include a preference for families residing in public housing who are victims of a crime of violence (as such term is defined in section 16 of Title 18) that has been reported to an appropriate law enforcement agency.

(ii) Content

Each system of preferences established pursuant to this subparagraph shall be based upon local housing needs and priorities, as determined by the public housing agency using generally accepted data sources, including any information obtained pursuant to an opportunity for public comment as provided under section 1437c–1(f) of this title and under the requirements applicable to the comprehensive housing affordability strategy for the relevant jurisdiction.

(B) Selection of tenants

Each housing assistance payment contract entered into by the public housing agency and the owner of a dwelling unit)[7] shall provide that the screening and selection of families for those units shall be the function of the owner. In addition, the public housing agency may elect to screen applicants for the program in accordance with such requirements as the Secretary may establish.

(C) PHA disapproval of owners

In addition to other grounds authorized by the Secretary, a public housing agency may elect not to enter into

[7] So in original. No opening parenthesis was enacted.

a housing assistance payments contract under this subsection with an owner who refuses, or has a history of refusing, to take action to terminate tenancy for activity engaged in by the tenant, any member of the tenant's household, any guest, or any other person under the control of any member of the household that—

(i) threatens the health or safety of, or right to peaceful enjoyment of the premises by, other tenants or employees of the public housing agency, owner, or other manager of the housing;

(ii) threatens the health or safety of, or right to peaceful enjoyment of the residences by, persons residing in the immediate vicinity of the premises; or

(iii) is drug-related or violent criminal activity.

(7) Leases and tenancy

Each housing assistance payment contract entered into by the public housing agency and the owner of a dwelling unit—

(A) shall provide that the lease between the tenant and the owner shall be for a term of not less than 1 year, except that the public housing agency may approve a shorter term for an initial lease between the tenant and the dwelling unit owner if the public housing agency determines that such shorter term would improve housing opportunities for the tenant and if such shorter term is considered to be a prevailing local market practice;

(B) shall provide that the dwelling unit owner shall offer leases to tenants assisted under this subsection that—

(i) are in a standard form used in the locality by the dwelling unit owner; and

(ii) contain terms and conditions that—

(I) are consistent with State and local law; and

(II) apply generally to tenants in the property who are not assisted under this section;

(C) shall provide that during the term of the lease, the owner shall not terminate the tenancy except for serious or repeated violation of the terms and conditions of the lease, for violation of applicable Federal, State, or local law, or for other good cause;

(D) shall provide that during the term of the lease, any criminal activity that threatens the health, safety, or right to peaceful enjoyment of the premises by other tenants, any criminal activity that threatens the health, safety, or right to peaceful enjoyment of their residences by persons residing in the immediate vicinity of the premises, or any violent or drug-related criminal activity on or near such premises, engaged in by a tenant of any unit, any member of the tenant's household, or any guest or other person under the tenant's control, shall be cause for termination of tenancy;

(E) shall provide that any termination of tenancy under this subsection shall be preceded by the provision of written notice by the owner to the tenant specifying the

grounds for that action, and any relief shall be consistent with applicable State and local law; and

(F) may include any addenda required by the Secretary to set forth the provisions of this subsection.

(8) Inspection of units by PHAs

(A) In general

Except as provided in paragraph (11), for each dwelling unit for which a housing assistance payment contract is established under this subsection, the public housing agency shall inspect the unit before any assistance payment is made to determine whether the dwelling unit meets the housing quality standards under subparagraph (B).

(B) Housing quality standards

The housing quality standards under this subparagraph are standards for safe and habitable housing established—

(i) by the Secretary for purposes of this subsection; or

(ii) by local housing codes or by codes adopted by public housing agencies that—

(I) meet or exceed housing quality standards, except that the Secretary may waive the requirement under this subclause to significantly increase access to affordable housing and to expand housing opportunities for families assisted under this subsection, except where such waiver could adversely affect the health or safety of families assisted under this subsection; and

(II) do not severely restrict housing choice [8]

(C) Inspection

The determination required under subparagraph (A) shall be made by the public housing agency (or other entity, as provided in paragraph (11)) pursuant to an inspection of the dwelling unit conducted before any assistance payment is made for the unit. Inspections of dwelling units under this subparagraph shall be made before the expiration of the 15-day period beginning upon a request by the resident or landlord to the public housing agency or, in the case of any public housing agency that provides assistance under this subsection on behalf of more than 1250 families, before the expiration of a reasonable period beginning upon such request. The performance of the agency in meeting the 15-day inspection deadline shall be taken into consideration in assessing the performance of the agency.

(D) Annual inspections

Each public housing agency providing assistance under this subsection (or other entity, as provided in paragraph (11)) shall make an annual inspection of each assisted

[8] So in original. Probably should be followed by a period.

dwelling unit during the term of the housing assistance payments contract for the unit to determine whether the unit is maintained in accordance with the requirements under subparagraph (A). The agency (or other entity) shall retain the records of the inspection for a reasonable time and shall make the records available upon request to the Secretary, the Inspector General for the Department of Housing and Urban Development, and any auditor conducting an audit under section 1437c(h) of this title.

(E) Inspection guidelines

The Secretary shall establish procedural guidelines and performance standards to facilitate inspections of dwelling units and conform such inspections with practices utilized in the private housing market. Such guidelines and standards shall take into consideration variations in local laws and practices of public housing agencies and shall provide flexibility to authorities appropriate to facilitate efficient provision of assistance under this subsection.

(9) Vacated units

If an assisted family vacates a dwelling unit for which rental assistance is provided under a housing assistance payment contract before the expiration of the term of the lease for the unit, rental assistance pursuant to such contract may not be provided for the unit after the month during which the unit was vacated.

(10) Rent

(A) Reasonableness

The rent for dwelling units for which a housing assistance payment contract is established under this subsection shall be reasonable in comparison with rents charged for comparable dwelling units in the private, unassisted local market.

(B) Negotiations

A public housing agency (or other entity, as provided in paragraph (11)) shall, at the request of a family receiving tenant-based assistance under this subsection, assist that family in negotiating a reasonable rent with a dwelling unit owner. A public housing agency (or such other entity) shall review the rent for a unit under consideration by the family (and all rent increases for units under lease by the family) to determine whether the rent (or rent increase) requested by the owner is reasonable. If a public housing agency (or other such entity) determines that the rent (or rent increase) for a dwelling unit is not reasonable, the public housing agency (or other such entity) shall not make housing assistance payments to the owner under this subsection with respect to that unit.

(C) Units exempt from local rent control

If a dwelling unit for which a housing assistance payment contract is established under this subsection is exempt from local rent control provisions during the term of that contract, the rent for that unit shall be reasonable in comparison with other units in the market area that are exempt from local rent control provisions.

(D) Timely payments

Each public housing agency shall make timely payment of any amounts due to a dwelling unit owner under this subsection. The housing assistance payment contract between the owner and the public housing agency may provide for penalties for the late payment of amounts due under the contract, which shall be imposed on the public housing agency in accordance with generally accepted practices in the local housing market.

(E) Penalties

Unless otherwise authorized by the Secretary, each public housing agency shall pay any penalties from administrative fees collected by the public housing agency, except that no penalty shall be imposed if the late payment is due to factors that the Secretary determines are beyond the control of the public housing agency.

(11) Leasing of units owned by PHA

If an eligible family assisted under this subsection leases a dwelling unit (other than a public housing dwelling unit) that is owned by a public housing agency administering assistance under this subsection, the Secretary shall require the unit of general local government or another entity approved by the Secretary, to make inspections required under paragraph (8) and rent determinations required under paragraph (10). The agency shall be responsible for any expenses of such inspections and determinations.

(12) Assistance for rental of manufactured housing

(A) In general

A public housing agency may make assistance payments in accordance with this subsection on behalf of a family that utilizes a manufactured home as a principal place of residence. Such payments may be made only for the rental of the real property on which the manufactured home owned by any such family is located.

(B) Rent calculation

(i) Charges included

For assistance pursuant to this paragraph, the rent for the space on which a manufactured home is located and with respect to which assistance payments are to

be made shall include maintenance and management charges and tenant-paid utilities.

(ii) Payment standard

The public housing agency shall establish a payment standard for the purpose of determining the monthly assistance that may be paid for any family under this paragraph. The payment standard may not exceed an amount approved or established by the Secretary.

(iii) Monthly assistance payment

The monthly assistance payment for a family assisted under this paragraph shall be determined in accordance with paragraph (2).

(13) PHA project-based assistance

(A) In general

A public housing agency may use amounts provided under an annual contributions contract under this subsection to enter into a housing assistance payment contract with respect to an existing, newly constructed, or rehabilitated structure, that is attached to the structure, subject to the limitations and requirements of this paragraph.

(B) Percentage limitation

Not more than 20 percent of the funding available for tenant-based assistance under this section that is administered by the agency may be attached to structures pursuant to this paragraph.

(C) Consistency with PHA plan and other goals

A public housing agency may approve a housing assistance payment contract pursuant to this paragraph only if the contract is consistent with—

(i) the public housing agency plan for the agency approved under section 1437c–1 of this title; and

(ii) the goal of deconcentrating poverty and expanding housing and economic opportunities.

(D) Income mixing requirement

(i) In general

Not more than 25 percent of the dwelling units in any building may be assisted under a housing assistance payment contract for project-based assistance pursuant to this paragraph.

(ii) Exceptions

The limitation under clause (i) shall not apply in the case of assistance under a contract for housing consisting of single family properties or for dwelling units that are specifically made available for households

comprised of elderly families, disabled families, and families receiving supportive services.

(E) Resident choice requirement

A housing assistance payment contract pursuant to this paragraph shall provide as follows:

(i) Mobility

Each low-income family occupying a dwelling unit assisted under the contract may move from the housing at any time after the family has occupied the dwelling unit for 12 months.

(ii) Continued assistance

Upon such a move, the public housing agency shall provide the low-income family with tenant-based rental assistance under this section or such other tenant-based rental assistance that is subject to comparable income, assistance, rent contribution, affordability, and other requirements, as the Secretary shall provide by regulation. If such rental assistance is not immediately available to fulfill the requirement under the preceding sentence with respect to a low-income family, such requirement may be met by providing the family priority to receive the next voucher or other tenant-based rental assistance amounts that become available under the program used to fulfill such requirement.

(F) Contract term

A housing assistance payment contract pursuant to this paragraph between a public housing agency and the owner of a structure may have a term of up to 10 years, subject to the availability of sufficient appropriated funds for the purpose of renewing expiring contracts for assistance payments, as provided in appropriations Acts and in the agency's annual contributions contract with the Secretary, and to annual compliance with the inspection requirements under paragraph (8), except that the agency shall not be required to make annual inspections of each assisted unit in the development. The contract may specify additional conditions for its continuation. If the units covered by the contract are owned by the agency, the term of the contract shall be agreed upon by the agency and the unit of general local government or other entity approved by the Secretary in the manner provided under paragraph (11).

(G) Extension of contract term

A public housing agency may enter into a contract with the owner of a structure assisted under a housing assistance payment contract pursuant to this paragraph to extend the term of the underlying housing assistance payment contract for such period as the agency determines to be appropriate to achieve long-term affordability of the

housing or to expand housing opportunities. Such a contract shall provide that the extension of such term shall be contingent upon the future availability of appropriated funds for the purpose of renewing expiring contracts for assistance payments, as provided in appropriations Acts, and may obligate the owner to have such extensions of the underlying housing assistance payment contract accepted by the owner and the successors in interest of the owner.

(H) Rent calculation

A housing assistance payment contract pursuant to this paragraph shall establish rents for each unit assisted in an amount that does not exceed 110 percent of the applicable fair market rental (or any exception payment standard approved by the Secretary pursuant to paragraph (1)(D)), except that if a contract covers a dwelling unit that has been allocated low-income housing tax credits pursuant to section 42 of Title 26 and is not located in a qualified census tract (as such term is defined in subsection (d) of such section 42, the rent for such unit may be established at any level that does not exceed the rent charged for comparable units in the building that also receive the low-income housing tax credit but do not have additional rental assistance. The rents established by housing assistance payment contracts pursuant to this paragraph may vary from the payment standards established by the public housing agency pursuant to paragraph (1)(B), but shall be subject to paragraph (10)(A).

(I) Rent adjustments

A housing assistance payments contract pursuant to this paragraph shall provide for rent adjustments, except that—

(i) the adjusted rent for any unit assisted shall be reasonable in comparison with rents charged for comparable dwelling units in the private, unassisted, local market and may not exceed the maximum rent permitted under subparagraph (H); and

(ii) the provisions of subsection (c)(2)(C) of this section shall not apply.

(J) Tenant selection

A public housing agency shall select families to receive project-based assistance pursuant to this paragraph from its waiting list for assistance under this subsection. Eligibility for such project-based assistance shall be subject to the provisions of section 1437n(b) of this title that apply to tenant-based assistance. The agency may establish preferences or criteria for selection for a unit assisted under this paragraph that are consistent with the public housing agency plan for the agency approved under section 1437c–1 of this title. Any family that rejects an offer of project-based assistance under this paragraph or that is rejected for admission to a structure by the owner or manager of

a structure assisted under this paragraph shall retain its place on the waiting list as if the offer had not been made. The owner or manager of a structure assisted under this paragraph shall not admit any family to a dwelling unit assisted under a contract pursuant to this paragraph other than a family referred by the public housing agency from its waiting list. Subject to its waiting list policies and selection preferences, a public housing agency may place on its waiting list a family referred by the owner or manager of a structure and may maintain a separate waiting list for assistance under this paragraph, but only if all families on the agency's waiting list for assistance under this subsection are permitted to place their names on the separate list.

(K) Vacated units

Notwithstanding paragraph (9), a housing assistance payment contract pursuant to this paragraph may provide as follows:

(i) Payment for vacant units

That the public housing agency may, in its discretion, continue to provide assistance under the contract, for a reasonable period not exceeding 60 days, for a dwelling unit that becomes vacant, but only: (I) if the vacancy was not the fault of the owner of the dwelling unit; and (II) the agency and the owner take every reasonable action to minimize the likelihood and extent of any such vacancy. Rental assistance may not be provided for a vacant unit after the expiration of such period.

(ii) Reduction of contract

That, if despite reasonable efforts of the agency and the owner to fill a vacant unit, no eligible family has agreed to rent the unit within 120 days after the owner has notified the agency of the vacancy, the agency may reduce its housing assistance payments contract with the owner by the amount equivalent to the remaining months of subsidy attributable to the vacant unit. Amounts deobligated pursuant to such a contract provision shall be available to the agency to provide assistance under this subsection.

Eligible applicants for assistance under this subsection may enforce provisions authorized by this subparagraph.

(14) Inapplicability to tenant-based assistance

Subsection (c) of this section shall not apply to tenant-based assistance under this subsection.

(15) Homeownership option

(A) In general

A public housing agency providing assistance under this subsection may, at the option of the agency, provide assistance for homeownership under subsection (y) of this section.

(B) Alternative administration

A public housing agency may contract with a nonprofit organization to administer a homeownership program under subsection (y) of this section.

(16) Rental vouchers for relocation of witnesses and victims of crime

(A) Witnesses

Of amounts made available for assistance under this subsection in each fiscal year, the Secretary, in consultation with the Inspector General, shall make available such sums as may be necessary for the relocation of witnesses in connection with efforts to combat crime in public and assisted housing pursuant to requests from law enforcement or prosecution agencies.

(B) Victims of crime

(i) In general

Of amounts made available for assistance under this section in each fiscal year, the Secretary shall make available such sums as may be necessary for the relocation of families residing in public housing who are victims of a crime of violence (as that term is defined in section 16 of Title 18) that has been reported to an appropriate law enforcement agency.

(ii) Notice

A public housing agency that receives amounts under this subparagraph shall establish procedures for providing notice of the availability of that assistance to families that may be eligible for that assistance.

(17) Deed restrictions

Assistance under this subsection may not be used in any manner that abrogates any local deed restriction that applies to any housing consisting of 1 to 4 dwelling units. This paragraph may not be construed to affect the provisions or applicability of the Fair Housing Act [42 U.S.C. 3601 et seq.].

(18) Rental assistance for assisted living facilities

(A) In general

A public housing agency may make assistance payments on behalf of a family that uses an assisted living facility

as a principal place of residence and that uses such supportive services made available in the facility as the agency may require. Such payments may be made only for covering costs of rental of the dwelling unit in the assisted living facility and not for covering any portion of the cost of residing in such facility that is attributable to service relating to assisted living.

(B) Rent calculation

(i) Charges included

For assistance pursuant to this paragraph, the rent of the dwelling unit that is an assisted living facility with respect to which assistance payments are made shall include maintenance and management charges related to the dwelling unit and tenant-paid utilities. Such rent shall not include any charges attributable to services relating to assisted living.

(ii) Payment standard

In determining the monthly assistance that may be paid under this paragraph on behalf of any family residing in an assisted living facility, the public housing agency shall utilize the payment standard established under paragraph (1), for the market area in which the assisted living facility is located, for the applicable size dwelling unit.

(iii) Monthly assistance payment

The monthly assistance payment for a family assisted under this paragraph shall be determined in accordance with paragraph (2) (using the rent and payment standard for the dwelling unit as determined in accordance with this subsection).

(C) Definition

For the purposes of this paragraph, the term "assisted living facility" has the meaning given that term in section 232(b) of the National Housing Act (12 U.S.C. 1715w(b)), except that such a facility may be contained within a portion of a larger multifamily housing project.

(19) Rental vouchers for Veterans Affairs supported housing program

(A) Set aside

Subject to subparagraph (C), the Secretary shall set aside, from amounts made available for rental assistance under this subsection, the amounts specified in subparagraph (B) for use only for providing such assistance through a supported housing program administered in conjunction with the Department of Veterans Affairs. Such program shall provide rental assistance on behalf of homeless veterans who have chronic mental illnesses or chronic substance use disorders, shall require agreement of the

veteran to continued treatment for such mental illness or substance use disorder as a condition of receipt of such rental assistance, and shall ensure such treatment and appropriate case management for each veteran receiving such rental assistance.

(B) Amount

The amount specified in this subparagraph is—

(i) for fiscal year 2003, the amount necessary to provide 500 vouchers for rental assistance under this subsection;

(ii) for fiscal year 2004, the amount necessary to provide 1,000 vouchers for rental assistance under this subsection;

(iii) for fiscal year 2005, the amount necessary to provide 1,500 vouchers for rental assistance under this subsection; and

(iv) for fiscal year 2006, the amount necessary to provide 2,000 vouchers for rental assistance under this subsection.

(C) Funding through incremental assistance

In any fiscal year, to the extent that this paragraph requires the Secretary to set aside rental assistance amounts for use under this paragraph in an amount that exceeds the amount set aside in the preceding fiscal year, such requirement shall be effective only to such extent or in such amounts as are or have been provided in appropriation Acts for such fiscal year for incremental rental assistance under this subsection.

(p) Shared housing for elderly and handicapped

In order to assist elderly families (as defined in section 1437a(b)(3) of this title) who elect to live in a shared housing arrangement in which they benefit as a result of sharing the facilities of a dwelling with others in a manner that effectively and efficiently meets their housing needs and thereby reduces their cost of housing, the Secretary shall permit assistance provided under the existing housing and moderate rehabilitation programs to be used by such families in such arrangements. In carrying out this subsection, the Secretary shall issue minimum habitability standards for the purpose of assuring decent, safe, and sanitary housing for such families while taking into account the special circumstances of shared housing.

(q) Administrative fees

(1) Fee for ongoing costs of administration

(A) In general

The Secretary shall establish fees for the costs of administering the tenant-based assistance, certificate, voucher, and moderate rehabilitation programs under this section.

(B) Fiscal year 1999

(i) Calculation

For fiscal year 1999, the fee for each month for which a dwelling unit is covered by an assistance contract shall be—

(I) in the case of a public housing agency that, on an annual basis, is administering a program for not more than 600 dwelling units, 7.65 percent of the base amount; and

(II) in the case of an agency that, on an annual basis, is administering a program for more than 600 dwelling units (aa) for the first 600 units, 7.65 percent of the base amount, and (bb) for any additional dwelling units under the program, 7.0 percent of the base amount.

(ii) Base amount

For purposes of this subparagraph, the base amount shall be the higher of—

(I) the fair market rental established under subsection (c) of this title (as in effect immediately before the effective date under section 503(a) of the Quality Housing and Work Responsibility Act of 1998) for fiscal year 1993 for a 2-bedroom existing rental dwelling unit in the market area of the agency, and

(II) the amount that is the lesser of (aa) such fair market rental for fiscal year 1994, or (bb) 103.5 percent of the amount determined under clause (i),

adjusted based on changes in wage data or other objectively measurable data that reflect the costs of administering the program, as determined by the Secretary. The Secretary may require that the base amount be not less than a minimum amount and not more than a maximum amount.

(C) Subsequent fiscal years

For subsequent fiscal years, the Secretary shall publish a notice in the Federal Register, for each geographic area, establishing the amount of the fee that would apply for public housing agencies administering the program, based on changes in wage data or other objectively measurable data that reflect the costs of administering the program, as determined by the Secretary.

(D) Increase

The Secretary may increase the fee if necessary to reflect the higher costs of administering small programs and programs operating over large geographic areas.

(E) Decrease

The Secretary may decrease the fee for units owned by a public housing agency to reflect reasonable costs of administration.

(2) Fee for preliminary expenses

The Secretary shall also establish reasonable fees (as determined by the Secretary) for—

(A) the costs of preliminary expenses, in the amount of $500, for a public housing agency, except that such fee shall apply to an agency only in the first year that the agency administers a tenant-based assistance program under this section, and only if, immediately before the effective date under section 503(a) of the Quality Housing and Work Responsibility Act of 1998, the agency was not administering a tenant-based assistance program under this chapter (as in effect immediately before such effective date), in connection with its initial increment of assistance received;

(B) the costs incurred in assisting families who experience difficulty (as determined by the Secretary) in obtaining appropriate housing under the programs; and

(C) extraordinary costs approved by the Secretary.

(3) Transfer of fees in cases of concurrent geographical jurisdiction

In each fiscal year, if any public housing agency provides tenant-based assistance under this section on behalf of a family who uses such assistance for a dwelling unit that is located within the jurisdiction of such agency but is also within the jurisdiction of another public housing agency, the Secretary shall take such steps as may be necessary to ensure that the public housing agency that provides the services for a family receives all or part of the administrative fee under this section (as appropriate).

(4) Applicability

This subsection shall apply to fiscal year 1999 and fiscal years thereafter.

(r) Portability

(1) IN GENERAL.—(A) Any family receiving tenant-based assistance under subsection (o) of this section may receive such assistance to rent an eligible dwelling unit if the dwelling unit to which the family moves is within any area in which a program is being administered under this section.

(B)(i) Notwithstanding subparagraph (A) and subject to any exceptions established under clause (ii) of this subparagraph, a public housing agency may require that any family not living within the jurisdiction of the public housing agency at the time the family applies for assistance from the agency shall, during the 12-month period beginning on the date of initial receipt of housing assistance made available on behalf of the family from such agency, lease and

occupy an eligible dwelling unit located within the jurisdiction served by the agency.

(ii) The Secretary may establish such exceptions to the authority of public housing agencies established under clause (i).

(2) The public housing agency having authority with respect to the dwelling unit to which a family moves under this subsection shall have the responsibility of carrying out the provisions of this subsection with respect to the family.

(3) In providing assistance under subsection (o) of this section for any fiscal year, the Secretary shall give consideration to any reduction in the number of resident families incurred by a public housing agency in the preceding fiscal year as a result of the provisions of this subsection. The Secretary shall establish procedures for the compensation of public housing agencies that issue vouchers to families that move into or out of the jurisdiction of the public housing agency under portability procedures. The Secretary may reserve amounts available for assistance under subsection (o) of this section to compensate those public housing agencies.

(4) The provisions of this subsection may not be construed to restrict any authority of the Secretary under any other provision of law to provide for the portability of assistance under this section.

(5) LEASE VIOLATIONS.—A family may not receive a voucher from a public housing agency and move to another jurisdiction under the tenant-based assistance program if the family has moved out of the assisted dwelling unit of the family in violation of a lease.

(s) Prohibition of denial of certificates and vouchers to residents of public housing

In selecting families for the provision of assistance under this section (including subsection (o) of this section), a public housing agency may not exclude or penalize a family solely because the family resides in a public housing project.

(t) Enhanced vouchers

(1) In general

Enhanced voucher assistance under this subsection for a family shall be voucher assistance under subsection (o) of this section, except that under such enhanced voucher assistance—

(A) subject only to subparagraph (D), the assisted family shall pay as rent no less than the amount the family was paying on the date of the eligibility event for the project in which the family was residing on such date;

(B) the assisted family may elect to remain in the same project in which the family was residing on the date of the eligibility event for the project, and if, during any period the family makes such an election and continues to so reside, the rent for the dwelling unit of the family in such project exceeds the applicable payment standard established pursuant to subsection (o) of this section for the unit, the amount of rental assistance provided on behalf of the family shall be determined using a payment standard that is equal to the rent for the dwelling unit (as such rent may be increased from time-to-time), subject to paragraph

(10)(A) of subsection (o) of this section and any other reasonable limit prescribed by the Secretary, except that a limit shall not be considered reasonable for purposes of this subparagraph if it adversely affects such assisted families;

(C) subparagraph (B) of this paragraph shall not apply and the payment standard for the dwelling unit occupied by the family shall be determined in accordance with subsection (o) of this section if—

(i) the assisted family moves, at any time, from such project; or

(ii) the voucher is made available for use by any family other than the original family on behalf of whom the voucher was provided; and

(D) if the income of the assisted family declines to a significant extent, the percentage of income paid by the family for rent shall not exceed the greater of 30 percent or the percentage of income paid at the time of the eligibility event for the project.

(2) Eligibility event

For purposes of this subsection, the term "eligibility event" means, with respect to a multifamily housing project, the prepayment of the mortgage on such housing project, the voluntary termination of the insurance contract for the mortgage for such housing project (including any such mortgage prepayment during fiscal year 1996 or a fiscal year thereafter or any insurance contract voluntary termination during fiscal year 1996 or a fiscal year thereafter), the termination or expiration of the contract for rental assistance under this section for such housing project (including any such termination or expiration during fiscal years after fiscal year 1994 prior to October 27, 2000), or the transaction under which the project is preserved as affordable housing, that, under paragraphs (3) and (4) of section 515(c), section 524(d) of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (42 U.S.C. 1437f note), section 223(f) of the Low-Income Housing Preservation and Resident Homeownership Act of 1990 (12 U.S.C. 4113(f)), or section 201(p) of the Housing and Community Development Amendments of 1978 (12 U.S.C. 1715z–1a(p)), results in tenants in such housing project being eligible for enhanced voucher assistance under this subsection.

(3) Treatment of enhanced vouchers provided under other authority

(A) In general

Notwithstanding any other provision of law, any enhanced voucher assistance provided under any authority specified in subparagraph (B) shall (regardless of the date that the amounts for providing such assistance were made available) be treated, and subject to the same requirements, as enhanced voucher assistance under this subsection.

(B) Identification of other authority

The authority specified in this subparagraph is the authority under—

(i) the 10th, 11th, and 12th provisos under the "Preserving Existing Housing Investment" account in title II of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1997 (Public Law 104–204; 110 Stat. 2884), pursuant to such provisos, the first proviso under the "Housing Certificate Fund" account in title II of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1998 (Public Law 105–65; 111 Stat. 1351), or the first proviso under the "Housing Certificate Fund" account in title II of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1999 (Public Law 105–276; 112 Stat. 2469); and

(ii) paragraphs (3) and (4) of section 515(c) of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (42 U.S.C. 1437f note), as in effect before October 20, 1999.

(4) Authorization of appropriations

There are authorized to be appropriated for each of fiscal years 2000, 2001, 2002, 2003, and 2004 such sums as may be necessary for enhanced voucher assistance under this subsection.

(u) Assistance for residents of rental rehabilitation projects

In the case of low-income families living in rental projects rehabilitated under section 1437o of this title or 1490m of this title before rehabilitation—

(1) vouchers under this section shall be made for families who are required to move out of their units because of the physical rehabilitation activities or because of overcrowding;

(2) at the discretion of each public housing agency or other agency administering the allocation of assistance or vouchers under this section may be made for families who would have to pay more than 30 percent of their adjusted income for rent after rehabilitation whether they choose to remain in, or to move from, the project; and

(3) the Secretary shall allocate assistance for vouchers under this section to ensure that sufficient resources are available to address the physical or economic displacement, or potential economic displacement, of existing tenants pursuant to paragraphs (1) and (2).

(v) Extension of expiring contracts

The Secretary may extend expiring contracts entered into under this section for project-based loan management assistance to the

extent necessary to prevent displacement of low-income families receiving such assistance as of September 30, 1996.

(x)[9] Family unification

(1) Increase in budget authority

The budget authority available under section 1437c(c) of this title for assistance under subsection (b) of this section is authorized to be increased by $100,000,000 on or after October 1, 1992, and by $104,200,000 on or after October 1, 1993.

(2) Use of funds

The amounts made available under this subsection shall be used only in connection with tenant-based assistance under this section on behalf of (A) any family (i) who is otherwise eligible for such assistance, and (ii) who the public child welfare agency for the jurisdiction has certified is a family for whom the lack of adequate housing is a primary factor in the imminent placement of the family's child or children in out-of-home care or the delayed discharge of a child or children to the family from out-of-home care and (B) for a period not to exceed 18 months, otherwise eligible youths who have attained at least 18 years of age and not more than 21 years of age and who have left foster care at age 16 or older.

(3) Allocation

The amounts made available under this subsection shall be allocated by the Secretary through a national competition among applicants based on demonstrated need for the assistance under this subsection. To be considered for assistance, an applicant shall submit to the Secretary a written proposal containing a report from the public child welfare agency serving the jurisdiction of the applicant that describes how a lack of adequate housing in the jurisdiction is resulting in the initial or prolonged separation of children from their families, and how the applicant will coordinate with the public child welfare agency to identify eligible families and provide the families with assistance under this subsection.

(4) Definitions

For purposes of this subsection:

(A) Applicant

The term "applicant" means a public housing agency or any other agency responsible for administering assistance under this section.

(B) Public child welfare agency

The term "public child welfare agency" means the public agency responsible under applicable State law for determining that a child is at imminent risk of placement in out-of-home care or that a child in out-of-home care under

[9] Subsection (w) was repealed by Public Law 106–74, Title V, § 531(d)(2), Oct. 20, 1999, 113 Stat. 1116.

the supervision of the public agency may be returned to his or her family.

(y) Homeownership option

(1) Use of assistance for homeownership

A public housing agency providing tenant-based assistance on behalf of an eligible family under this section may provide assistance for an eligible family that purchases a dwelling unit (including a unit under a lease-purchase agreement) that will be owned by 1 or more members of the family, and will be occupied by the family, if the family—

(A) is a first-time homeowner, or owns or is acquiring shares in a cooperative;

(B) demonstrates that the family has income from employment or other sources (other than public assistance, except that the Secretary may provide for the consideration of public assistance in the case of an elderly family or a disabled family), as determined in accordance with requirements of the Secretary, that is not less than twice the payment standard established by the public housing agency (or such other amount as may be established by the Secretary);

(C) except as provided by the Secretary, demonstrates at the time the family initially receives tenant-based assistance under this subsection that one or more adult members of the family have achieved employment for the period as the Secretary shall require;

(D) participates in a homeownership and housing counseling program provided by the agency; and

(E) meets any other initial or continuing requirements established by the public housing agency in accordance with requirements established by the Secretary.

(2) Determination of amount of assistance

(A) Monthly expenses not exceeding payment standard

If the monthly homeownership expenses, as determined in accordance with requirements established by the Secretary, do not exceed the payment standard, the monthly assistance payment shall be the amount by which the homeownership expenses exceed the highest of the following amounts, rounded to the nearest dollar:

(i) 30 percent of the monthly adjusted income of the family.

(ii) 10 percent of the monthly income of the family.

(iii) If the family is receiving payments for welfare assistance from a public agency, and a portion of those payments, adjusted in accordance with the actual housing costs of the family, is specifically designated by that agency to meet the housing costs of the family, the portion of those payments that is so designated.

(B) Monthly expenses exceed payment standard

If the monthly homeownership expenses, as determined in accordance with requirements established by the Secretary, exceed the payment standard, the monthly assistance payment shall be the amount by which the applicable payment standard exceeds the highest of the amounts under clauses (i), (ii), and (iii) of subparagraph (A).

(3) Inspections and contract conditions

(A) In general

Each contract for the purchase of a unit to be assisted under this section shall—

(i) provide for pre-purchase inspection of the unit by an independent professional; and

(ii) require that any cost of necessary repairs be paid by the seller.

(B) Annual inspections not required

The requirement under subsection (o)(8)(A)(ii) of this section for annual inspections shall not apply to units assisted under this section.

(4) Other authority of the Secretary

The Secretary may—

(A) limit the term of assistance for a family assisted under this subsection; and

(B) modify the requirements of this subsection as the Secretary determines to be necessary to make appropriate adaptations for lease-purchase agreements.

(5) Inapplicability of certain provisions

Assistance under this subsection shall not be subject to the requirements of the following provisions:

(A) Subsection (c)(3)(B) of this section.

(B) Subsection (d)(1)(B)(i) of this section.

(C) Any other provisions of this section governing maximum amounts payable to owners and amounts payable by assisted families.

(D) Any other provisions of this section concerning contracts between public housing agencies and owners.

(E) Any other provisions of this chapter that are inconsistent with the provisions of this subsection.

(6) Reversion to rental status

(A) FHA-insured mortgages

If a family receiving assistance under this subsection for occupancy of a dwelling defaults under a mortgage for the dwelling insured by the Secretary under the National Housing Act [12 U.S.C. 1701 et seq.], the family may not continue to receive rental assistance under this section unless the family (i) transfers to the Secretary marketable title to the dwelling, (ii) moves from the dwelling within

the period established or approved by the Secretary, and (iii) agrees that any amounts the family is required to pay to reimburse the escrow account under section 1437u(d)(3) of this title may be deducted by the public housing agency from the assistance payment otherwise payable on behalf of the family.

(B) Other mortgages

If a family receiving assistance under this subsection defaults under a mortgage not insured under the National Housing Act [12 U.S.C. 1701 et seq.], the family may not continue to receive rental assistance under this section unless it complies with requirements established by the Secretary.

(C) All mortgages

A family receiving assistance under this subsection that defaults under a mortgage may not receive assistance under this subsection for occupancy of another dwelling owned by one or more members of the family.

(7) Downpayment assistance

(A) Authority

A public housing agency may, in lieu of providing monthly assistance payments under this subsection on behalf of a family eligible for such assistance and at the discretion of the public housing agency, provide assistance for the family in the form of a single grant to be used only as a contribution toward the downpayment required in connection with the purchase of a dwelling for fiscal year 2000 and each fiscal year thereafter to the extent provided in advance in appropriations Acts.

(B) Amount

The amount of a downpayment grant on behalf of an assisted family may not exceed the amount that is equal to the sum of the assistance payments that would be made during the first year of assistance on behalf of the family, based upon the income of the family at the time the grant is to be made.

(8) "First-time homeowner" defined

For purposes of this subsection, the term "first-time homeowner" means—

(A) a family, no member of which has had a present ownership interest in a principal residence during the 3 years preceding the date on which the family initially receives assistance for homeownership under this subsection; and

(B) any other family, as the Secretary may prescribe.

(z) Termination of Section 1437f Contracts and reuse of recaptured budget authority

(1) General authority

The Secretary may reuse any budget authority, in whole or part, that is recaptured on account of expiration or termination of a housing assistance payments contract only for one or more of the following:

(A) Tenant-based assistance

Pursuant to a contract with a public housing agency, to provide tenant-based assistance under this section to families occupying units formerly assisted under the terminated contract.

(B) Project-based assistance

Pursuant to a contract with an owner, to attach assistance to one or more structures under this section, for relocation of families occupying units formerly assisted under the terminated contract.

(2) Families occupying units formerly assisted under terminated contract

Pursuant to paragraph (1), the Secretary shall first make available tenant-or project-based assistance to families occupying units formerly assisted under the terminated contract. The Secretary shall provide project-based assistance in instances only where the use of tenant-based assistance is determined to be infeasible by the Secretary.

(aa) Omitted

(bb) Transfer, reuse, and rescission of budget authority

(1) Transfer of budget authority

If an assistance contract under this section, other than a contract for tenant-based assistance, is terminated or is not renewed, or if the contract expires, the Secretary shall, in order to provide continued assistance to eligible families, including eligible families receiving the benefit of the project-based assistance at the time of the termination, transfer any budget authority remaining in the contract to another contract. The transfer shall be under such terms as the Secretary may prescribe.

(2) Reuse and rescission of certain recaptured budget authority

Notwithstanding paragraph (1), if a project-based assistance contract for an eligible multifamily housing project subject to actions authorized under this subchapter is terminated or amended as part of restructuring under section 517 of the Multifamily Assisted Housing Reform and Affordability Act of 1997, the Secretary shall recapture the budget authority not required for the terminated or amended contract and use such amounts as are necessary to provide housing assistance for the

same number of families covered by such contract for the remaining term of such contract, under a contract providing for project-based or tenant-based assistance. The amount of budget authority saved as a result of the shift to project-based or tenant-based assistance shall be rescinded.

(cc) Law enforcement and security personnel

(1) In general

Notwithstanding any other provision of this chapter, in the case of assistance attached to a structure, for the purpose of increasing security for the residents of a project, an owner may admit, and assistance under this section may be provided to, police officers and other security personnel who are not otherwise eligible for assistance under the chapter.

(2) Rent requirements

With respect to any assistance provided by an owner under this subsection, the Secretary may—

(A) permit the owner to establish such rent requirements and other terms and conditions of occupancy that the Secretary considers to be appropriate; and

(B) require the owner to submit an application for those rent requirements, which application shall include such information as the Secretary, in the discretion of the Secretary, determines to be necessary.

(3) Applicability

This subsection shall apply to fiscal year 1999 and fiscal years thereafter.

(dd) Tenant-based contract renewals

Subject to amounts provided in appropriation Acts, starting in fiscal year 1999, the Secretary shall renew all expiring tenant-based annual contribution contracts under this section by applying an inflation factor based on local or regional factors to an allocation baseline. The allocation baseline shall be calculated by including, at a minimum, amounts sufficient to ensure continued assistance for the actual number of families assisted as of October 1, 1997, with appropriate upward adjustments for incremental assistance and additional families authorized subsequent to that date.

42 U.S.C. § 1437n

United States Housing Act, Public Law 75–412 (Act of September 1, 1937), sec. 16

Production of methamphetamine on the premises renders an individual immediately and permanently ineligible for public housing occupancy or assistance

§ 1437n. Eligibility for assisted housing[1]

(a) Income eligibility for public housing—

(1) Income mix within projects

A public housing agency may establish and utilize income-mix criteria for the selection of residents for dwelling units in public housing projects, subject to the requirements of this section.

(2) PHA income mix

(A)[2] Targeting

Except as provided in paragraph (4), of the public housing dwelling units of a public housing agency made available for occupancy in any fiscal year by eligible families, not less than 40 percent shall be occupied by families whose incomes at the time of commencement of occupancy do not exceed 30 percent of the area median income, as determined by the Secretary with adjustments for smaller and larger families; except that the Secretary may establish income ceilings higher or lower than 30 percent of the area median income on the basis of the Secretary's findings that such variations are necessary because of unusually high or low family incomes.

(3) Prohibition of concentration of low-income families

(A) Prohibition

A public housing agency may not, in complying with the requirements under paragraph (2), concentrate very low-

[1] Sept. 1, 1937, c. 896, Title I, § 16, as added Aug. 13, 1981, Public Law 97–35, Title III, § 323, 95 Stat. 404, and amended Nov. 30, 1983, Public Law 98–181, Title II, § 213, 97 Stat. 1184; Feb. 5, 1988, Public Law 100–242, Title I, §§ 103, 112(b)(8), 101 Stat. 1822, 1824, redesignated Title I, June 29, 1988, Public Law 100–358, § 5, 102 Stat. 681; Nov. 7, 1988, Public Law 100–628, Title X, § 1001(a), 102 Stat. 3263; Nov. 28, 1990, Public Law 101–625, Title V, §§ 511, 572(1), 104 Stat. 4194, 4236; Oct. 28, 1992, Public Law 102–550, Title I, § 105, 106 Stat. 3684; Jan. 26, 1996, Public Law 104–99, Title IV, § 402(d)(6)(A)(v), 110 Stat. 42; Mar. 28, 1996, Public Law 104–120, § 9(d), 110 Stat. 837; Oct. 26, 1996, Public Law 104–330, Title V, § 501(b)(7), 110 Stat. 4042; Oct. 21, 1998, Public Law 105–276, Title IV, § 428, Title V, §§ 513(a), 576(d)(2), 112 Stat. 2511, 2546, 2640; Oct. 21, 1998, Public Law 105–277, Div. A, § 123, 112 Stat. 2681–546; Oct. 20, 1999, Public Law 106–74, Title II, § 205, 113 Stat. 1069.

[2] So in original. No subsection (a)(2)(B) enacted.

income families (or other families with relatively low incomes) in public housing dwelling units in certain public housing projects or certain buildings within projects. The Secretary shall review the income and occupancy characteristics of the public housing projects and the buildings of such projects of such agencies to ensure compliance with the provisions of this paragraph and paragraph (2).

(B) Deconcentration

(i) In general

A public housing agency shall submit with its annual public housing agency plan under section 1437c–1 of this title an admissions policy designed to provide for deconcentration of poverty and income-mixing by bringing higher income tenants into lower income projects and lower income tenants into higher income projects. This clause may not be construed to impose or require any specific income or racial quotas for any project or projects.

(ii) Incentives

In implementing the policy under clause (i), a public housing agency may offer incentives for eligible families having higher incomes to occupy dwelling unit in projects predominantly occupied by eligible families having lower incomes, and provide for occupancy of eligible families having lower incomes in projects predominantly occupied by eligible families having higher incomes.

(iii) Family choice

Incentives referred to in clause (ii) may be made available by a public housing agency only in a manner that allows for the eligible family to have the sole discretion in determining whether to accept the incentive and an agency may not take any adverse action toward any eligible family for choosing not to accept an incentive and occupancy of a project described in clause (i)(II),[3] *Provided*, That the skipping of a family on a waiting list to reach another family to implement the policy under clause (i) shall not be considered an adverse action. An agency implementing an admissions policy under this subparagraph shall implement the policy in a manner that does not prevent or interfere with the use of site-based waiting lists authorized under section 1437d(s) of this title.

(4) Fungibility with tenant-based assistance

(A) Authority

Except as provided under subparagraph (D), the number of public housing dwelling units that a public housing

[3] So in original. Clause (i) does not contain subclauses.

agency shall otherwise make available in accordance with paragraph (2)(A) to comply with the percentage requirement under such paragraph for a fiscal year shall be reduced by the credit number for the agency under subparagraph (B).

(B) Credit for exceeding tenant-based assistance targeting requirement

Subject to subparagraph (C), the credit number under this subparagraph for a public housing agency for a fiscal year shall be the number by which—

(i) the aggregate number of qualified families who, in such fiscal year, are initially provided tenant-based assistance under section 1437f of this title by the agency; exceeds

(ii) the number of qualified families that is required for the agency to comply with the percentage requirement under subsection (b)(1) of this section for such fiscal year.

(C) Limitations on credit number

The credit number under subparagraph (B) for a public housing agency for a fiscal year may not in any case exceed the lesser of—

(i) the number of dwelling units that is equivalent to 10 percent of the aggregate number of families initially provided tenant-based assistance under section 1437f of this title by the agency in such fiscal year; or

(ii) the number of public housing dwelling units of the agency that—

(I) are in projects that are located in census tracts having a poverty rate of 30 percent or more; and

(II) are made available for occupancy during such fiscal year and are actually filled only by families whose incomes at the time of commencement of such occupancy exceed 30 percent of the area median income, as determined by the Secretary with adjustments for smaller and larger families.

(D) Fungibility floor

Notwithstanding any authority under subparagraph (A), of the public housing dwelling units of a public housing agency made available for occupancy in any fiscal year by eligible families, not less than 30 percent shall be occupied by families whose incomes at the time of commencement of occupancy do not exceed 30 percent of the area median income, as determined by the Secretary with adjustments for smaller and larger families.

(E) Qualified family

For purposes of this paragraph, the term "qualified family" means a family having an income described in subsection (b)(1) of this section.

(b) Income eligibility for tenant-based section 1437f assistance

(1) In general

Of the families initially provided tenant-based assistance under section 1437f of this title by a public housing agency in any fiscal year, not less than 75 percent shall be families whose incomes do not exceed 30 percent of the area median income, as determined by the Secretary with adjustments for smaller and larger families; except that the Secretary may establish income ceilings higher or lower than 30 percent of the area median income on the basis of the Secretary's findings that such variations are necessary because of unusually high or low family incomes.

(2) Jurisdictions served by multiple PHAs

In the case of any 2 or more public housing agencies that administer tenant-based assistance under section 1437f of this title with respect solely to identical geographical areas, such agencies shall be treated as a single public housing agency for purposes of paragraph (1).

(c) Income eligibility for project-based section 1437f assistance

(1) Pre-1981 act projects

Not more than 25 percent of the dwelling units that were available for occupancy under section 8 [42 U.S.C. 1437f] of this title, housing assistance payments contracts under this chapter before October 1, 1981, and which will be leased on or after October 1, 1981, shall be available for leasing by low-income families other than very low-income families.

(2) Post-1981 act projects

Not more than 15 percent of the dwelling units which become available for occupancy under section 8 [42 U.S.C. 1437f] of this title, housing assistance payments contracts under this chapter on or after October 1, 1981, shall be available for leasing by low-income families other than very low-income families.

(3) Targeting

For each project assisted under a contract for project-based assistance, of the dwelling units that become available for occupancy in any fiscal year that are assisted under the contract, not less than 40 percent shall be available for leasing only by families whose incomes at the time of commencement of occupancy do not exceed 30 percent of the area median income, as determined by the Secretary with adjustments for smaller and

larger families; except that the Secretary may establish income ceilings higher or lower than 30 percent of the area median income on the basis of the Secretary's findings that such variations are necessary because of unusually high or low family incomes.

(4) Prohibition of skipping

In developing admission procedures implementing paragraphs (1), (2), and (3), the Secretary shall prohibit project owners from selecting families for residence in an order different from the order on the waiting list for the purpose of selecting relatively higher income families for residence. Nothing in this paragraph or this subsection may be construed to prevent an owner of housing assisted under a contract for project-based assistance from establishing a preference for occupancy in such housing for families containing a member who is employed.

(5) Exception

The limitations established in paragraphs (1), (2), and (3) shall not apply to dwelling units made available under project-based contracts under section 1437f of this title for the purpose of preventing displacement, or ameliorating the effects of displacement.

(6) Definition

For purposes of this subsection, the term "project-based assistance" means assistance under any of the following programs:

(A) The new construction or substantial rehabilitation program under section 1437f(b)(2) of this title (as in effect before October 1, 1983).

(B) The property disposition program under section 1437f(b) of this title (as in effect before the effective date under section 503(a) of the Quality Housing and Work Responsibility Act of 1998).

(C) The loan management set-aside program under subsections (b) and (v) of section 1437f of this title.

(D) The project-based certificate program under section 1437f(d)(2) of this title.

(E) The moderate rehabilitation program under section 1437f(e)(2) of this title (as in effect before October 1, 1991).

(F) The low-income housing preservation program under Low-Income Housing Preservation and Resident Homeownership Act of 1990 [12 U.S.C. 4101 et seq.] or the provisions of the Emergency Low Income Housing Preservation Act of 1987 (as in effect before November 28, 1990).

(G) Section 1437f of this title (as in effect before the effective date under section 503(a) of the Quality Housing and Work Responsibility Act of 1998), following conversion from assistance under section 1701s of Title 12 or section 1715z–1(f)(2) of Title 12.

(d) Establishment of different standards

Notwithstanding subsection (a)(2) or (b)(1) of this section, if approved by the Secretary, a public housing agency may for good cause establish and implement, in accordance with the public housing agency plan, an admission standard other than the standard under such subsection.

(f)[4] Ineligibility of individuals convicted of manufacturing or producing methamphetamine on the premises

Notwithstanding any other provision of law, a public housing agency shall establish standards for occupancy in public housing dwelling units and assistance under section 1437f of this title that—

(1) permanently prohibit occupancy in any public housing dwelling unit by, and assistance under section 1437f of this title for, any person who has been convicted of manufacturing or otherwise producing methamphetamine on the premises in violation of any Federal or State law; and

(2) immediately and permanently terminate the tenancy in any public housing unit of, and the assistance under section 1437f of this title for, any person who is convicted of manufacturing or otherwise producing methamphetamine on the premises in violation of any Federal or State law.

[4] Subsection (e) was repealed by Public Law 105–276, Title V, § 576(d)(2), Oct. 21, 1998, 112 Stat. 2640.

42 U.S.C. § 1437w

United States Housing Act, Public Law 75–412 (Act of September 1, 1937), sec. 25

Transfer of management of certain housing to independent manager at the request of residents in areas of recurrent criminal activity including drug-related activity, inter alia

§ 1437w. Transfer of management of certain housing to independent manager at request of residents [1]

(a) Authority

The Secretary may transfer the responsibility and authority for management of specified housing (as such term is defined in subsection (h) of this section) from a public housing agency to an eligible management entity, in accordance with the requirements of this section, if—

(1) a request for transfer of management of such housing is made and approved in accordance with subsection (b) of this section; and

(2) the Secretary or the public housing agency, as appropriate pursuant to subsection (b) of this section, determines that—

(A) due to the mismanagement of the agency, such housing has deferred maintenance, physical deterioration, or obsolescence of major systems and other deficiencies in the physical plant of the project;

(B) such housing is located in an area such that the housing is subject to recurrent vandalism and criminal activity (including drug-related criminal activity); and

(C) the residents can demonstrate that the elements of distress for such housing specified in subparagraphs (A) and (B) can be remedied by an entity or entities, identified by the residents, that has or have a demonstrated capacity to manage, with reasonable expenses for modernization.

(b) Request for transfer

The responsibility and authority for managing specified housing may be transferred only pursuant to a request made by a majority vote of the residents for the specified housing that—

(1) in the case of specified housing that is owned by a public housing agency that is designated as a troubled agency under section 1437d(j)(2) of this title—

(A) is made to the public housing agency or the Secretary; and

(B) is approved by the agency or the Secretary; or

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[1] Sept. 1, 1937, c. 896, Title I, § 25, as added Oct. 21, 1998, Public Law 105–276, Title V, § 534, 112 Stat. 2579.

(2) in the case of specified housing that is owned by a public housing agency that is not designated as a troubled agency under section 1437d(j)(2) of this title—

(A) is made to and approved by the public housing agency; or

(B) if a request is made to the agency pursuant to subparagraph (A) and is not approved, is subsequently made to and approved by the Secretary.

(c) Capital and operating assistance

Pursuant to a contract under subsection (d) of this section, the Secretary shall require the public housing agency for specified housing to provide to the manager for the housing, from any assistance from the Capital and Operating Funds under section 1437g of this title for the agency, fair and reasonable amounts for the housing for eligible capital and operating activities under subsection (d)(1) and (e)(1) of section 1437g of this title. The amount made available under this subsection to a manager shall be determined by the Secretary based on the share for the specified housing of the aggregate amount of assistance from such Funds for the public housing agency transferring the housing, taking into consideration the operating and capital improvement needs of the specified housing, the operating and capital improvement needs of the remaining public housing units managed by the public housing agency, and the public housing agency plan of such agency.

(d) Contract between Secretary and manager

(1) Requirements

Pursuant to the approval of a request under this section for transfer of the management of specified housing, the Secretary shall enter into a contract with the eligible management entity.

(2) Terms

A contract under this subsection shall contain provisions establishing the rights and responsibilities of the manager with respect to the specified housing and the Secretary and shall be consistent with the requirements of this chapter applicable to public housing projects.

(e) Compliance with public housing agency plan

A manager of specified housing under this section shall comply with the approved public housing agency plan applicable to the housing and shall submit such information to the public housing agency from which management was transferred as may be necessary for such agency to prepare and update its public housing agency plan.

(f) Demolition and disposition by manager

A manager under this section may demolish or dispose of specified housing only if, and in the manner, provided for in the public housing agency plan for the agency transferring management of the housing.

(g) Limitation on PHA liability

A public housing agency that is not a manager for specified housing shall not be liable for any act or failure to act by a manager or resident council for the specified housing.

(h) Definitions

For purposes of this section, the following definitions shall apply:

(1) Eligible management entity

The term "eligible management entity" means, with respect to any public housing project, any of the following entities:

(A) Nonprofit organization

A public or private nonprofit organization, which may—
(i) include a resident management corporation; and
(ii) not include the public housing agency that owns or operates the project.

(B) For-profit entity

A for-profit entity that has demonstrated experience in providing low-income housing.

(C) State or local government

A State or local government, including an agency or instrumentality thereof.

(D) Public housing agency

A public housing agency (other than the public housing agency that owns or operates the project).
The term does not include a resident council.

(2) Manager

The term "manager" means any eligible management entity that has entered into a contract under this section with the Secretary for the management of specified housing.

(3) Nonprofit

The term "nonprofit" means, with respect to an organization, association, corporation, or other entity, that no part of the net earnings of the entity inures to the benefit of any member, founder, contributor, or individual.

(4) Private nonprofit organization

The term "private nonprofit organization" means any private organization (including a State or locally chartered organization) that—
(A) is incorporated under State or local law;
(B) is nonprofit in character;
(C) complies with standards of financial accountability acceptable to the Secretary; and
(D) has among its purposes significant activities related to the provision of decent housing that is affordable to low-income families.

(5) Public nonprofit organization

The term "public nonprofit organization" means any public entity that is nonprofit in character.

(6) Specified housing

The term "specified housing" means a public housing project or projects, or a portion of a project or projects, for which the transfer of management is requested under this section. The term includes one or more contiguous buildings and an area of contiguous row houses, but in the case of a single building, the building shall be sufficiently separable from the remainder of the project of which it is part to make transfer of the management of the building feasible for purposes of this section.

42 U.S.C. § 1786
Child Nutrition Act, Public Law 89–642, sec. 17
Drug abuse education; disqualification of vendors convicted of trafficking or illegal sales of controlled substances

Chapter 13A. Child Nutrition

§ 1786. Special supplemental nutrition program for women, infants, and children [1]

(a) Congressional findings and declaration of purpose

Congress finds that substantial numbers of pregnant, postpartum, and breastfeeding women, infants, and young children from families with inadequate income are at special risk with respect to their physical and mental health by reason of inadequate nutrition or health care, or both. It is, therefore, the purpose of the program authorized by this section to provide, up to the authorization levels set forth in subsection (g) of this section, supplemental foods and nutrition education through any eligible local agency that applies for participation in the program. The program shall serve as an adjunct to good health care, during critical times of growth

[1] Public Law 89–642, § 17, as added Public Law 92–433, § 9, Sept. 26, 1972, 86 Stat. 729, and amended by Public Law 93–150, § 6, Nov. 7, 1973, 87 Stat. 563; Public Law 93–326, § 6, June 30, 1974, 88 Stat. 287; Public Law 94–28, May 28, 1975, 89 Stat. 96; Public Law 94–105, § 14, Oct. 7, 1975, 89 Stat. 518; Public Law 95–166, §§ 18, 20(6), Nov. 10, 1977, 91 Stat. 1345, 1346; Public Law 95–627, § 3, Nov. 10, 1978, 92 Stat. 3611; Public Law 96–88, Title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Public Law 96–108, Title III, § 301, Nov. 9, 1979, 93 Stat. 838; Public Law 96–499, Title II, § 203(d), Dec. 5, 1980, 94 Stat. 2601; Public Law 97–35, Title VIII, § 815, Aug. 13, 1981, 95 Stat. 531; Public Law 99–500, Title III, §§ 314, 341, 342(a), 343, 344(a), 345 to 348(a), 349 to 353(a), 372(b)(1), Oct. 18, 1986, 100 Stat. 1783–360, 1783–364 to 1783–367, 1783–369, and Public Law 99–591, Title III, §§ 314, 341, 342(a), 343, 344(a), 345 to 348(a), 349 to 353(a), 372(b)(1), Oct. 30, 1986, 100 Stat. 3341–363, 3341–367 to 3341–370, 3341–372; Public Law 99–661, Div. D, Title I, § 4104, Title III, §§ 4301, 4302(a), 4303, 4304(a), 4305 to 4308(a), 4309 to 4313(a), Title V, § 4502(b)(1), Nov. 14, 1986, 100 Stat. 4071, 4075 to 4078, 4080; Public Law 100–71, Title I, July 11, 1987, 101 Stat. 425; Public Law 100–237, §§ 8(a), (b), 9, 11, 12, Jan. 8, 1988, 101 Stat. 1740, 1741; Public Law 100–356, § 3, June 28, 1988, 102 Stat. 669; Public Law 100–435, Title II, § 212, Title V, § 501(b), Sept. 19, 1988, 102 Stat. 1657, 1668; Public Law 100–690, Title III, § 3201, Nov. 18, 1988, 102 Stat. 4246; Public Law 101–147, Title I, § 123(a), Title II, § 213(a), Title III, § 326, Nov. 10, 1989, 103 Stat. 894, 912, 917; Public Law 101–330, § 1, July 12, 1990, 104 Stat. 311; Public Law 102–314, § 3, July 2, 1992, 106 Stat. 280; Public Law 102–342, Title II, § 204, Aug. 14, 1992, 106 Stat. 913; Public Law 102–512, Title II, §§ 203 to 207, Oct. 24, 1992, 106 Stat. 3364 to 3368; Public Law 103–448, Title II, § 204(a) to (n), (o)(1), (p) to (u), (v)(1) to (11), (w)(1), Nov. 2, 1994, 108 Stat. 4738 to 4741, 4742 to 4744, 4745, 4746; Public Law 104–66, Title I, § 1011(l), Dec. 21, 1995, 109 Stat. 710; Public Law 104–193, Title I, § 109(h), Title VII, § 729(a) to (g)(1), (h) to (j), Aug. 22, 1996, 110 Stat. 2171, 2303, 2304, 2305; Public Law 105–336, § 203, Oct. 31, 1998, 112 Stat. 3158; Public Law 105–362, Title I, § 101(i), Nov. 10, 1998, 112 Stat. 3281; Public Law 106–65, Div. A, Title VI, § 674(e), Oct. 5, 1999, 113 Stat. 675; Public Law 106–78, Title VII, § 752(b)(16), Oct. 22, 1999, 113 Stat. 1170; Public Law 106–224, Title II, §§ 242(b)(1), (2), 244(a) to (e), June 20, 2000, 114 Stat. 411, 421; Public Law 106–472, Title III, § 307(b), Nov. 9, 2000, 114 Stat. 2073; Public Law 107–171, Title IV, §§ 4306(a), 4307(a), May 13, 2002, 116 Stat. 332, 333; Public Law 108–265, Title II, § 203(a) to (c)(2)(A), (3) to (5), (d), (e)(1) to (4)(A), (5) to (6)(A), (7)(A), (B), (8), (10) to (13), (f) to (i)(1), June 30, 2004, 118 Stat. 771 to 780; Public Law 108–447, Title VII, §§ 788(d), (e), Dec. 8, 2004, 118 Stat. 2851.

and development, to prevent the occurrence of health problems, including drug abuse, and improve the health status of these persons.

(b) Definitions

As used in this section—

(1) "Breastfeeding women" means women up to one year postpartum who are breastfeeding their infants.

(2) "Children" means persons who have had their first birthday but have not yet attained their fifth birthday.

(3) "Competent professional authority" means physicians, nutritionists, registered nurses, dietitians, or State or local medically trained health officials, or persons designated by physicians or State or local medically trained health officials, in accordance with standards prescribed by the Secretary, as being competent professionally to evaluate nutritional risk.

(4) "Costs of nutrition services and administration" or "nutrition services and administration" means costs that shall include, but not be limited to, costs for certification of eligibility of persons for participation in the program (including centrifuges, measuring boards, spectrophotometers, and scales used for the certification), food delivery, monitoring, nutrition education, outreach, startup costs, and general administration applicable to implementation of the program under this section, such as the cost of staff, transportation, insurance, developing and printing food instruments, and administration of State and local agency offices.

(5) "Infants" means persons under one year of age.

(6) "Local agency" means a public health or welfare agency or a private nonprofit health or welfare agency, which, directly or through an agency or physician with which it has contracted, provides health services. The term shall include an Indian tribe, band, or group recognized by the Department of the Interior, the Indian Health Service of the Department of Health and Human Services, or an intertribal council or group that is an authorized representative of Indian tribes, bands, or groups recognized by the Department of the Interior.

(7) NUTRITION EDUCATION.—The term "nutrition education" means individual and group sessions and the provision of material that are designed to improve health status and achieve positive change in dietary and physical activity habits, and that emphasize the relationship between nutrition, physical activity, and health, all in keeping with the personal and cultural preferences of the individual.

(8) "Nutritional risk" means (A) detrimental or abnormal nutritional conditions detectable by biochemical or anthropometric measurements, (B) other documented nutritionally related medical conditions, (C) dietary deficiencies that impair or endanger health, (D) conditions that directly affect the nutritional health of a person, such as alcoholism or drug abuse, or (E) conditions that predispose persons to inadequate nutritional patterns or nutritionally related medical conditions, including, but not limited to, homelessness and migrancy.

(9) "Plan of operation and administration" means a document that describes the manner in which the State agency intends to implement and operate the program.

(10) "Postpartum women" means women up to six months after termination of pregnancy.

(11) "Pregnant women" means women determined to have one or more fetuses in utero.

(12) "Secretary" means the Secretary of Agriculture.

(13) "State agency" means the health department or comparable agency of each State; an Indian tribe, band, or group recognized by the Department of the Interior; an intertribal council or group that is the authorized representative of Indian tribes, bands, or groups recognized by the Department of the Interior; or the Indian Health Service of the Department of Health and Human Services.

(14) "Supplemental foods" means those foods containing nutrients determined by nutritional research to be lacking in the diets of pregnant, breastfeeding, and postpartum women, infants, and children and foods that promote the health of the population served by the program authorized by this section, as indicated by relevant nutrition science, public health concerns, and cultural eating patterns, as prescribed by the Secretary. State agencies may, with the approval of the Secretary, substitute different foods providing the nutritional equivalent of foods prescribed by the Secretary, to allow for different cultural eating patterns.

(15) "Homeless individual" means—

(A) an individual who lacks a fixed and regular nighttime residence; or

(B) an individual whose primary nighttime residence is—

(i) a supervised publicly or privately operated shelter (including a welfare hotel or congregate shelter) designed to provide temporary living accommodations;

(ii) an institution that provides a temporary residence for individuals intended to be institutionalized;

(iii) a temporary accommodation of not more than 365 days in the residence of another individual; or

(iv) a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings.

(16) "Drug abuse education" means—

(A) the provision of information concerning the dangers of drug abuse; and

(B) the referral of participants who are suspected drug abusers to drug abuse clinics, treatment programs, counselors, or other drug abuse professionals.

(17) "Competitive bidding" means a procurement process under which the Secretary or a State agency selects a single source (a single infant formula manufacturer) offering the lowest price, as determined by the submission of sealed bids, for a product for which bids are sought for use in the program authorized by this section.

(18) "Rebate" means the amount of money refunded under cost containment procedures to any State agency from the manufacturer or other supplier of the particular food product as the result of the purchase of the supplemental food with a voucher or other purchase instrument by a participant in each such agency's program established under this section.

(19) "Discount" means, with respect to a State agency that provides program foods to participants without the use of retail grocery stores (such as a State that provides for the home delivery or direct distribution of supplemental food), the amount of the price reduction or other price concession provided to any State agency by the manufacturer or other supplier of the particular food product as the result of the purchase of program food by each such State agency, or its representative, from the supplier.

(20) "Net price" means the difference between the manufacturer's wholesale price for infant formula and the rebate level or the discount offered or provided by the manufacturer under a cost containment contract entered into with the pertinent State agency.

(21) Remote Indian or Native village

The term "remote Indian or Native village" means an Indian or Native village that—

(A) is located in a rural area;

(B) has a population of less than 5,000 inhabitants; and

(C) is not accessible year-around by means of a public road (as defined in section 101 of Title 23).

(22) PRIMARY CONTRACT INFANT FORMULA.—The term "primary contract infant formula" means the specific infant formula for which manufacturers submit a bid to a State agency in response to a rebate solicitation under this section and for which a contract is awarded by the State agency as a result of that bid.

(23) STATE ALLIANCE.—The term "State alliance" means 2 or more State agencies that join together for the purpose of procuring infant formula under the program by soliciting competitive bids for infant formula.

(c) Grants-in-aid; cash grants; ratable reduction of amount an agency may distribute; affirmative action; regulations relating to dual receipt of benefits under commodity supplemental food program

(1) The Secretary may carry out a special supplemental nutrition program to assist State agencies through grants-in-aid and other means to provide, through local agencies, at no cost, supplemental foods and nutrition education to low-income pregnant, postpartum, and breastfeeding women, infants, and children who satisfy the eligibility requirements specified in subsection (d) of this section. The program shall be supplementary to—

(A) the food stamp program;

(B) any program under which foods are distributed to needy families in lieu of food stamps; and

(C) receipt of food or meals from soup kitchens, or shelters, or other forms of emergency food assistance.

(2) Subject to amounts appropriated to carry out this section under subsection (g) of this section—

(A) the Secretary shall make cash grants to State agencies for the purpose of administering the program, and

(B) any State agency approved eligible local agency that applies to participate in or expand the program under this section shall immediately be provided with the necessary funds to carry out the program.

(3) Nothing in this subsection shall be construed to permit the Secretary to reduce ratably the amount of foods that an eligible local agency shall distribute under the program to participants. The Secretary shall take affirmative action to ensure that the program is instituted in areas most in need of supplemental foods. The existence of a commodity supplemental food program under section 4 of the Agriculture and Consumer Protection Act of 1973 shall not preclude the approval of an application from an eligible local agency to participate in the program under this section nor the operation of such program within the same geographic area as that of the commodity supplemental food program, but the Secretary shall issue such regulations as are necessary to prevent dual receipt of benefits under the commodity supplemental food program and the program under this section.

(4) A State shall be ineligible to participate in programs authorized under this section if the Secretary determines that State or local sales taxes are collected within the State on purchases of food made to carry out this section.

(d) Eligible participants

(1) Participation in the program under this section shall be limited to pregnant, postpartum, and breastfeeding women, infants, and children from low-income families who are determined by a competent professional authority to be at nutritional risk.

(2)(A) The Secretary shall establish income eligibility standards to be used in conjunction with the nutritional risk criteria in determining eligibility of individuals for participation in the program. Any individual at nutritional risk shall be eligible for the program under this section only if such individual—

(i) is a member of a family with an income that is less than the maximum income limit prescribed under section 1758(b) of this title for free and reduced price meals;

(ii)(I) receives food stamps under the Food Stamp Act of 1977 [7 U.S.C. 2011 et seq.]; or

(II) is a member of a family that receives assistance under the State program funded under part A of title IV of the Social Security Act [42 U.S.C. 601 et seq.] that the Secretary determines complies with standards established by the Secretary that ensure that the standards under the State program are comparable to or more restrictive than those in effect on June 1, 1995; or

(iii)(I) receives medical assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]; or

(II) is a member of a family in which a pregnant woman or an infant receives such assistance.

(B) For the purpose of determining income eligibility under this section, any State agency may choose to exclude from income—

(i) any basic allowance—

(I) for housing received by military service personnel residing off military installations; or

(II) provided under section 403 of Title 37 for housing that is acquired or constructed under subchapter IV of chapter 169 of Title 10, or any related provision of law; and

(ii) any cost-of-living allowance provided under section 405 of Title 37 to a member of a uniformed service who is on duty outside the contiguous States of the United States.

(C) In the case of a pregnant woman who is otherwise ineligible for participation in the program because the family of the woman is of insufficient size to meet the income eligibility standards of the program, the pregnant woman shall be considered to have satisfied the income eligibility standards if, by increasing the number of individuals in the family of the woman by 1 individual, the income eligibility standards would be met.

(3) CERTIFICATION.—

(A) PROCEDURES.—

(i) IN GENERAL.—Subject to clause (ii), a person shall be certified for participation in accordance with general procedures prescribed by the Secretary.

(ii) BREASTFEEDING WOMEN.—A State may elect to certify a breastfeeding woman for a period of 1 year postpartum or until a woman discontinues breastfeeding, whichever is earlier.

(B) A State may consider pregnant women who meet the income eligibility standards to be presumptively eligible to participate in the program and may certify the women for participation immediately, without delaying certification until an evaluation is made concerning nutritional risk. A nutritional risk evaluation of such a woman shall be completed not later than 60 days after the woman is certified for participation. If it is subsequently determined that the woman does not meet nutritional risk criteria, the certification of the woman shall terminate on the date of the determination.

(C) PHYSICAL PRESENCE.—

(i) IN GENERAL.—Except as provided in clause (ii) and subject to the requirements of the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) and section 794 of Title 29, each individual seeking certification or recertification for participation in the program shall be physically present at each certification or recertification determination in order to determine eligibility under the program.

(ii) WAIVERS.—If the agency determines that the requirement of clause (i) would present an unreasonable barrier to participation, a local agency may waive the requirement of clause (i) with respect to—

(I) an infant or child who—

(aa) was present at the initial certification visit; and

(bb) is receiving ongoing health care;

(II) an infant or child who—

(aa) was present at the initial certification visit;

(bb) was present at a certification or recertification determination within the 1-year period ending on the date of the certification or recertification determination described in clause (i); and

(cc) has one or more parents who work; and

(III) an infant under 8 weeks of age—

(aa) who cannot be present at certification for a reason determined appropriate by the local agency; and

(bb) for whom all necessary certification information is provided.

(D) INCOME DOCUMENTATION.—

(i) IN GENERAL.—Except as provided in clause (ii), in order to participate in the program pursuant to clause (i) of paragraph (2)(A), an individual seeking certification or recertification for participation in the program shall provide documentation of family income.

(ii) WAIVERS.—A State agency may waive the documentation requirement of clause (i), in accordance with criteria established by the Secretary, with respect to—

(I) an individual for whom the necessary documentation is not available; or

(II) an individual, such as a homeless woman or child, for whom the agency determines the requirement of clause (i) would present an unreasonable barrier to participation.

(E) ADJUNCT DOCUMENTATION.—In order to participate in the program pursuant to clause (ii) or (iii) of paragraph (2)(A), an individual seeking certification or recertification for participation in the program shall provide documentation of receipt of assistance described in that clause.

(F) PROOF OF RESIDENCY.—An individual residing in a remote Indian or Native village or an individual served by an Indian tribal organization and residing on a reservation or pueblo may, under standards established by the Secretary, establish proof of residency under this section by providing to the State agency the mailing address of the individual and the name of the remote Indian or Native village.

(e) Nutrition education and drug abuse education

(1) The State agency shall ensure that nutrition education and drug abuse education is provided to all pregnant, postpartum, and breastfeeding participants in the program and to parents or caretakers of infant and child participants in the program. The State agency may also provide nutrition education and drug abuse education to pregnant, postpartum, and breastfeeding women and to parents or caretakers of infants and children enrolled at local agencies operating the program under this section who do not participate in the program. A local agency participating in the program

shall provide education or educational materials relating to the effects of drug and alcohol use by a pregnant, postpartum, or breastfeeding woman on the developing child of the woman.

(2) The Secretary shall prescribe standards to ensure that adequate nutrition education services and breastfeeding promotion and support are provided. The State agency shall provide training to persons providing nutrition education under this section.

(3) NUTRITION EDUCATION MATERIALS.—

(A) IN GENERAL.—The Secretary shall, after submitting proposed nutrition education materials to the Secretary of Health and Human Services for comment, issue such materials for use in the program under this section.

(B) SHARING OF MATERIALS.—The Secretary may provide, in bulk quantity, nutrition education materials (including materials promoting breastfeeding) developed with funds made available for the program authorized under this section to State agencies administering the commodity supplemental food program authorized under sections 4(a) and 5 of the Agriculture and Consumer Protection Act of 1973 (7 U.S.C. 612c note; Public Law 93–86) at no cost to that program.

(4) The State agency—

(A) shall provide each local agency with materials showing the maximum income limits, according to family size, applicable to pregnant women, infants, and children up to age 5 under the medical assistance program established under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] (in this section referred to as the ''medicaid program'');

(B) shall provide to individuals applying for the program under this section, or reapplying at the end of their certification period, written information about the medicaid program and referral to such program or to agencies authorized to determine presumptive eligibility for such program, if such individuals are not participating in such program and appear to have family income below the applicable maximum income limits for such program; and

(C) may provide a local agency with materials describing other programs for which a participant in the program may be eligible.

(5) Each local agency shall maintain and make available for distribution a list of local resources for substance abuse counseling and treatment.

(f) Plan of operation and administration by State agency

(1)(A) Each State agency shall submit to the Secretary, by a date specified by the Secretary, an initial plan of operation and administration for a fiscal year. After submitting the initial plan, a State shall be required to submit to the Secretary for approval only a substantive change in the plan.

(B) To be eligible to receive funds under this section for a fiscal year, a State agency must receive the approval of the Secretary for the plan submitted for the fiscal year.

(C) The plan shall include—

(i) a description of the food delivery system of the State agency and the method of enabling participants to receive supplemental foods under the program at any of the authorized retail stores under the program, to be administered in accordance with standards developed by the Secretary, including a description of the State agency's vendor peer group system, competitive price criteria, and allowable reimbursement levels that demonstrate that the State is in compliance with the cost-containment provisions in subsection (h)(11);

(ii) procedures for accepting and processing vendor applications outside of the established timeframes if the State agency determines there will be inadequate access to the program, including in a case in which a previously authorized vendor sells a store under circumstances that do not permit timely notification to the State agency of the change in ownership;

(iii) a description of the financial management system of the State agency;

(iv) a plan to coordinate operations under the program with other services or programs that may benefit participants in, and applicants for, the program;

(v) a plan to provide program benefits under this section to, and to meet the special nutrition education needs of, eligible migrants, homeless individuals, and Indians;

(vi) a plan to expend funds to carry out the program during the relevant fiscal year;

(vii) a plan to provide program benefits under this section to unserved and underserved areas in the State (including a plan to improve access to the program for participants and prospective applicants who are employed, or who reside in rural areas), if sufficient funds are available to carry out this clause;

(viii) a plan for reaching and enrolling eligible women in the early months of pregnancy, including provisions to reach and enroll eligible migrants;

(ix) a plan to provide program benefits under this section to unserved infants and children under the care of foster parents, protective services, or child welfare authorities, including infants exposed to drugs perinatally;

(x) a plan to provide nutrition education and promote breastfeeding; and

(xi) such other information as the Secretary may reasonably require.

(D) The Secretary may not approve any plan that permits a person to participate simultaneously in both the program authorized under this section and the commodity supplemental food program authorized under sections 4 and 5 of the Agriculture and Consumer Protection Act of 1973 (7 U.S.C. 612c note).

(2) A State agency shall establish a procedure under which members of the general public are provided an opportunity to comment on the development of the State agency plan.

(3) The Secretary shall establish procedures under which eligible migrants may, to the maximum extent feasible, continue to participate in the program under this section when they are present in States other than the State in which they were originally certified

for participation in the program and shall ensure that local programs provide priority consideration to serving migrant participants who are residing in the State for a limited period of time. Each State agency shall be responsible for administering the program for migrant populations within its jurisdiction.

(4) State agencies shall submit monthly financial reports and participation data to the Secretary.

(5) State and local agencies operating under the program shall keep such accounts and records, including medical records, as may be necessary to enable the Secretary to determine whether there has been compliance with this section and to determine and evaluate the benefits of the nutritional assistance provided under this section. Such accounts and records shall be available at any reasonable time for inspection and audit by representatives of the Secretary and shall be preserved for such period of time, not in excess of five years, as the Secretary determines necessary.

(6)(A) Local agencies participating in the program under this section shall notify persons of their eligibility or ineligibility for the program within twenty days of the date that the household, during office hours of a local agency, personally makes an oral or written request to participate in the program. The Secretary shall establish a shorter notification period for categories of persons who, due to special nutritional risk conditions, must receive benefits more expeditiously.

(B) State agencies may provide for the delivery of vouchers to any participant who is not scheduled for nutrition education counseling or a recertification interview through means, such as mailing, that do not require the participant to travel to the local agency to obtain vouchers. The State agency shall describe any plans for issuance of vouchers by mail in its plan submitted under paragraph (1). The Secretary may disapprove a State plan with respect to the issuance of vouchers by mail in any specified jurisdiction or part of a jurisdiction within a State only if the Secretary finds that such issuance would pose a significant threat to the integrity of the program under this section in such jurisdiction or part of a jurisdiction.

(7)(A) The State agency shall, in cooperation with participating local agencies, publicly announce and distribute information on the availability of program benefits (including the eligibility criteria for participation and the location of local agencies operating the program) to offices and organizations that deal with significant numbers of potentially eligible individuals (including health and medical organizations, hospitals and clinics, welfare and unemployment offices, social service agencies, farmworker organizations, Indian tribal organizations, organizations and agencies serving homeless individuals and shelters for victims of domestic violence, and religious and community organizations in low income areas).

(B) The information shall be publicly announced by the State agency and by local agencies at least annually.

(C) The State agency and local agencies shall distribute the information in a manner designed to provide the information to potentially eligible individuals who are most in need of the benefits, including pregnant women in the early months of pregnancy.

(D) Each local agency operating the program within a hospital and each local agency operating the program that has a cooperative arrangement with a hospital shall—

(i) advise potentially eligible individuals that receive inpatient or outpatient prenatal, maternity, or postpartum services, or accompany a child under the age of 5 who receives well-child services, of the availability of program benefits; and

(ii) to the extent feasible, provide an opportunity for individuals who may be eligible to be certified within the hospital for participation in such program.

(8)(A) The State agency shall grant a fair hearing, and a prompt determination thereafter, in accordance with regulations issued by the Secretary, to any applicant, participant, or local agency aggrieved by the action of a State or local agency as it affects participation.

(B) Any State agency that must suspend or terminate benefits to any participant during the participant's certification period due to a shortage of funds for the program shall first issue a notice to such participant.

(9) If an individual certified as eligible for participation in the program under this section in one area moves to another area in which the program is operating, that individual's certification of eligibility shall remain valid for the period for which the individual was originally certified.

(10) The Secretary shall establish standards for the proper, efficient, and effective administration of the program. If the Secretary determines that a State agency has failed without good cause to administer the program in a manner consistent with this section or to implement the approved plan of operation and administration under this subsection, the Secretary may withhold such amounts of the State agency's funds for nutrition services and administration as the Secretary deems appropriate. Upon correction of such failure during a fiscal year by a State agency, any funds so withheld for such fiscal year shall be provided the State agency.

(11) SUPPLEMENTAL FOODS.—

(A) IN GENERAL.—The Secretary shall prescribe by regulation the supplemental foods to be made available in the program under this section.

(B) APPROPRIATE CONTENT.—To the degree possible, the Secretary shall assure that the fat, sugar, and salt content of the prescribed foods is appropriate.

(C) ALLOWABLE USE OF FUNDS.—Subject to the availability of funds, the Secretary shall award grants to not more than 10 local sites determined by the Secretary to be geographically and culturally representative of State, local, and Indian agencies, to evaluate the feasibility of including fresh, frozen, or canned fruits and vegetables (to be made available through private funds) as an addition to the supplemental foods prescribed under this section.

(D) REVIEW OF AVAILABLE SUPPLEMENTAL FOODS.—As frequently as determined by the Secretary to be necessary to reflect the most recent scientific knowledge, the Secretary shall—

(i) conduct a scientific review of the supplemental foods available under the program; and

(ii) amend the supplemental foods available, as necessary, to reflect nutrition science, public health concerns, and cultural eating patterns.

(12) A competent professional authority shall be responsible for prescribing the appropriate supplemental foods, taking into account medical and nutritional conditions and cultural eating patterns, and, in the case of homeless individuals, the special needs and problems of such individuals.

(13) The State agency may (A) provide nutrition education, breastfeeding promotion, and drug abuse education materials and instruction in languages other than English and (B) use appropriate foreign language materials in the administration of the program, in areas in which a substantial number of low-income households speak a language other than English.

(14) If a State agency determines that a member of a family has received an overissuance of food benefits under the program authorized by this section as the result of such member intentionally making a false or misleading statement or intentionally misrepresenting, concealing, or withholding facts, the State agency shall recover, in cash, from such member an amount that the State agency determines is equal to the value of the overissued food benefits, unless the State agency determines that the recovery of the benefits would not be cost effective.

(15) To be eligible to participate in the program authorized by this section, a manufacturer of infant formula that supplies formula for the program shall—

(A) register with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]; and

(B) before bidding for a State contract to supply infant formula for the program, certify with the State health department that the formula complies with such Act and regulations issued pursuant to such Act.

(16) The State agency may adopt methods of delivering benefits to accommodate the special needs and problems of homeless individuals.

(17) Notwithstanding subsection (d)(2)(A)(i) of this section, not later than July 1 of each year, a State agency may implement income eligibility guidelines under this section concurrently with the implementation of income eligibility guidelines under the medicaid program established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(18) Each local agency participating in the program under this section may provide information about other potential sources of food assistance in the local area to individuals who apply in person to participate in the program under this section, but who cannot be served because the program is operating at capacity in the local area.

(19) The State agency shall adopt policies that—

(A) require each local agency to attempt to contact each pregnant woman who misses an appointment to apply for participation in the program under this section, in order to reschedule the appointment, unless the phone number and the address of the woman are unavailable to such local agency; and

(B) in the case of local agencies that do not routinely schedule appointments for individuals seeking to apply or be recertified for participation in the program under this section, require each such local agency to schedule appointments for each employed individual seeking to apply or be recertified for participation in such program so as to minimize the time each such individual is absent from the workplace due to such application or request for recertification.

(20) Each State agency shall conduct monitoring reviews of each local agency at least biennially.

(21) USE OF CLAIMS FROM LOCAL AGENCIES, VENDORS, AND PARTICIPANTS.—A State agency may use funds recovered from local agencies, vendors, and participants, as a result of a claim arising under the program, to carry out the program during—

(A) the fiscal year in which the claim arises;

(B) the fiscal year in which the funds are collected; and

(C) the fiscal year following the fiscal year in which the funds are collected.

(22) The Secretary and the Secretary of Health and Human Services shall carry out an initiative to assure that, in a case in which a State medicaid program uses coordinated care providers under a contract entered into under section 1903(m), or a waiver granted under section 1915(b), of the Social Security Act (42 U.S.C. 1396b(m) or 1396n(b)), coordination between the program authorized by this section and the medicaid program is continued, including—

(A) the referral of potentially eligible women, infants, and children between the 2 programs; and

(B) the timely provision of medical information related to the program authorized by this section to agencies carrying out the program.

(23) INDIVIDUALS PARTICIPATING AT MORE THAN ONE SITE.—Each State agency shall implement a system designed by the State agency to identify individuals who are participating at more than one site under the program.

(24) HIGH RISK VENDORS.—Each State agency shall—

(A) identify vendors that have a high probability of program abuse; and

(B) conduct compliance investigations of the vendors.

(25) INFANT FORMULA BENEFITS.—A State agency may round up to the next whole can of infant formula to allow all participants under the program to receive the full-authorized nutritional benefit specified by regulation.

(26) NOTIFICATION OF VIOLATIONS.—If a State agency finds that a vendor has committed a violation that requires a pattern of occurrences in order to impose a penalty or sanction, the State agency shall notify the vendor of the initial violation in writing prior to documentation of another violation, unless the State agency determines that notifying the vendor would compromise an investigation.

(g) Authorization of appropriations.—

(1) IN GENERAL.—

(A) AUTHORIZATION.—There are authorized to be appropriated to carry out this section such sums as are necessary for each of fiscal years 2004 through 2009.

(B) ADVANCE APPROPRIATIONS; AVAILABILITY.—As authorized by section 1752 of this title, appropriations to carry out the provisions of this section may be made not more than 1 year in advance of the beginning of the fiscal year in which the funds will become available for disbursement to the States, and shall remain available for the purposes for which appropriated until expended.

(2)(A) Notwithstanding any other provision of law, unless enacted in express limitation of this subparagraph, the Secretary—

(i) in the case of legislation providing funds through the end of a fiscal year, shall issue—

(I) an initial allocation of funds provided by the enactment of such legislation not later than the expiration of the 15-day period beginning on the date of the enactment of such legislation; and

(II) subsequent allocations of funds provided by the enactment of such legislation not later than the beginning of each of the second, third, and fourth quarters of the fiscal year; and

(ii) in the case of legislation providing funds for a period that ends prior to the end of a fiscal year, shall issue an initial allocation of funds provided by the enactment of such legislation not later than the expiration of the 10-day period beginning on the date of the enactment of such legislation.

(B) In any fiscal year—

(i) unused amounts from a prior fiscal year that are identified by the end of the first quarter of the fiscal year shall be recovered and reallocated not later than the beginning of the second quarter of the fiscal year; and

(ii) unused amounts from a prior fiscal year that are identified after the end of the first quarter of the fiscal year shall be recovered and reallocated on a timely basis.

(3) Notwithstanding any other provision of law, unless enacted in express limitation of this paragraph—

(A) the allocation of funds required by paragraph (2)(A)(i)(I) shall include not less than ⅓ of the amounts appropriated by the legislation described in such paragraph;

(B) the allocations of funds required by paragraph (2)(A)(i)(II) to be made not later than the beginning of the second and third quarters of the fiscal year shall each include not less than ¼ of the amounts appropriated by the legislation described in such paragraph; and

(C) in the case of the enactment of legislation providing appropriations for a period of not more than 4 months, the allocation of funds required by paragraph (2)(A)(ii) shall include all amounts appropriated by such legislation except amounts reserved by the Secretary for purposes of carrying out paragraph (5).

(4) Of the sums appropriated for any fiscal year for programs authorized under this section, not less than nine-tenths of 1 percent shall be available first for services to eligible members of migrant

populations. The migrant services shall be provided in a manner consistent with the priority system of a State for program participation.

(5) Of the sums appropriated for any fiscal year for the program under this section, one-half of 1 percent, not to exceed $5,000,000, shall be available to the Secretary for the purpose of evaluating program performance, evaluating health benefits, preparing reports on program participant characteristics, providing technical assistance to improve State agency administrative systems, administration of pilot projects, including projects designed to meet the special needs of migrants, Indians, and rural populations, and carrying out technical assistance and research evaluation projects of the programs under this section.

(h) Funds for nutrition services and administration

(1)(A) Each fiscal year, the Secretary shall make available, from amounts appropriated for such fiscal year under subsection (g)(1) of this section and amounts remaining from amounts appropriated under such subsection for the preceding fiscal year, an amount sufficient to guarantee a national average per participant grant to be allocated among State agencies for costs of nutrition services and administration incurred by State and local agencies for such year.

(B)(i) The amount of the national average per participant grant for nutrition services and administration for any fiscal year shall be an amount equal to the amount of the national average per participant grant for nutrition services and administration issued for the preceding fiscal year, as adjusted.

(ii) Such adjustment, for any fiscal year, shall be made by revising the national average per participant grant for nutrition services and administration for the preceding fiscal year to reflect the percentage change between—

(I) the value of the index for State and local government purchases, as published by the Bureau of Economic Analysis of the Department of Commerce, for the 12-month period ending June 30 of the second preceding fiscal year; and

(II) the best estimate that is available as of the start of the fiscal year of the value of such index for the 12-month period ending June 30 of the previous fiscal year.

(C) REMAINING AMOUNTS.—

(i) IN GENERAL.—Except as provided in clause (ii), in any fiscal year, amounts remaining from amounts appropriated for such fiscal year under subsection (g)(1) of this section and from amounts appropriated under such section for the preceding fiscal year, after carrying out subparagraph (A), shall be made available for food benefits under this section, except to the extent that such amounts are needed to carry out the purposes of subsections (g)(4) and (g)(5) of this section.

(ii) BREAST PUMPS.—A State agency may use amounts made available under clause (i) for the purchase of breast pumps.

(2)(A) The Secretary shall allocate to each State agency from the amount described in paragraph (1)(A) an amount for costs of nutrition services and administration on the basis of a formula prescribed by the Secretary. Such formula—

(i) shall be designed to take into account—

(I) the varying needs of each State;

(II) the number of individuals participating in each State; and

(III) other factors which serve to promote the proper, efficient, and effective administration of the program under this section;

(ii) shall provide for each State agency—

(I) an estimate of the number of participants for the fiscal year involved; and

(II) a per participant grant for nutrition services and administration for such year;

(iii) shall provide for a minimum grant amount for State agencies; and

(iv) may provide funds to help defray reasonable anticipated expenses associated with innovations in cost containment or associated with procedures that tend to enhance competition.

(B)(i) Except as provided in clause (ii) and subparagraph (C), in any fiscal year, the total amount allocated to a State agency for costs of nutrition services and administration under the formula prescribed by the Secretary under subparagraph (A) shall constitute the State agency's operational level for such costs for such year even if the number of participants in the program at such agency is lower than the estimate provided under subparagraph (A)(ii)(I).

(ii) If a State agency's per participant expenditure for nutrition services and administration is more than 10 percent (except that the Secretary may establish a higher percentage for State agencies that are small) higher than its per participant grant for nutrition services and administration without good cause, the Secretary may reduce such State agency's operational level for costs of nutrition services and administration.

(C) In any fiscal year, the Secretary may reallocate amounts provided to State agencies under subparagraph (A) for such fiscal year. When reallocating amounts under the preceding sentence, the Secretary may provide additional amounts to, or recover amounts from, any State agency.

(3)(A) Except as provided in subparagraphs (B) and (C), in each fiscal year, each State agency shall expend—

(i) for nutrition education activities and breastfeeding promotion and support activities, an aggregate amount that is not less than the sum of—

(I) ⅙ of the amounts expended by the State for costs of nutrition services and administration; and

(II) except as otherwise provided in subparagraphs (F) and (G), an amount equal to a proportionate share of the national minimum breastfeeding promotion expenditure, as described in subparagraph (E), with each State's share determined on the basis of the number of pregnant women and breastfeeding women in the program in the State as a percentage of the number of pregnant women and breastfeeding women in the program in all States; and

(ii) for breastfeeding promotion and support activities an amount that is not less than the amount determined for such State under clause (i)(II).

(B) The Secretary may authorize a State agency to expend an amount less than the amount described in subparagraph (A)(ii) for purposes of breastfeeding promotion and support activities if—

(i) the State agency so requests; and

(ii) the request is accompanied by documentation that other funds will be used to conduct nutrition education activities at a level commensurate with the level at which such activities would be conducted if the amount described in subparagraph (A)(ii) were expended for such activities.

(C) The Secretary may authorize a State agency to expend for purposes of nutrition education an amount that is less than the difference between the aggregate amount described in subparagraph (A) and the amount expended by the State for breastfeeding promotion and support programs if—

(i) the State agency so requests; and

(ii) the request is accompanied by documentation that other funds will be used to conduct such activities.

(D) The Secretary shall limit to a minimal level any documentation required under this paragraph.

(E) For each fiscal year, the national minimum breastfeeding promotion expenditure means an amount that is—

(i) equal to $21 multiplied by the number of pregnant women and breastfeeding women participating in the program nationwide, based on the average number of pregnant women and breastfeeding women so participating during the last 3 months for which the Secretary has final data; and

(ii) adjusted for inflation on October 1, 1996, and each October 1 thereafter, in accordance with paragraph (1)(B)(ii).

(4) The Secretary shall—

(A) in consultation with the Secretary of Health and Human Services, develop a definition of breastfeeding for the purposes of the program under this section;

(B) authorize the purchase of breastfeeding aids by State and local agencies as an allowable expense under nutrition services and administration;

(C) require each State agency to designate an agency staff member to coordinate breastfeeding promotion efforts identified in the State plan of operation and administration;

(D) require the State agency to provide training on the promotion and management of breastfeeding to staff members of local agencies who are responsible for counseling participants in the program under this section concerning breastfeeding;

(E) not later than 1 year after November 2, 1994, develop uniform requirements for the collection of data regarding the incidence and duration of breastfeeding among participants in the program; and

(F) partner with communities, State and local agencies, employers, health care professionals, and other entities in the private sector to build a supportive breastfeeding environment for women participating in the program under this section to support the breastfeeding goals of the Healthy People 2010 initiative.

(5)(A) Subject to subparagraph (B), in any fiscal year that a State agency submits a plan to reduce average food costs per participant

and to increase participation above the level estimated for the State agency, the State agency may, with the approval of the Secretary, convert amounts allocated for food benefits for such fiscal year for costs of nutrition services and administration to the extent that such conversion is necessary—

(i) to cover allowable expenditures in such fiscal year; and

(ii) to ensure that the State agency maintains the level established for the per participant grant for nutrition services and administration for such fiscal year.

(B) If a State agency increases its participation level through measures that are not in the nutritional interests of participants or not otherwise allowable (such as reducing the quantities of foods provided for reasons not related to nutritional need), the Secretary may refuse to allow the State agency to convert amounts allocated for food benefits to defray costs of nutrition services and administration.

(C) For the purposes of this paragraph, the term "acceptable measures" includes use of cost containment measures, curtailment of vendor abuse, and breastfeeding promotion activities.

(D) REMOTE INDIAN OR NATIVE VILLAGES.—For noncontiguous States containing a significant number of remote Indian or Native villages, a State agency may convert amounts allocated for food benefits for a fiscal year to the costs of nutrition services and administration to the extent that the conversion is necessary to cover expenditures incurred in providing services (including the full cost of air transportation and other transportation) to remote Indian or Native villages and to provide breastfeeding support in remote Indian or Native villages.

(6) In each fiscal year, each State agency shall provide, from the amounts allocated to such agency for such year for costs of nutrition services and administration, an amount to each local agency for its costs of nutrition services and administration. The amount to be provided to each local agency under the preceding sentence shall be determined under allocation standards developed by the State agency in cooperation with the several local agencies, taking into account factors deemed appropriate to further proper, efficient, and effective administration of the program, such as—

(A) local agency staffing needs;

(B) density of population;

(C) number of individuals served; and

(D) availability of administrative support from other sources.

(7) The State agency may provide in advance to any local agency any amounts for nutrition services and administration deemed necessary for successful commencement or significant expansion of program operations during a reasonable period following approval of—

(A) a new local agency;

(B) a new cost containment measure; or

(C) a significant change in an existing cost containment measure.

(8)(A)(i) Except as provided in subparagraphs (B) and (C)(iii), any State that provides for the purchase of foods under the program at retail grocery stores shall, with respect to the procurement of infant formula, use—

(I) a competitive bidding system; or

(II) any other cost containment measure that yields savings equal to or greater than savings generated by a competitive bidding system when such savings are determined by comparing the amounts of savings that would be provided over the full term of contracts offered in response to a single invitation to submit both competitive bids and bids for other cost containment systems for the sale of infant formula.

(ii) In determining whether a cost containment measure other than competitive bidding yields equal or greater savings, the State, in accordance with regulations issued by the Secretary, may take into account other cost factors (in addition to rebate levels and procedures for adjusting rebate levels when wholesale price levels change), such as—

(I) the number of infants who would not be expected to receive the primary contract infant formula under a competitive bidding system;

(II) the number of cans of infant formula for which no rebate would be provided under another rebate system; and

(III) differences in administrative costs relating to the implementation of the various cost containment systems (such as costs of converting a computer system for the purpose of operating a cost containment system and costs of preparing participants for conversion to a new or alternate cost containment system).

(iii) COMPETITIVE BIDDING SYSTEM.—A State agency using a competitive bidding system for infant formula shall award contracts to bidders offering the lowest net price for a specific infant formula for which manufacturers submit a bid unless the State agency demonstrates to the satisfaction of the Secretary that the weighted average retail price for different brands of infant formula in the State does not vary by more than 5 percent.

(iv) SIZE OF STATE ALLIANCES.—

(I) IN GENERAL.—Except as provided in subclauses (II) through (IV), no State alliance may exist among States if the total number of infants served by States participating in the alliance as of October 1, 2003, or such subsequent date determined by the Secretary for which data is available, would exceed 100,000.

(II) ADDITION OF INFANT PARTICIPANTS.—In the case of a State alliance that exists on June 30, 2004, the alliance may continue and may expand to serve more than 100,000 infants but, except as provided in subclause (III), may not expand to include any additional State agency.

(III) ADDITION OF SMALL STATE AGENCIES AND INDIAN STATE AGENCIES.—Any State alliance may expand to include any State agency that served less than 5,000 infant participants as of October 1, 2003, or such subsequent date determined by the Secretary for which data is available, or any Indian State agency, if the State agency or Indian State agency requests to join the State alliance.

(IV) SECRETARIAL WAIVER.—The Secretary may waive the requirements of this clause not earlier than 30 days after submitting to the Committee on Education and the Workforce of

the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a written report that describes the cost-containment and competitive benefits of the proposed waiver.

(v) FIRST CHOICE OF ISSUANCE.—The State agency shall use the primary contract infant formula as the first choice of issuance (by formula type), with all other infant formulas issued as an alternative to the primary contract infant formula.

(vi) REBATE INVOICES.—Effective beginning October 1, 2004, each State agency shall have a system to ensure that infant formula rebate invoices, under competitive bidding, provide a reasonable estimate or an actual count of the number of units sold to participants in the program under this section.

(vii) SEPARATE SOLICITATIONS.—In soliciting bids for infant formula under a competitive bidding system, any State agency, or State alliance, that served under the program a monthly average of more than 100,000 infants during the preceding 12-month period shall solicit bids from infant formula manufacturers under procedures that require that bids for rebates or discounts are solicited for milk-based and soy-based infant formula separately.

(viii) CENT-FOR-CENT ADJUSTMENTS.—A bid solicitation for infant formula under the program shall require the manufacturer to adjust for price changes subsequent to the opening of the bidding process in a manner that requires—

(I) a cent-for-cent increase in the rebate amounts if there is an increase in the lowest national wholesale price for a full truckload of the particular infant formula; and

(II) a cent-for-cent decrease in the rebate amounts if there is a decrease in the lowest national wholesale price for a full truckload of the particular infant formula.

(ix) LIST OF INFANT FORMULA WHOLESALERS, DISTRIBUTORS, RETAILERS, AND MANUFACTURERS.—The State agency shall maintain a list of—

(I) infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations); and

(II) infant formula manufacturers registered with the Food and Drug Administration that provide infant formula.

(x) PURCHASE REQUIREMENT.—A vendor authorized to participate in the program under this section shall only purchase infant formula from the list described in clause (ix).

(B)(i) The Secretary shall waive the requirement of subparagraph (A) in the case of any State that demonstrates to the Secretary that—

(I) compliance with subparagraph (A) would be inconsistent with efficient or effective operation of the program operated by such State under this section; or

(II) the amount by which the savings yielded by an alternative cost containment system would be less than the savings yielded by a competitive bidding system is sufficiently minimal that the difference is not significant.

(ii) The Secretary shall prescribe criteria under which a waiver may be granted pursuant to clause (i).

(iii) The Secretary shall provide information on a timely basis to the Committee on Education and Labor of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate on waivers that have been granted under clause (i).

(C)(i) The Secretary shall provide technical assistance to small Indian State agencies carrying out this paragraph in order to assist such agencies to achieve the maximum cost containment savings feasible.

(ii) The Secretary shall also provide technical assistance, on request, to State agencies that desire to consider a cost containment system that covers more than 1 State agency.

(iii) The Secretary may waive the requirement of subparagraph (A) in the case of any Indian State agency that has not more than 1,000 participants.

(D) No State may enter into a cost containment contract (in this subparagraph referred to as the "original contract") that prescribes conditions that would void, reduce the savings under, or otherwise limit the original contract if the State solicited or secured bids for, or entered into, a subsequent cost containment contract to take effect after the expiration of the original contract.

(E) The Secretary shall offer to solicit bids on behalf of State agencies regarding cost-containment contracts to be entered into by infant formula manufacturers and State agencies. The Secretary shall make the offer to State agencies once every 12 months. Each such bid solicitation shall only take place if two or more State agencies request the Secretary to perform the solicitation. For such State agencies, the Secretary shall solicit bids and select the winning bidder for a cost containment contract to be entered into by State agencies and infant formula manufacturers or suppliers.

(F) In soliciting bids for contracts for infant formula for the program authorized by this section, the Secretary shall solicit bids from infant formula manufacturers under procedures in which bids for rebates or discounts are solicited for milk-based and soy-based infant formula, separately, except where the Secretary determines that such solicitation procedures are not in the best interest of the program.

(G) To reduce the costs of any supplemental foods, the Secretary may make available additional funds to State agencies out of the funds otherwise available under paragraph (1)(A) for nutrition services and administration in an amount not exceeding one half of 1 percent of the amounts to help defray reasonable anticipated expenses associated with innovations in cost containment or associated with procedures that tend to enhance competition.

(H)(i) Any person, company, corporation, or other legal entity that submits a bid to supply infant formula to carry out the program authorized by this section and announces or otherwise discloses the amount of the bid, or the rebate or discount practices of such entities, in advance of the time the bids are opened by the Secretary or the State agency, or any person, company, corporation, or other legal entity that makes a statement (prior to the opening of bids) relating to levels of rebates or discounts, for the purpose of influencing a bid submitted by any other person, shall be ineligible to submit bids to supply infant formula to the program for the bidding in progress for up to 2 years from the date the bids are

opened and shall be subject to a civil penalty of up to $100,000,000, as determined by the Secretary to provide restitution to the program for harm done to the program. The Secretary shall issue regulations providing such person, company, corporation, or other legal entity appropriate notice, and an opportunity to be heard and to respond to charges.

(ii) The Secretary shall determine the length of the disqualification, and the amount of the civil penalty referred to in clause (i) based on such factors as the Secretary by regulation determines appropriate.

(iii) Any person, company, corporation, or other legal entity disqualified under clause (i) shall remain obligated to perform any requirements under any contract to supply infant formula existing at the time of the disqualification and until each such contract expires by its terms.

(I) Not later than the expiration of the 180-day period beginning on October 24, 1992, the Secretary shall prescribe regulations to carry out this paragraph.

(J) A State shall not incur any interest liability to the Federal Government on rebate funds for infant formula and other foods if all interest earned by the State on the funds is used for program purposes.

(9) For purposes of this subsection, the term ''cost containment measure'' means a competitive bidding, rebate, direct distribution, or home delivery system implemented by a State agency as described in its approved plan of operation and administration.

(10) FUNDS FOR INFRASTRUCTURE, MANAGEMENT INFORMATION SYSTEMS, AND SPECIAL NUTRITION EDUCATION.—

(A) IN GENERAL.—For each of fiscal years 2006 through 2009, the Secretary shall use for the purposes specified in subparagraph (B), $64,000,000 or the amount of nutrition services and administration funds and supplemental food funds for the prior fiscal year that have not been obligated, whichever is less.

(B) PURPOSES.—Of the amount made available under subparagraph (A) for a fiscal year, not more than—

(i) $14,000,000 shall be used for—

(I) infrastructure for the program under this section;

(II) special projects to promote breastfeeding, including projects to assess the effectiveness of particular breastfeeding promotion strategies; and

(III) special State projects of regional or national significance to improve the services of the program;

(ii) $30,000,000 shall be used to establish, improve, or administer management information systems for the program, including changes necessary to meet new legislative or regulatory requirements of the program; and

(iii) $20,000,000 shall be used for special nutrition education such as breast feeding peer counselors and other related activities.

(C) PROPORTIONAL DISTRIBUTION.—In a case in which less than $64,000,000 is available to carry out this paragraph, the Secretary shall make a proportional distribution of funds allocated under subparagraph (B).

(11) VENDOR COST CONTAINMENT.—

(A) PEER GROUPS.—

(i) IN GENERAL.—The State agency shall—

(I) establish a vendor peer group system;

(II) in accordance with subparagraphs (B) and (C), establish competitive price criteria and allowable reimbursement levels for each vendor peer group; and

(III) if the State agency elects to authorize any types of vendors described in subparagraph (D)(ii)(I)—

(aa) distinguish between vendors described in subparagraph (D)(ii)(I) and other vendors by establishing—

(AA) separate peer groups for vendors described in subparagraph (D)(ii)(I);or

(BB) distinct competitive price criteria and allowable reimbursement levels for vendors described in subparagraph (D)(ii)(I) within a peer group that contains both vendors described in subparagraph (D)(ii)(I) and other vendors; and

(bb) establish competitive price criteria and allowable reimbursement levels that comply with subparagraphs (B) and (C), respectively, and that do not result in higher food costs if program participants redeem supplemental food vouchers at vendors described in subparagraph (D)(ii)(I) rather than at vendors other than vendors described in subparagraph (D)(ii)(I).

Nothing in this paragraph shall be construed to compel a State agency to achieve lower food costs if program participants redeem supplemental food vouchers at vendors described in subparagraph (D)(ii)(I) rather than at vendors other than vendors described in subparagraph (D)(ii)(I).

(ii) EXEMPTIONS.—The Secretary may exempt from the requirements of clause (i)—

(I) a State agency that elects not to authorize any types of vendors described in subparagraph (D)(ii)(I) and that demonstrates to the Secretary that—

(aa) compliance with clause (i) would be inconsistent with efficient and effective operation of the program administered by the State under this section; or

(bb) an alternative cost-containment system would be as effective as a vendor peer group system; or

(II) a State agency—

(aa) in which the sale of supplemental foods that are obtained with food instruments from vendors described in subparagraph (D)(ii)(I) constituted less than 5 percent of total sales of supplemental foods that were obtained with food instruments in the State in the year preceding a year in which the exemption is effective; and

(bb) that demonstrates to the Secretary that an alternative cost-containment system would be as

effective as the vendor peer group system and would not result in higher food costs if program participants redeem supplemental food vouchers at vendors described in subparagraph (D)(ii)(I) rather than at vendors other than vendors described in subparagraph (D)(ii)(I).

(B) COMPETITIVE PRICING.—

(i) IN GENERAL.—The State agency shall establish competitive price criteria for each peer group for the selection of vendors for participation in the program that—

(I) ensure that the retail prices charged by vendor applicants for the program are competitive with the prices charged by other vendors; and

(II) consider—

(aa) the shelf prices of the vendor for all buyers; or

(bb) the prices that the vendor bid for supplemental foods, which shall not exceed the shelf prices of the vendor for all buyers.

(ii) PARTICIPANT ACCESS.—In establishing competitive price criteria, the State agency shall consider participant access by geographic area.

(iii) SUBSEQUENT PRICE INCREASES.—The State agency shall establish procedures to ensure that a retail store selected for participation in the program does not, subsequent to selection, increase prices to levels that would make the store ineligible for selection to participate in the program.

(C) ALLOWABLE REIMBURSEMENT LEVELS.—

(i) IN GENERAL.—The State agency shall establish allowable reimbursement levels for supplemental foods for each vendor peer group that ensure—

(I) that payments to vendors in the vendor peer group reflect competitive retail prices; and

(II) that the State agency does not reimburse a vendor for supplemental foods at a level that would make the vendor ineligible for authorization under the criteria established under subparagraph (B).

(ii) PRICE FLUCTUATIONS.—The allowable reimbursement levels may include a factor to reflect fluctuations in wholesale prices.

(iii) PARTICIPANT ACCESS.—In establishing allowable reimbursement levels, the State agency shall consider participant access in a geographic area.

(D) EXEMPTIONS.—The State agency may exempt from competitive price criteria and allowable reimbursement levels established under this paragraph—

(i) pharmacy vendors that supply only exempt infant formula or medical foods that are eligible under the program; and

(ii) vendors—

(I)(aa) for which more than 50 percent of the annual revenue of the vendor from the sale of food items consists of revenue from the sale of supplemental foods that are obtained with food instruments; or

(bb) who are new applicants likely to meet the criteria of item (aa) under criteria approved by the Secretary; and

(II) that are nonprofit.

(E) COST CONTAINMENT.—If a State agency elects to authorize any types of vendors described in subparagraph (D)(ii)(I), the State agency shall demonstrate to the Secretary, and the Secretary shall certify, that the competitive price criteria and allowable reimbursement levels established under this paragraph for vendors described in subparagraph (D)(ii)(I) do not result in average payments per voucher to vendors described in subparagraph (D)(ii)(I) that are higher than average payments per voucher to comparable vendors other than vendors described in subparagraph (D)(ii)(I).

(F) LIMITATION ON PRIVATE RIGHTS OF ACTION.—Nothing in this paragraph may be construed as creating a private right of action.

(G) IMPLEMENTATION.—A State agency shall comply with this paragraph not later than 18 months after June 30, 2004.

(12) IMPOSITION OF COSTS ON RETAIL STORES.—The Secretary may not impose, or allow a State agency to impose, the costs of any equipment, system, or processing required for electronic benefit transfers on any retail store authorized to transact food instruments, as a condition for authorization or participation in the program.

(13) UNIVERSAL PRODUCT CODES DATABASE.—The Secretary shall—

(A) establish a national universal product code database for use by all State agencies in carrying out the program; and

(B) make available from appropriated funds such sums as are required for hosting, hardware and software configuration, and support of the database.

(14) INCENTIVE ITEMS.—A State agency shall not authorize or make payments to a vendor described in paragraph (11)(D)(ii)(I) that provides incentive items or other free merchandise, except food or merchandise of nominal value (as determined by the Secretary), to program participants unless the vendor provides to the State agency proof that the vendor obtained the incentive items or merchandise at no cost.

(i) Division of funds formula; reallocation of unspent funds; use of State allocation to buy supplemental foods; use of amounts available for succeeding fiscal year

(1) By the beginning of each fiscal year, the Secretary shall divide, among the State agencies, the amounts made available for food benefits under subsection (h)(1)(C) of this section on the basis of a formula determined by the Secretary.

(2) Each State agency's allocation, as so determined, shall constitute the State agency's authorized operational level for that year, except that the Secretary shall reallocate funds periodically if the

Secretary determines that a State agency is unable to spend its allocation.

(3)(A) Notwithstanding paragraph (2) and subject to subparagraph (B)—

(i)(I) not more than 1 percent (except as provided in subparagraph (C)) of the amount of funds allocated to a State agency under this section for supplemental foods for a fiscal year may be expended by the State agency for allowable expenses incurred under this section for supplemental foods during the preceding fiscal year; and

(II) not more than 1 percent of the amount of funds allocated to a State agency under this section for nutrition services and administration for a fiscal year may be expended by the State agency for allowable expenses incurred under this section for supplemental foods and nutrition services and administration during the preceding fiscal year; and

(ii)(I) for each fiscal year, of the amounts allocated to a State agency for nutrition services and administration, an amount equal to not more than 3 percent of the amount allocated to the State agency under this section for the fiscal year may be expended by the State agency for allowable expenses incurred under this section for nutrition services and administration during the subsequent fiscal year; and

(II) for each fiscal year, of the amounts allocated to a State agency for nutrition services and administration, an amount equal to not more than ½ of 1 percent of the amount allocated to the State agency under this section for the fiscal year may be expended by the State agency, with the prior approval of the Secretary, for the development of a management information system, including an electronic benefit transfer system, during the subsequent fiscal year.

(B) Any funds made available to a State agency in accordance with subparagraph (A)(ii) for a fiscal year shall not affect the amount of funds allocated to the State agency for such year.

(C) The Secretary may authorize a State agency to expend not more than 3 percent of the amount of funds allocated to a State under this section for supplemental foods for a fiscal year for expenses incurred under this section for supplemental foods during the preceding fiscal year, if the Secretary determines that there has been a significant reduction in infant formula cost containment savings provided to the State agency that would affect the ability of the State agency to at least maintain the level of participation by eligible participants served by the State agency.

(4) For purposes of the formula, if Indians are served by the health department of a State, the formula shall be based on the State population inclusive of the Indians within the State boundaries.

(5) If Indians residing in the State are served by a State agency other than the health department of the State, the population of the tribes within the jurisdiction of the State being so served shall not be included in the formula for such State, and shall instead be included in the formula for the State agency serving the Indians.

(6) Notwithstanding any other provision of this section, the Secretary may use a portion of a State agency's allocation to purchase

supplemental foods for donation to the State agency under this section.

(7) In addition to any amounts expended under paragraph (3)(A)(i), any State agency using cost containment measures as defined in subsection (h)(9) of this section may temporarily use amounts made available to such agency for the first quarter of a fiscal year to defray expenses for costs incurred during the final quarter of the preceding fiscal year. In any fiscal year, any State agency that uses amounts made available for a succeeding fiscal year under the authority of the preceding sentence shall restore or reimburse such amounts when such agency receives payment as a result of its cost containment measures for such expenses.

(j) Initiative to provide program services at community and migrant health centers

(1) The Secretary and the Secretary of Health and Human Services (referred to in this subsection as the "Secretaries") shall jointly establish and carry out an initiative for the purpose of providing both supplemental foods and nutrition education under the special supplemental nutrition program and health care services to low-income pregnant, postpartum, and breastfeeding women, infants, and children at substantially more community health centers and migrant health centers.

(2) The initiative shall also include—

(A) activities to improve the coordination of the provision of supplemental foods and nutrition education under the special supplemental nutrition program and health care services at facilities funded by the Indian Health Service; and

(B) the development and implementation of strategies to ensure that, to the maximum extent feasible, new community health centers, migrant health centers, and other federally supported health care facilities established in medically underserved areas provide supplemental foods and nutrition education under the special supplemental nutrition program.

(3) The initiative may include—

(A) outreach and technical assistance for State and local agencies and the facilities described in paragraph (2)(A) and the health centers and facilities described in paragraph (2)(B);

(B) demonstration projects in selected State or local areas; and

(C) such other activities as the Secretaries find are appropriate.

(4) As used in this subsection:

(A) The term "community health center" has the meaning given the term in section 254c(a) of this title.

(B) The term "migrant health center" has the meaning given the term in section 254b(a)(1) of this title.

(5) Redesignated (4)

(k) National Advisory Council on Maternal, Infant, and Fetal Nutrition; establishment; membership; term; officers; meetings; quorum; technical assistance by Secretary

(1) There is hereby established a National Advisory Council on Maternal, Infant, and Fetal Nutrition (referred to in this subsection as the "Council") composed of 24 members appointed by the Secretary. One member shall be a State director of a program under this section; one member shall be a State official responsible for a commodity supplemental food program under section 1304 of the Food and Agriculture Act of 1977; one member shall be a State fiscal officer of a program under this section (or the equivalent thereof); one member shall be a State health officer (or the equivalent thereof); one member shall be a local agency director of a program under this section in an urban area; one member shall be a local agency director of a program under this section in a rural area; one member shall be a project director of a commodity supplemental food program; one member shall be a State public health nutrition director (or the equivalent thereof); one member shall be a representative of an organization serving migrants; one member shall be an official from a State agency predominantly serving Indians; three members shall be parent participants of a program under this section or of a commodity supplemental food program; one member shall be a pediatrician; one member shall be an obstetrician; one member shall be a representative of a nonprofit public interest organization that has experience with and knowledge of the special supplemental nutrition program; one member shall be a person involved at the retail sales level of food in the special supplemental nutrition program; two members shall be officials of the Department of Health and Human Services appointed by the Secretary of Health and Human Services; two members shall be officials of the Department of Agriculture appointed by the Secretary; 1 member shall be an expert in the promotion of breast feeding; one member shall be an expert in drug abuse education and prevention; and one member shall be an expert in alcohol abuse education and prevention.

(2) Members of the Council appointed from outside the Department of Agriculture and the Department of Health and Human Services shall be appointed for terms not exceeding three years. State and local officials shall serve only during their official tenure, and the tenure of parent participants shall not exceed two years. Persons appointed to complete an unexpired term shall serve only for the remainder of such term.

(3) The Council shall elect a Chairman and a Vice Chairman. The Council shall meet at the call of the Chairman, but shall meet at least once a year. Eleven members shall constitute a quorum.

(4) The Secretary shall provide the Council with such technical and other assistance, including secretarial and clerical assistance, as may be required to carry out its functions.

(5) Members of the Council shall serve without compensation but shall be reimbursed for necessary travel and subsistence expenses incurred by them in the performance of the duties of the Council.

Parent participant members of the Council, in addition to reimbursement for necessary travel and subsistence, shall, at the discretion of the Secretary, be compensated in advance for other personal expenses related to participation on the Council, such as child care expenses and lost wages during scheduled Council meetings.

(l) Donation of foods by Secretary

Foods available under section 1431 of Title 7, including, but not limited to, dry milk, or purchased under section 612c of Title 7, may be donated by the Secretary, at the request of a State agency, for distribution to programs conducted under this section. The Secretary may purchase and distribute, at the request of a State agency, supplemental foods for donation to programs conducted under this section, with appropriated funds, including funds appropriated under this section.

(m) Women, infants, and children farmers' market nutrition program; establishment, grants, etc.

(1) Subject to the availability of funds appropriated for the purposes of this subsection, and as specified in this subsection, the Secretary shall award grants to States that submit State plans that are approved for the establishment or maintenance of programs designed to provide recipients of assistance under subsection (c) of this section, or those who are on the waiting list to receive the assistance, with coupons that may be exchanged for fresh, nutritious, unprepared foods at farmers' markets and (at the option of a State) roadside stands, as defined in the State plans submitted under this subsection.

(2) A grant provided to any State under this subsection shall be provided to the chief executive officer of the State, who shall—

(A) designate the appropriate State agency or agencies to administer the program in conjunction with the appropriate nonprofit organizations; and

(B) ensure coordination of the program among the appropriate agencies and organizations.

(3) The Secretary shall not make a grant to any State under this subsection unless the State agrees to provide State, local, or private funds for the program in an amount that is equal to not less than 30 percent of the administrative cost of the program, which may be satisfied from program income or State contributions that are made for similar programs. The Secretary may negotiate with an Indian State agency a lower percentage of matching funds than is required under the preceding sentence, but not lower than 10 percent of the administrative cost of the program, if the Indian State agency demonstrates to the Secretary financial hardship for the affected Indian tribe, band, group, or council.

(4) Subject to paragraph (6), the Secretary shall establish a formula for determining the amount of the grant to be awarded under this subsection to each State for which a State plan is approved under paragraph (6), according to the number of recipients proposed to participate as specified in the State plan. In determining the amount to be awarded to new States, the Secretary shall rank order the State plans according to the criteria of operation set forth

in this subsection, and award grants accordingly. The Secretary shall take into consideration the minimum amount needed to fund each approved State plan, and need not award grants to each State that submits a State plan.

(5) Each State that receives a grant under this subsection shall ensure that the program for which the grant is received complies with the following requirements:

(A) Individuals who are eligible to receive Federal benefits under the program shall only be individuals who are receiving assistance under subsection (c) of this section, or who are on the waiting list to receive the assistance.

(B) Construction or operation of a farmers' market may not be carried out using funds—

(i) provided under the grant; or

(ii) required to be provided by the State under paragraph (3).

(C) The value of the Federal share of the benefits received by any recipient under the program may not be—

(i) less than $10 per year; or

(ii) more than $30 per year.

(D) The coupon issuance process under the program shall be designed to ensure that coupons are targeted to areas with—

(i) the highest concentration of eligible individuals;

(ii) the greatest access to farmers' markets; and

(iii) certain characteristics, in addition to those described in clauses (i) and (ii), that are determined to be relevant by the Secretary and that maximize the availability of benefits to eligible individuals.

(E) The coupon redemption process under the program shall be designed to ensure that the coupons may be—

(i) redeemed only by producers authorized by the State to participate in the program; and

(ii) redeemed only to purchase fresh nutritious unprepared food for human consumption.

(F)(i) Except as provided in clauses (ii) and (iii), the State may use for administration of the program in any fiscal year not more than 17 percent of the total amount of program funds.

(ii) During any fiscal year for which a State receives assistance under this subsection, the Secretary shall permit the State to use not more than 2 percent of total program funds for market development or technical assistance to farmers' markets if the Secretary determines that the State intends to promote the development of farmers' markets in socially or economically disadvantaged areas, or remote rural areas, where individuals eligible for participation in the program have limited access to locally grown fruits and vegetables.

(iii) The provisions of clauses (i) and (ii) with respect to the use of program funds shall not apply to any funds that a State may contribute in excess of the funds used by the State to meet the requirements of paragraph (3).

(G) The State shall ensure that no State or local taxes are collected within the State on purchases of food with coupons distributed under the program.

(6)(A) The Secretary shall give the same preference for funding under this subsection to eligible States that participated in the program under this subsection in a prior fiscal year as to States that participated in the program in the most recent fiscal year. The Secretary shall inform each State of the award of funds as prescribed by subparagraph (G) by February 15 of each year.

(B)(i) Subject to the availability of appropriations, if a State provides the amount of matching funds required under paragraph (3), the State shall receive assistance under this subsection in an amount that is not less than the amount of such assistance that the State received in the most recent fiscal year in which it received such assistance.

(ii) If amounts appropriated for any fiscal year pursuant to the authorization contained in paragraph (10) for grants under this subsection are not sufficient to pay to each State for which a State plan is approved under paragraph (6) the amount that the Secretary determines each such State is entitled to under this subsection, each State's grant shall be ratably reduced, except that (if sufficient funds are available) each State shall receive at least $75,000 or the amount that the State received for the prior fiscal year if that amount is less than $75,000.

(C) In providing funds to a State that received assistance under this subsection in the previous fiscal year, the Secretary shall consider—

(i) the availability of any such assistance not spent by the State during the program year for which the assistance was received;

(ii) documentation that demonstrates that—

(I) there is a need for an increase in funds; and

(II) the use of the increased funding will be consistent with serving nutritionally at-risk persons and expanding the awareness and use of farmers' markets;

(iii) demonstrated ability to satisfactorily operate the existing program; and

(iv) whether, in the case of a State that intends to use any funding provided under subparagraph (G)(i) to increase the value of the Federal share of the benefits received by a recipient, the funding provided under subparagraph (G)(i) will increase the rate of coupon redemption.

(D)(i) A State that desires to receive a grant under this subsection shall submit, for each fiscal year, a State plan to the Secretary by November 15 of each year.

(ii) Each State plan submitted under this paragraph shall contain—

(I) the estimated cost of the program and the estimated number of individuals to be served by the program;

(II) a description of the State plan for complying with the requirements established in paragraph (5); and

(III) criteria developed by the State with respect to authorization of producers to participate in the program.

(iii) The criteria developed by the State as required by clause (ii)(III) shall require any authorized producer to sell fresh nutritious unprepared foods (such as fruits and vegetables) to recipients, in exchange for coupons distributed under the program.

(E) The Secretary shall establish objective criteria for the approval and ranking of State plans submitted under this paragraph.

(F)(i) An amount equal to 75 percent of the funds available after satisfying the requirements of subparagraph (B) shall be made available to States participating in the program whose State plan is approved by the Secretary. If this amount is greater than that necessary to satisfy the approved State plans, the unallocated amount shall be applied toward satisfying any unmet need of States that have not participated in the program in the prior fiscal year, and whose State plans have been approved.

(ii) An amount equal to 25 percent of the funds available after satisfying the requirements of subparagraph (B) shall be made available to States that have not participated in the program in the prior fiscal year, and whose State plans have been approved by the Secretary. If this amount is greater than that necessary to satisfy the approved State plans for new States, the unallocated amount shall be applied toward satisfying any unmet need of States whose State plans have been approved.

(iii) In any fiscal year, any funds that remain unallocated after satisfying the requirements of clauses (i) and (ii) shall be reallocated in the following fiscal year according to procedures established pursuant to paragraph (10)(B)(ii).

(7)(A) The value of the benefit received by any recipient under any program for which a grant is received under this subsection may not affect the eligibility or benefit levels for assistance under other Federal or State programs.

(B) Any programs for which a grant is received under this subsection shall be supplementary to the food stamp program carried out under the Food Stamp Act of 1977 (7 U.S.C. 2011 et seq.) and to any other Federal or State program under which foods are distributed to needy families in lieu of food stamps.

(8) For each fiscal year, the Secretary shall collect from each State that receives a grant under this subsection information relating to—

(A) the number and type of recipients served by both Federal and non-Federal benefits under the program for which the grant is received;

(B) the rate of redemption of coupons distributed under the program;

(C) the average amount distributed in coupons to each recipient;

(D) the change in consumption of fresh fruits and vegetables by recipients, if the information is available;

(E) the effects of the program on farmers' markets, if the information is available; and

(F) any other information determined to be necessary by the Secretary.

(9) FUNDING

(A) IN GENERAL

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection such sums as are necessary for each of fiscal years 2004 through 2009.

(ii) MANDATORY FUNDING

Not later than 30 days after May 13, 2002, of the funds of the Commodity Credit Corporation, the Secretary shall make available to carry out this subsection $15,000,000, to remain available until expended.

(B)(i)(I) Each State shall return to the Secretary any funds made available to the State that are unobligated at the end of the fiscal year for which the funds were originally allocated. The unexpended funds shall be returned to the Secretary by February 1st of the following fiscal year.

(II) Notwithstanding any other provision of this subsection, a total of not more than 5 percent of funds made available to a State for any fiscal year may be expended by the State to reimburse expenses incurred for a program assisted under this subsection during the preceding fiscal year.

(ii) The Secretary shall establish procedures to reallocate funds that are returned under clause (i).

(10) For purposes of this subsection:

(A) The term "coupon" means a coupon, voucher, or other negotiable financial instrument by which benefits under this section are transferred.

(B) The term "program" means—

(i) the State farmers' market coupon nutrition program authorized by this subsection (as it existed on September 30, 1991); or

(ii) the farmers' market nutrition program authorized by this subsection.

(C) The term "recipient" means a person or household, as determined by the State, who is chosen by a State to receive benefits under this subsection, or who is on a waiting list to receive such benefits.

(D) The term "State agency" has the meaning provided in subsection (b)(13) of this section, except that the term also includes the agriculture department of each State and any other agency approved by the chief executive officer of the State.

(n) Disqualification of vendors who are disqualified under food stamp program

(1) In general

The Secretary shall issue regulations providing criteria for the disqualification under this section of an approved vendor that is disqualified from accepting benefits under the food stamp program established under the Food Stamp Act of 1977 (7 U.S.C. 2011 et seq.).

(2) Terms

A disqualification under paragraph (1)—

(A) shall be for the same period as the disqualification from the program referred to in paragraph (1);

(B) may begin at a later date than the disqualification from the program referred to in paragraph (1); and

(C) shall not be subject to judicial or administrative review.

(o) Disqualification of vendors convicted of trafficking or illegal sales

(1) In general

Except as provided in paragraph (4), a State agency shall permanently disqualify from participation in the program authorized under this section a vendor convicted of—

(A) trafficking in food instruments (including any voucher, draft, check, or access device (including an electronic benefit transfer card or personal identification number) issued in lieu of a food instrument under this section); or

(B) selling firearms, ammunition, explosives, or controlled substances (as defined in section 802 of Title 21) in exchange for food instruments (including any item described in subparagraph (A) issued in lieu of a food instrument under this section).

(2) Notice of disqualification

The State agency shall—

(A) provide the vendor with notification of the disqualification; and

(B) make the disqualification effective on the date of receipt of the notice of disqualification.

(3) Prohibition of receipt of lost revenues

A vendor shall not be entitled to receive any compensation for revenues lost as a result of disqualification under this subsection.

(4) Exceptions in lieu of disqualification

(A) In general

A State agency may permit a vendor that, but for this paragraph, would be disqualified under paragraph (1), to continue to participate in the program if the State agency determines, in its sole discretion according to criteria established by the Secretary, that—

(i) disqualification of the vendor would cause hardship to participants in the program authorized under this section; or

(ii)(I) the vendor had, at the time of the violation under paragraph (1), an effective policy and program in effect to prevent violations described in paragraph (1); and

(II) the ownership of the vendor was not aware of, did not approve of, and was not involved in the conduct of the violation.

(B) Civil penalty

If a State agency under subparagraph (A) permits a vendor to continue to participate in the program in lieu of disqualification, the State agency shall assess the vendor a

civil penalty in an amount determined by the State agency, in accordance with criteria established by the Secretary, except that—

(i) the amount of the civil penalty shall not exceed $10,000 for each violation; and

(ii) the amount of civil penalties imposed for violations investigated as part of a single investigation may not exceed $40,000.

(p) Criminal forfeiture

(1) In general

Notwithstanding any provision of State law and in addition to any other penalty authorized by law, a court may order a person that is convicted of a violation of a provision of law described in paragraph (2), with respect to food instruments (including any item described in subsection (o)(1)(A) of this section issued in lieu of a food instrument under this section), funds, assets, or property that have a value of $100 or more and that are the subject of a grant or other form of assistance under this section, to forfeit to the United States all property described in paragraph (3).

(2) Applicable laws

A provision of law described in this paragraph is—

(A) section 1760(g) of this title; and

(B) any other Federal law imposing a penalty for embezzlement, willful misapplication, stealing, obtaining by fraud, or trafficking in food instruments (including any item described in subsection (o)(1)(A) of this section issued in lieu of a food instrument under this section), funds, assets, or property.

(3) Property subject to forfeiture

The following property shall be subject to forfeiture under paragraph (1):

(A) All property, real and personal, used in a transaction or attempted transaction, to commit, or to facilitate the commission of, a violation described in paragraph (1).

(B) All property, real and personal, constituting, derived from, or traceable to any proceeds a person obtained directly or indirectly as a result of a violation described in paragraph (1).

(4) Procedures; interest of owner

Except as provided in paragraph (5), all property subject to forfeiture under this subsection, any seizure or disposition of the property, and any proceeding relating to the forfeiture, seizure, or disposition shall be subject to section 853 of Title 21, other than subsection (d) of that section.

(5) Proceeds

The proceeds from any sale of forfeited property and any amounts forfeited under this subsection shall be used—

(A) first, to reimburse the Department of Justice, the Department of the Treasury, and the United States Postal Service for the costs incurred by the Departments or Service to initiate and complete the forfeiture proceeding;

(B) second, to reimburse the Office of Inspector General of the Department of Agriculture for any costs incurred by the Office in the law enforcement effort resulting in the forfeiture;

(C) third, to reimburse any Federal, State, or local law enforcement agency for any costs incurred in the law enforcement effort resulting in the forfeiture; and

(D) fourth, by the State agency to carry out approval, reauthorization, and compliance investigations of vendors.

(q) Provision of technical assistance to Secretary of Defense

The Secretary of Agriculture shall provide technical assistance to the Secretary of Defense, if so requested by the Secretary of Defense, for the purpose of carrying out the overseas special supplemental food program established under section 1060a(a) of Title 10.

42 U.S.C. § 2000e–2(k)
Civil Rights Act of 1964, Public Law 88–352, sec. 703(k)
Employment discrimination on the basis of unlawful controlled substance use with the intent to discriminate on the basis of race, color, sex, or national origin

Chapter 21. Civil Rights

§ 2000e–2. Unlawful employment practices [1]

* * * * * * *

(k) Burden of proof in disparate impact cases

(1)(A) An unlawful employment practice based on disparate impact is established under this subchapter only if—

(i) a complaining party demonstrates that a respondent uses a particular employment practice that causes a disparate impact on the basis of race, color, religion, sex, or national origin and the respondent fails to demonstrate that the challenged practice is job related for the position in question and consistent with business necessity; or

(ii) the complaining party makes the demonstration described in subparagraph (C) with respect to an alternative employment practice and the respondent refuses to adopt such alternative employment practice.

(B)(i) With respect to demonstrating that a particular employment practice causes a disparate impact as described in subparagraph (A)(i), the complaining party shall demonstrate that each particular challenged employment practice causes a disparate impact, except that if the complaining party can demonstrate to the court that the elements of a respondent's decisionmaking process are not capable of separation for analysis, the decisionmaking process may be analyzed as one employment practice.

(ii) If the respondent demonstrates that a specific employment practice does not cause the disparate impact, the respondent shall not be required to demonstrate that such practice is required by business necessity.

(C) The demonstration referred to by subparagraph (A)(ii) shall be in accordance with the law as it existed on June 4, 1989, with respect to the concept of ''alternative employment practice''.

(2) A demonstration that an employment practice is required by business necessity may not be used as a defense against a claim of intentional discrimination under this subchapter.

(3) Notwithstanding any other provision of this subchapter, a rule barring the employment of an individual who currently and

[1] Public Law 88–352, Title VII, § 703, July 2, 1964, 78 Stat. 255, as added by Public Law 102–166, Title I, § 105(a), Nov. 21, 1991, 105 Stat. 1074–1076.

knowingly uses or possesses a controlled substance, as defined in schedules I and II of section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6)), other than the use or possession of a drug taken under the supervision of a licensed health care professional, or any other use or possession authorized by the Controlled Substances Act or any other provision of Federal law, shall be considered an unlawful employment practice under this subchapter only if such rule is adopted or applied with an intent to discriminate because of race, color, religion, sex, or national origin.

* * * * * * *

42 U.S.C. § 2473c
Civil Space Employee Testing Act, Public Law 85–568, sec. 203
National Aeronautics and Space Administration drug testing

Chapter 26. National Space Program

§ 2473c. Drug and alcohol testing [1]

(a) Short title

This section may be cited as the "Civil Space Employee Testing Act of 1991".

(b) Findings

The Congress finds that—

(1) alcohol abuse and illegal drug use pose significant dangers to the safety and welfare of the Nation;

(2) the success of the United States civil space program is contingent upon the safe and successful development and deployment of the many varied components of that program;

(3) the greatest efforts must be expended to eliminate the abuse of alcohol and use of illegal drugs, whether on duty or off duty, by those individuals who are involved in the positions affecting safety, security, and national security;

(4) the use of alcohol and illegal drugs has been demonstrated to adversely affect the performance of individuals, and has been proven to have been a critical factor in accidents in the workplace;

(5) the testing of uniformed personnel of the Armed Forces has shown that the most effective deterrent to abuse of alcohol and use of illegal drugs is increased testing, including random testing;

(6) adequate safeguards can be implemented to ensure that testing for abuse of alcohol or use of illegal drugs is performed in a manner which protects an individual's right of privacy, ensures that no individual is harassed by being treated differently from other individuals, and ensures that no individual's reputation or career development is unduly threatened or harmed; and

(7) rehabilitation is a critical component of any testing program for abuse of alcohol or use of illegal drugs, and should be made available to individuals, as appropriate.

(c) Testing program

(1) The Administrator shall establish a program applicable to employees of the National Aeronautics and Space Administration

[1] Public Law 102–195, § 21, Dec. 9, 1991, 105 Stat. 1616.

whose duties include responsibility for safety-sensitive, security, or national security functions. Such program shall provide for preemployment, reasonable suspicion, random, and post-accident testing for use, in violation of applicable law or Federal regulation, of alcohol or a controlled substance. The Administrator may also prescribe regulations, as the Administrator considers appropriate in the interest of safety, security, and national security, for the conduct of periodic recurring testing of such employees for such use in violation of applicable law or Federal regulation.

(2) The Administrator shall, in the interest of safety, security, and national security, prescribe regulations within 18 months after December 9, 1991. Such regulations shall establish a program which requires National Aeronautics and Space Administration contractors to conduct preemployment, reasonable suspicion, random, and post-accident testing of contractor employees responsible for safety-sensitive, security, or national security functions (as determined by the Administrator) for use, in violation of applicable law or Federal regulation, of alcohol or a controlled substance. The Administrator may also prescribe regulations, as the Administrator considers appropriate in the interest of safety, security, and national security, for the conduct of periodic recurring testing of such employees for such use in violation of applicable law or Federal regulation.

(3) In prescribing regulations under the programs required by this subsection, the Administrator shall require, as the Administrator considers appropriate, the suspension, disqualification, or dismissal of any employee to which paragraph (1) or (2) applies, in accordance with the provisions of this section, in any instance where a test conducted and confirmed under this section indicates that such employee has used, in violation of applicable law or Federal regulation, alcohol or a controlled substance.

(d) Prohibition on service

(1) No individual who is determined by the Administrator under this section to have used, in violation of applicable law or Federal regulation, alcohol or a controlled substance after December 9, 1991, shall serve as a National Aeronautics and Space Administration employee with responsibility for safety-sensitive, security, or national security functions (as determined by the Administrator), or as a National Aeronautics and Space Administration contractor employee with such responsibility, unless such individual has completed a program of rehabilitation described in subsection (e) of this section.

(2) Any such individual determined by the Administrator under this section to have used, in violation of applicable law or Federal regulation, alcohol or a controlled substance after December 9, 1991, who—

(A) engaged in such use while on duty;

(B) prior to such use had undertaken or completed a rehabilitation program described in subsection (e) of this section;

(C) following such determination refuses to undertake such a rehabilitation program; or

(D) following such determination fails to complete such a rehabilitation program,

shall not be permitted to perform the duties which such individual performed prior to the date of such determination.

(e) Program for rehabilitation

(1) The Administrator shall prescribe regulations setting forth requirements for rehabilitation programs which at a minimum provide for the identification and opportunity for treatment of employees referred to in subsection (c) of this section in need of assistance in resolving problems with the use, in violation of applicable law or Federal regulation, of alcohol or a controlled substance. Each contractor is encouraged to make such a program available to all of its employees in addition to those employees referred to in subsection (c)(2) of this section. The Administrator shall determine the circumstances under which such employees shall be required to participate in such a program. Nothing in this subsection shall preclude any National Aeronautics and Space Administration contractor from establishing a program under this subsection in cooperation with any other such contractor.

(2) The Administrator shall establish and maintain a rehabilitation program which at a minimum provides for the identification and opportunity for treatment of those employees of the National Aeronautics and Space Administration whose duties include responsibility for safety-sensitive, security, or national security functions who are in need of assistance in resolving problems with the use of alcohol or controlled substances.

(f) Procedures for testing

In establishing the programs required under subsection (c) of this section, the Administrator shall develop requirements which shall—

(1) promote, to the maximum extent practicable, individual privacy in the collection of specimen samples;

(2) with respect to laboratories and testing procedures for controlled substances, incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any subsequent amendments thereto, including mandatory guidelines which—

(A) establish comprehensive standards for all aspects of laboratory controlled substances testing and laboratory procedures to be applied in carrying out this section, including standards which require the use of the best available technology for ensuring the full reliability and accuracy of controlled substances tests and strict procedures governing the chain of custody of specimen samples collected for controlled substances testing;

(B) establish the minimum list of controlled substances for which individuals may be tested; and

(C) establish appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform controlled substances testing in carrying out this section;

(3) require that all laboratories involved in the controlled substances testing of any individual under this section shall

have the capability and facility, at such laboratory, of performing screening and confirmation tests;

(4) provide that all tests which indicate the use, in violation of applicable law or Federal regulation, of alcohol or a controlled substance by any individual shall be confirmed by a scientifically recognized method of testing capable of providing quantitative data regarding alcohol or a controlled substance;

(5) provide that each specimen sample be subdivided, secured, and labelled in the presence of the tested individual and that a portion thereof be retained in a secure manner to prevent the possibility of tampering, so that in the event the individual's confirmation test results are positive the individual has an opportunity to have the retained portion assayed by a confirmation test done independently at a second certified laboratory if the individual requests the independent test within 3 days after being advised of the results of the initial confirmation test;

(6) ensure appropriate safeguards for testing to detect and quantify alcohol in breath and body fluid samples, including urine and blood, through the development of regulations as may be necessary and in consultation with the Department of Health and Human Services;

(7) provide for the confidentiality of test results and medical information of employees; and

(8) ensure that employees are selected for tests by nondiscriminatory and impartial methods, so that no employee is harassed by being treated differently from other employees in similar circumstances.

(g) Effect on other laws and regulations

(1) No State or local government shall adopt or have in effect any law, rule, regulation, ordinance, standard, or order that is inconsistent with the regulations promulgated under this section.

(2) Nothing in this section shall be construed to restrict the discretion of the Administrator to continue in force, amend, or further supplement any regulations issued before December 9, 1991, that govern the use of alcohol and controlled substances by National Aeronautics and Space Administration employees with responsibility for safety-sensitive, security, and national security functions (as determined by the Administrator), or by National Aeronautics and Space Administration contractor employees with such responsibility.

(h) "Controlled substance" defined

For the purposes of this section, the term "controlled substance" means any substance under section 802(6) of Title 21 specified by the Administrator.

42 U.S.C. §§ 3401, 3402
Narcotic Addict Rehabilitation Act, Public Law 89–793, secs. 2, 3
Assistance to State narcotic addict treatment, care, and rehabilitation facilities

Chapter 42. Narcotic Addict Rehabilitation

§ 3401. Declaration of policy [1]

It is the policy of the Congress that certain persons charged with or convicted of violating Federal criminal laws, who are determined to be addicted to narcotic drugs, and likely to be rehabilitated through treatment, should, in lieu of prosecution or sentencing, be civilly committed for confinement and treatment designed to effect their restoration to health, and return to society as useful members.

It is the further policy of the Congress that certain persons addicted to narcotic drugs who are not charged with the commission of any offense should be afforded the opportunity, through civil commitment, for treatment, in order that they may be rehabilitated and returned to society as useful members and in order that society may be protected more effectively from crime and delinquency which result from narcotic addiction.

§ 3402. State facilities and personnel for care and treatment; encouragement of adequate provision; benefit of experience of Surgeon General and Attorney General [2]

The Surgeon General and the Attorney General are authorized to give representatives of States and local subdivisions thereof the benefit of their experience in the care, treatment, and rehabilitation of narcotic addicts so that each State may be encouraged to provide adequate facilities and personnel for the care and treatment of narcotic addicts in its jurisdiction.

[1] Public Law 89–793, § 2, Nov. 8, 1966, 80 Stat. 1438.
[2] Public Law 89–793, Title VI, § 602, Nov. 8, 1966, 80 Stat. 1450.

42 U.S.C. § 3602
Fair Housing Act, Public Law 90–284, sec. 802
Handicap for purposes of the Act does not include illicit use or addiction to controlled substances

Chapter 45. Fair Housing

§ 3602. Definitions [1]

As used in this subchapter—

(a) "Secretary" means the Secretary of Housing and Urban Development.

(b) "Dwelling" means any building, structure, or portion thereof which is occupied as, or designed or intended for occupancy as, a residence by one or more families, and any vacant land which is offered for sale or lease for the construction or location thereon of any such building, structure, or portion thereof.

(c) "Family" includes a single individual.

(d) "Person" includes one or more individuals, corporations, partnerships, associations, labor organizations, legal representatives, mutual companies, joint-stock companies, trusts, unincorporated organizations, trustees, trustees in cases under Title 11, receivers, and fiduciaries.

(e) "To rent" includes to lease, to sublease, to let and otherwise to grant for a consideration the right to occupy premises not owned by the occupant.

(f) "Discriminatory housing practice" means an act that is unlawful under section 3604, 3605, 3606, or 3617 of this title.

(g) "State" means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, or any of the territories and possessions of the United States.

(h) "Handicap" means, with respect to a person—

(1) a physical or mental impairment which substantially limits one or more of such person's major life activities,

(2) a record of having such an impairment, or

(3) being regarded as having such an impairment,

but such term does not include current, illegal use of or addiction to a controlled substance (as defined in section 802 of Title 21).

(i) "Aggrieved person" includes any person who—

(1) claims to have been injured by a discriminatory housing practice; or

(2) believes that such person will be injured by a discriminatory housing practice that is about to occur.

(j) "Complainant" means the person (including the Secretary) who files a complaint under section 3610 of this title.

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[1] Public Law 90–284, Title VIII, § 802, Apr. 11, 1968, 82 Stat. 81; Public Law 95–598, Title III, § 331, Nov. 6, 1978, 92 Stat. 2679; Public Law 100–430, § 5, Sept. 13, 1988, 102 Stat. 1619.

(k) "Familial status" means one or more individuals (who have not attained the age of 18 years) being domiciled with—

(1) a parent or another person having legal custody of such individual or individuals; or

(2) the designee of such parent or other person having such custody, with the written permission of such parent or other person.

The protections afforded against discrimination on the basis of familial status shall apply to any person who is pregnant or is in the process of securing legal custody of any individual who has not attained the age of 18 years.

(l) "Conciliation" means the attempted resolution of issues raised by a complaint, or by the investigation of such complaint, through informal negotiations involving the aggrieved person, the respondent, and the Secretary.

(m) "Conciliation agreement" means a written agreement setting forth the resolution of the issues in conciliation.

(n) "Respondent" means—

(1) the person or other entity accused in a complaint of an unfair housing practice; and

(2) any other person or entity identified in the course of investigation and notified as required with respect to respondents so identified under section 3610(a) of this title.

(o) "Prevailing party" has the same meaning as such term has in section 1988 of this title.

42 U.S.C. § 3607
Fair Housing Act, Public Law 90–284, sec. 807
Act's prohibitions do not apply to actions taken against those convicted of controlled substances offenses

§ 3607. Religious organization or private club exemption [1]

(a) Nothing in this subchapter shall prohibit a religious organization, association, or society, or any nonprofit institution or organization operated, supervised or controlled by or in conjunction with a religious organization, association, or society, from limiting the sale, rental or occupancy of dwellings which it owns or operates for other than a commercial purpose to persons of the same religion, or from giving preference to such persons, unless membership in such religion is restricted on account of race, color, or national origin. Nor shall anything in this subchapter prohibit a private club not in fact open to the public, which as an incident to its primary purpose or purposes provides lodgings which it owns or operates for other than a commercial purpose, from limiting the rental or occupancy of such lodgings to its members or from giving preference to its members.

(b)(1) Nothing in this subchapter limits the applicability of any reasonable local, State, or Federal restrictions regarding the maximum number of occupants permitted to occupy a dwelling. Nor does any provision in this subchapter regarding familial status apply with respect to housing for older persons.

(2) As used in this section, "housing for older persons" means housing—

(A) provided under any State or Federal program that the Secretary determines is specifically designed and operated to assist elderly persons (as defined in the State or Federal program); or

(B) intended for, and solely occupied by, persons 62 years of age or older; or

(C) intended and operated for occupancy by persons 55 years of age or older, and—

(i) at least 80 percent of the occupied units are occupied by at least one person who is 55 years of age or older;

(ii) the housing facility or community publishes and adheres to policies and procedures that demonstrate the intent required under this subparagraph; and

(iii) the housing facility or community complies with rules issued by the Secretary for verification of occupancy, which shall—

(I) provide for verification by reliable surveys and affidavits; and

[1] Public Law 90–284, Title VIII, § 807, Apr. 11, 1968, 82 Stat. 84; Public Law 100–430, § 6(d), Sept. 13, 1988, 102 Stat. 1622; Public Law 104–76, §§ 2, 3, Dec. 28, 1995, 109 Stat. 787.

(II) include examples of the types of policies and procedures relevant to a determination of compliance with the requirement of clause (ii). Such surveys and affidavits shall be admissible in administrative and judicial proceedings for the purposes of such verification.

(3) Housing shall not fail to meet the requirements for housing for older persons by reason of:

(A) persons residing in such housing as of September 13, 1988, who do not meet the age requirements of subsections [2] (2)(B) or (C): Provided, That new occupants of such housing meet the age requirements of subsections [3] (2)(B) or (C); or

(B) unoccupied units: Provided, That such units are reserved for occupancy by persons who meet the age requirements of subsections [4] (2)(B) or (C).

(4) Nothing in this subchapter prohibits conduct against a person because such person has been convicted by any court of competent jurisdiction of the illegal manufacture or distribution of a controlled substance as defined in section 802 of Title 21.

(5)(A) A person shall not be held personally liable for monetary damages for a violation of this subchapter if such person reasonably relied, in good faith, on the application of the exemption under this subsection relating to housing for older persons.

(B) For the purposes of this paragraph, a person may only show good faith reliance on the application of the exemption by showing that—

(i) such person has no actual knowledge that the facility or community is not, or will not be, eligible for such exemption; and

(ii) the facility or community has stated formally, in writing, that the facility or community complies with the requirements for such exemption.

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[2] So in original. Probably should be "paragraph".
[3] So in original. Probably should be "paragraph".
[4] So in original. Probably should be "paragraph".

42 U.S.C. § 3732

Omnibus Crime Control and Safe Streets Act, Public Law 90–351, sec. 302

Bureau of Justice Statistics may provide for development and enhancement of State information systems relating to data about drug offenses and drug dependent offenders

Chapter 46. Justice System Improvement

§ 3732. Bureau of Justice Statistics [1]

(a) Establishment

There is established within the Department of Justice, under the general authority of the Attorney General, a Bureau of Justice Statistics (hereinafter referred to in this subchapter as "Bureau").

(b) Appointment of Director; experience; authority; restrictions

The Bureau shall be headed by a Director appointed by the President, by and with the advice and consent of the Senate. The Director shall have had experience in statistical programs. The Director shall have final authority for all grants, cooperative agreements, and contracts awarded by the Bureau. The Director shall report to the Attorney General through the Assistant Attorney General. The Director shall not engage in any other employment than that of serving as Director; nor shall the Director hold any office in, or act in any capacity for, any organization, agency, or institution with which the Bureau makes any contract or other arrangement under this Act.

(c) Duties and functions of Bureau

The Bureau is authorized to—

(1) make grants to, or enter into cooperative agreements or contracts with public agencies, institutions of higher education, private organizations, or private individuals for purposes related to this subchapter; grants shall be made subject to continuing compliance with standards for gathering justice statistics set forth in rules and regulations promulgated by the Director;

(2) collect and analyze information concerning criminal victimization, including crimes against the elderly, and civil disputes;

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[1] Public Law 90–351, Title I, § 302, as added Public Law 96–157, § 2, Dec. 27, 1979, 93 Stat. 1176, and amended by Public Law 98–473, Title II, § 605(b), Oct. 12, 1984, 98 Stat. 2079; Public Law 100–690, Title VI, § 6092(a), Nov. 18, 1988, 102 Stat. 4339; Public Law 103–322, Title XXXIII, § 330001(h)(2), Sept. 13, 1994, 108 Stat. 2139.

(3) collect and analyze data that will serve as a continuous and comparable national social indication of the prevalence, incidence, rates, extent, distribution, and attributes of crime, juvenile delinquency, civil disputes, and other statistical factors related to crime, civil disputes, and juvenile delinquency, in support of national, State, and local justice policy and decision-making;

(4) collect and analyze statistical information, concerning the operations of the criminal justice system at the Federal, State, and local levels;

(5) collect and analyze statistical information concerning the prevalence, incidence, rates, extent, distribution, and attributes of crime, and juvenile delinquency, at the Federal, State, and local levels;

(6) analyze the correlates of crime, civil disputes and juvenile delinquency, by the use of statistical information, about criminal and civil justice systems at the Federal, State, and local levels, and about the extent, distribution and attributes of crime, and juvenile delinquency, in the Nation and at the Federal, State, and local levels;

(7) compile, collate, analyze, publish, and disseminate uniform national statistics concerning all aspects of criminal justice and related aspects of civil justice, crime, including crimes against the elderly, juvenile delinquency, criminal offenders, juvenile delinquents, and civil disputes in the various States;

(8) recommend national standards for justice statistics and for insuring the reliability and validity of justice statistics supplied pursuant to this chapter;

(9) maintain liaison with the judicial branches of the Federal and State Governments in matters relating to justice statistics, and cooperate with the judicial branch in assuring as much uniformity as feasible in statistical systems of the executive and judicial branches;

(10) provide information to the President, the Congress, the judiciary, State and local governments, and the general public on justice statistics;

(11) establish or assist in the establishment of a system to provide State and local governments with access to Federal informational resources useful in the planning, implementation, and evaluation of programs under this Act;

(12) conduct or support research relating to methods of gathering or analyzing justice statistics;

(13) provide for the development of justice information systems programs and assistance to the States and units of local government relating to collection, analysis, or dissemination of justice statistics;

(14) develop and maintain a data processing capability to support the collection, aggregation, analysis and dissemination of information on the incidence of crime and the operation of the criminal justice system;

(15) collect, analyze and disseminate comprehensive Federal justice transaction statistics (including statistics on issues of Federal justice interest such as public fraud and high technology crime) and to provide technical assistance to and work

jointly with other Federal agencies to improve the availability and quality of Federal justice data;

(16) provide for the collection, compilation, analysis, publication and dissemination of information and statistics about the prevalence, incidence, rates, extent, distribution and attributes of drug offenses, drug related offenses and drug dependent offenders and further provide for the establishment of a national clearinghouse to maintain and update a comprehensive and timely data base on all criminal justice aspects of the drug crisis and to disseminate such information;

(17) provide for the collection, analysis, dissemination and publication of statistics on the condition and progress of drug control activities at the Federal, State and local levels with particular attention to programs and intervention efforts demonstrated to be of value in the overall national anti-drug strategy and to provide for the establishment of a national clearinghouse for the gathering of data generated by Federal, State, and local criminal justice agencies on their drug enforcement activities;

(18) provide for the development and enhancement of State and local criminal justice information systems, and the standardization of data reporting relating to the collection, analysis or dissemination of data and statistics about drug offenses, drug related offenses, or drug dependent offenders;

(19) provide for research and improvements in the accuracy, completeness, and inclusiveness of criminal history record information, information systems, arrest warrant, and stolen vehicle record information and information systems and support research concerning the accuracy, completeness, and inclusiveness of other criminal justice record information;

(20) maintain liaison with State and local governments and governments of other nations concerning justice statistics;

(21) cooperate in and participate with national and international organizations in the development of uniform justice statistics;

(22) ensure conformance with security and privacy requirement of section 3789g of this title and identify, analyze, and participate in the development and implementation of privacy, security and information policies which impact on Federal and State criminal justice operations and related statistical activities; and

(23) exercise the powers and functions set out in subchapter VIII of this chapter.

(d) Justice statistical collection, analysis, and dissemination

To insure that all justice statistical collection, analysis, and dissemination is carried out in a coordinated manner, the Director is authorized to—

(1) utilize, with their consent, the services, equipment, records, personnel, information, and facilities of other Federal, State, local, and private agencies and instrumentalities with or without reimbursement therefor, and to enter into agreements with such agencies and instrumentalities for purposes of data collection and analysis;

(2) confer and cooperate with State, municipal, and other local agencies;

(3) request such information, data, and reports from any Federal agency as may be required to carry out the purposes of this chapter;

(4) seek the cooperation of the judicial branch of the Federal Government in gathering data from criminal justice records; and

(5) encourage replication, coordination and sharing among justice agencies regarding information systems, information policy, and data.

(e) Furnishing of information, data, or reports by Federal agencies

Federal agencies requested to furnish information, data, or reports pursuant to subsection (d)(3) of this section shall provide such information to the Bureau as is required to carry out the purposes of this section.

(f) Consultation with representatives of State and local government and judiciary

In recommending standards for gathering justice statistics under this section, the Director shall consult with representatives of State and local government, including, where appropriate, representatives of the judiciary.

42 U.S.C. §§ 3751–3759

Omnibus Crime Control and Safe Streets Act, Public Law 90–351, secs. 501–509

Drug control and system improvement grant program

§ 3751. Description of drug control and system improvement grant program [1]

(a) Purpose of program

It is the purpose of this part to assist States and units of local government in carrying out specific programs which offer a high probability of improving the functioning of the criminal justice system, with special emphasis on a nationwide and multilevel drug control strategy by developing programs and projects to assist multijurisdictional and multi-State organizations in the drug control problem and to support national drug control priorities.

(b) Grants to States and units of local government; purposes of grants

The Director of the Bureau of Justice Assistance (hereafter in this subchapter referred to as the "Director") is authorized to make grants to States, for the use by States and units of local government in the States, for the purpose of enforcing State and local laws that establish offenses similar to offenses established in the Controlled Substances Act (21 U.S.C. 801 et seq.) and to improve the functioning of the criminal justice system with emphasis on violent crime and serious offenders. Such grants shall provide additional personnel, equipment, training, technical assistance, and information systems for the more widespread apprehension, prosecution, adjudication, and detention and rehabilitation of persons who violate these laws, and to assist the victims of such crimes (other than compensation), including—

(1) demand reduction education programs in which law enforcement officers participate;

(2) multijurisdictional task force programs that integrate Federal, State, and local drug law enforcement agencies and prosecutors for the purpose of enhancing interagency coordination, intelligence, and facilitating multijurisdictional investigations;

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[1] Public Law 90–351, Title I, § 501, as added and amended Public Law 100–690, Title V, § 5104, Title VI, § 6091(a), Nov. 18, 1988, 102 Stat. 4301, 4329; Public Law 101–647, Title VI, § 601(b), Nov. 29, 1990, 104 Stat. 4823; Public Law 103–322, Title X, § 100003, Title XIV, § 140004, Title XV, § 150003, Title XXI, § 210302(a), Sept. 13, 1994, 108 Stat. 1996, 2032, 2035, 2065; Public Law 104–132, Title VIII, § 822(a), Apr. 24, 1996, 110 Stat. 1317; Public Law 106–177, Title I, § 103, Mar. 10, 2000, 114 Stat. 35; Public Law 106–310, Div. B, Title XXXVI, § 3621(b), Oct. 17, 2000, 114 Stat. 1231; Public Law 106–561, § 2(a), Dec. 21, 2000, 114 Stat. 2787.

(3) programs designed to target the domestic sources of controlled and illegal substances, such as precursor chemicals, diverted pharmaceuticals, clandestine laboratories, and cannabis cultivations and to remove any hazardous substance or pollutant or contaminant associated with the illegal manufacture of amphetamine or methamphetamine;

(4) providing community and neighborhood programs that assist citizens in preventing and controlling crime, including special programs that address the problems of crimes committed against the elderly and special programs for rural jurisdictions;

(5) disrupting illicit commerce in stolen goods and property;

(6) improving the investigation and prosecution of white-collar crime, organized crime, public corruption crimes, and fraud against the government with priority attention to cases involving drug-related official corruption;

(7)(A) improving the operational effectiveness of law enforcement through the use of crime analysis techniques, street sales enforcement, schoolyard violator programs, gang-related and low-income housing drug control programs;

(B) developing and implementing antiterrorism plans for deep draft ports, international airports, and other important facilities;

(8) career criminal prosecution programs including the development of proposed model drug control legislation;

(9) financial investigative programs that target the identification of money laundering operations and assets obtained through illegal drug trafficking, including the development of proposed model legislation, financial investigative training, and financial information sharing systems;

(10) improving the operational effectiveness of the court process, by expanding prosecutorial, defender and judicial resources, and implementing court delay reduction programs;

(11) programs designed to provide additional public correctional resources and improve the corrections system, including treatment in prisons and jails, intensive supervision programs, and long-range corrections and sentencing strategies;

(12) providing prison industry projects designed to place inmates in a realistic working and training environment which will enable them to acquire marketable skills and to make financial payments for restitution to their victims, for support of their own families, and for support of themselves in the institution;

(13) providing programs which identify and meet the treatment needs of adult and juvenile drug-dependent and alcohol-dependent offenders;

(14) developing and implementing programs which provide assistance to jurors and witnesses, and assistance (other than compensation) to victims of crimes;

(15)(A) developing programs to improve drug control technology, such as pretrial drug testing programs, programs which provide for the identification, assessment, referral to

treatment, case management and monitoring of drug dependent offenders, enhancement of State and local forensic laboratories, and

(B) criminal and justice information systems to assist law enforcement, prosecution, courts, and corrections organization (including automated fingerprint identification systems);

(16) innovative programs that demonstrate new and different approaches to enforcement, prosecution, and adjudication of drug offenses and other serious crimes;

(17) addressing the problems of drug trafficking and the illegal manufacture of controlled substances in public housing;

(18) improving the criminal and juvenile justice system's response to domestic and family violence, including spouse abuse, child abuse, and abuse of the elderly;

(19) drug control evaluation programs which the State and local units of government may utilize to evaluate programs and projects directed at State drug control activities;

(20) providing alternatives to prevent detention, jail, and prison for persons who pose no danger to the community;

(21) programs of which the primary goal is to strengthen urban enforcement and prosecution efforts targeted at street drug sales;

(22) programs for the prosecution of driving while intoxicated charges and the enforcement of other laws relating to alcohol use and the operation of motor vehicles;

(23) programs that address the need for effective bindover systems for the prosecution of violent 16-and 17-year-old juveniles in courts with jurisdiction over adults for the crimes of—

(A) murder in the first degree;

(B) murder in the second degree;

(C) attempted murder;

(D) armed robbery when armed with a firearm;

(E) aggravated battery or assault when armed with a firearm;

(F) criminal sexual penetration when armed with a firearm; and

(G) drive-by shootings as described in section 36 of Title 18;

(24) law enforcement and prevention programs relating to gangs, or to youth who are involved or at risk of involvement in gangs;

(25) developing or improving in a forensic laboratory a capability to analyze deoxyribonucleic acid (hereinafter in this chapter referred to as "DNA") for identification purposes;

(26) to develop and implement antiterrorism training programs and to procure equipment for use by local law enforcement authorities;

(27)[2] enforcing child abuse and neglect laws, including laws protecting against child sexual abuse, and promoting programs designed to prevent child abuse and neglect; and[3]

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[2] So in original. Two paragraphs (27) have been enacted. This paragraph (27) and paragraph (28) were enacted by Public Law 106–177.

[3] So in original. The word "and" probably should be deleted.

(28) establishing or supporting cooperative programs between law enforcement and media organizations, to collect, record, retain, and disseminate information useful in the identification and apprehension of suspected criminal offenders.[4]

(27)[5] improving the quality, timeliness, and credibility of forensic science services for criminal justice purposes.

(c) Program evaluation component; waiver

Each program funded under this section shall contain an evaluation component, developed pursuant to guidelines established by the National Institute of Justice, in consultation with the Bureau of Justice Assistance. The Director of the Bureau of Justice Assistance may waive this requirement when in the opinion of the Director—

(1) the program is not of sufficient size to justify a full evaluation report; or

(2) the program is designed primarily to provide material resources and supplies, such as laboratory equipment, that would not justify a full evaluation report.

§ 3752. Eligibility[6]

The Bureau is authorized to make financial assistance under this part available to a State to enable it to carry out all or a substantial part of a program or project submitted and approved in accordance with the provisions of this part.

§ 3753. State applications[7]

(a) To request a grant under this part, the chief executive officer of a State shall submit an application within 60 days after the Bureau has promulgated regulations under this section, and for each subsequent year, within 60 days after the date that appropriations for this subchapter are enacted, in such form as the Director may require. Such application shall include the following:

(1) A statewide strategy for drug and violent crime control programs which improve the functioning of the criminal justice system, with an emphasis on drug trafficking, violent crime, and serious offenders. The strategy shall be prepared after consultation with State and local officials with emphasis on those whose duty it is to enforce drug and criminal laws and direct the administration of justice and shall contain—

(A) a definition and analysis of the drug and violent crime problem in the State, and an analysis of the problems in each of the counties and municipalities with major drug and violent crime problems;

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[4] So in original. The period should probably be changed to "; and".

[5] So in original. Two paragraphs (27) have been enacted. This paragraph (27) was enacted by Public Law 106–561. Probably should be "(29)".

[6] Public Law 90–351, Title I, § 502, as added Public Law 100–690, Title VI, § 6091(a), Nov. 18, 1988, 102 Stat. 4331.

[7] Public Law 90–351, Title I, § 503, as added Public Law 100–690, Title VI, § 6091(a), Nov. 18, 1988, 102 Stat. 4331, and amended by Public Law 101–649, Title V, § 507(a), Nov. 29, 1990, 104 Stat. 5050; Public Law 102–232, Title III, § 306(a)(6), Dec. 12, 1991, 105 Stat. 1751; Public Law 103–322, Title XXI, § 210302(b), Sept. 13, 1994, 108 Stat. 2065; Public Law 106–546, § 8(a), Dec. 19, 2000, 114 Stat. 2734; Public Law 106–561, § 2(b), Dec. 21, 2000, 114 Stat. 2787; Public Law 107–273, Div. B, Title V, § 5001(a), Nov. 2, 2002, 116 Stat. 1813.

(B) an assessment of the criminal justice resources being devoted to crime and drug control programs at the time of the application;

(C) coordination requirements;

(D) resource needs;

(E) the establishment of statewide priorities for crime and drug control activities and programs;

(F) an analysis of the relationship of the proposed State efforts to the national drug control strategy; and

(G) a plan for coordinating the programs to be funded under this subchapter with other federally funded programs, including State and local drug abuse education, treatment, and prevention programs.

(2) A certification that Federal funds made available under the formula grant of this part will not be used to supplant State or local funds, but will be used to increase the amounts of such funds that would, in the absence of Federal funds, be made available for law enforcement activities.

(3) A certification that funds required to pay the non-Federal portion of the cost of each program and project for which such grant is made shall be in addition to funds that would otherwise be made available for law enforcement by the recipients of grant funds.

(4) An assurance that the State application described in this section, and any amendment to such application, has been submitted for review to the State legislature or its designated body (for purposes of this section, such application or amendment shall be deemed to be reviewed if the State legislature or such body does not review such application or amendment within the 30-day period beginning on the date such application or amendment is so submitted).

(5) An assurance that the State application and any amendment thereto was made public before submission to the Bureau and, to the extent provided under State law or established procedure, an opportunity to comment thereon was provided to citizens and to neighborhood and community groups.

(6) An assurance that following the first fiscal year covered by an application and for each fiscal year thereafter, a performance evaluation and assessment report concerning the activities carried out pursuant to this section will be submitted to the Bureau.

(7) A provision for fund accounting, auditing, monitoring, and such evaluation procedures as may be necessary to keep such records that the Bureau shall prescribe to assure fiscal control, proper management, and efficient disbursement of funds reviewed under this section.

(8) An assurance that the applicant shall maintain such data and information and submit such reports in such form, at such times, and containing such data and information as the Bureau may reasonably require to administer other provisions of this part.

(9) A certification that its programs meet all the requirements of this section, that all the information contained in the

application is correct, that there has been appropriate coordination with affected agencies, and that the applicant will comply with all provisions of this part and all other applicable Federal laws. Such certification shall be made in a form acceptable to the Bureau and shall be executed by the chief executive or such other officer of the applicant qualified under regulations promulgated by the Office.

(10) A certification that the State is undertaking initiatives to reduce, through the enactment of innovative penalties or increasing law enforcement efforts, the demand for controlled substances by holding accountable those who unlawfully possess or use such substances.

(11) An assurance that the State has established a plan under which the State will provide without fee to the Immigration and Naturalization Service, within 30 days of the date of their conviction, notice of conviction of aliens who have been convicted of violating the criminal laws of the State and under which the State will provide the Service with the certified record of such a conviction within 30 days of the date of a request by the Service for such record.

(12) If any part of funds received from a grant made under this subchapter is to be used to develop or improve a DNA analysis capability in a forensic laboratory, a certification that—

(A) DNA analyses performed at such laboratory will satisfy or exceed then current standards for a quality assurance program for DNA analysis, issued by the Director of the Federal Bureau of Investigation under section 14131 of this title;

(B) DNA samples obtained by, and DNA analyses performed at, such laboratory will be accessible only—

(i) to criminal justice agencies for law enforcement identification purposes;

(ii) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;

(iii) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or

(iv) if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes; and

(C) such laboratory, and each analyst performing DNA analyses at such laboratory, will undergo semiannual external proficiency testing by a DNA proficiency testing program meeting the standards issued under section 14131 of this title.

(13) If any part of the amount received from a grant under this subchapter is to be used to improve the quality, timeliness, and credibility of forensic science services for criminal justice purposes, a certification that, as of December 21, 2000, the State, or unit of local government within the State, has an established—

(A) forensic science laboratory or forensic science laboratory system, that—

(i) employs 1 or more full-time scientists—

(I) whose principal duties are the examination of physical evidence for law enforcement agencies in criminal matters; and

(II) who provide testimony with respect to such physical evidence to the criminal justice system;

(ii) employs generally accepted practices and procedures, as established by appropriate accrediting organizations; and

(iii) is accredited by the Laboratory Accreditation Board of the American Society of Crime Laboratory Directors, the National Association of Medical Examiners, or any other nonprofit, professional organization that may be recognized within the forensic science community as competent to award such accreditation, or will use a portion of the grant amount to prepare and apply for such accreditation by not later than 2 years after the date on which a grant is initially awarded under this paragraph; or

(B) medical examiner's office (as defined by the National Association of Medical Examiners) that—

(i) employs generally accepted practices and procedures, as established by appropriate accrediting organizations; and

(ii) is accredited by the Laboratory Accreditation Board of the American Society of Crime Laboratory Directors or the National Association of Medical Examiners, or will use a portion of the grant amount to prepare and apply for such accreditation by not later than 2 years after the date on which a grant is initially awarded under this paragraph.

(b) Within 30 days after November 18, 1988, the Director shall promulgate regulations to implement this section (including the information that must be included and the requirements that the States must meet) in submitting the applications required under this section.

§ 3754. Grant limitations[8]

(a) Cost of identified uses

A grant made under this part may not—

(1) for fiscal year 1991 appropriations be expended for more than 75 per centum; and

(2) for any subsequent fiscal year appropriations be expended for more than 75 per centum;

of the cost of the identified uses for which such grant is received to carry out any purpose specified in section 3751(b) of this title,

[8] Public Law 90–351, Title I, § 504, as added Public Law 100–690, Title VI, § 6091(a), Nov. 18, 1988, 102 Stat. 4333, and amended by Public Law 101–162, Title II, § 211, Nov. 21, 1989, 103 Stat. 1006; Public Law 101–515, Title II, § 207, Nov. 5, 1990, 104 Stat. 2119; Public Law 101–647, Title VI, § 601(a), Nov. 29, 1990, 104 Stat. 4823; Public Law 102–140, Title I, §§ 108, 109, Oct. 28, 1991, 105 Stat. 794; Public Law 103–322, Title XV, § 150009, Sept. 13, 1994, 108 Stat. 2036; Public Law 107–273, Div. A, Title II, § 203(a)(1), Nov. 2, 2002, 116 Stat. 1775.

except that in the case of funds distributed to an Indian tribe which performs law enforcement functions (as determined by the Secretary of the Interior) for any such program or project, the amount of such grant shall be equal to 100 percent of such cost. The non-Federal portion of the expenditures for such uses shall be paid in cash.

(b) Administrative costs

Not more than 10 percent of a grant made to an eligible State under section 3756 of this title may be used for costs incurred to administer such grant.

(c) Participation in State and Local Task Force Program; use of grant

States and units of local government or combinations thereof are authorized to use a grant made under section 3756 of this title for the expenses associated with participation in the State and Local Task Force Program established by the Drug Enforcement Administration.

(d) Conduct of evaluation expenses

States and local units of government are authorized to use a grant made under section 3756 of this title for the expenses associated with conducting the evaluations required under section 3751(c) of this title.

(e) Non-Federal portion costs

The non-Federal portion of the cost of such program or project shall be in cash. State and local units of government may use cash received under the equitable sharing program to cover the non-Federal portion of the costs of programs funded under section 3756 of this title.

(f) Programs already receiving funds

Except for grants awarded to State and local governments for the purpose of participating in multijurisdictional drug task forces[9] victims assistance programs, or multijurisdictional gang task forces, no funds may be awarded under this part to a grant recipient for a program or project for which funds have been awarded under this chapter for 4 years (in the aggregate), including any period occurring before November 18, 1988.

§ 3755. Review of State applications[10]

(a) Financial assistance upon approval of application or amendment

The Bureau shall provide financial assistance to each State applicant under this part to carry out the programs or projects submitted by such applicant upon determining that—

(1) the application or amendment thereto is consistent with the requirements of this part; and

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[9] So in original. Probably should be followed by a comma.

[10] Public Law 90–351, Title I, § 505, as added Public Law 100–690, Title VI, § 6091(a), Nov. 18, 1988, 102 Stat. 4333.

(2) before the approval of the application and any amendment thereto the Bureau has made an affirmative finding in writing that the program or project has been reviewed in accordance with this part.

(b) Time limitation for approval; specific reasons for disapproval

Each application or amendment made and submitted for approval to the Bureau pursuant to section 3753 of this title shall be deemed approved, in whole or in part, by the Bureau not later than 45 days after first received unless the Bureau informs the applicant of specific reasons for disapproval.

(c) Limitation on use of grant funds for land acquisition or construction projects

Grant funds awarded under this part shall not be used for land acquisition or construction projects, other than penal and correctional institutions.

(d) Reasonable notice and opportunity for reconsideration before final disapproval

The Bureau shall not finally disapprove any application, or any amendment thereto, submitted to the Director under this section without first affording the applicant reasonable notice and opportunity for reconsideration.

§ 3756. Allocation and distribution of funds under formula grants [11]

(a) States

Subject to subsection (f) of this section, of the total amount appropriated for this subchapter in any fiscal year, the amount remaining after setting aside the amount required to be reserved to carry out section 3761 of this title shall be set aside for section 3752 of this title and allocated to States as follows:

(1) $500,000 or 0.25 percent, whichever is greater, shall be allocated to each of the States; and

(2) of the total funds remaining after the allocation under paragraph (1), there shall be allocated to each State an amount which bears the same ratio to the amount of remaining funds described in this paragraph as the population of such State bears to the population of all the States.

(b) Units of local government

(1) Each State which receives funds under subsection (a) of this section in a fiscal year shall distribute among units of local government, or combinations of units of local government, in such State for the purposes specified in section 3751(b) of this title that portion of such funds which bears the same ratio to the aggregate amount of such funds as the amount of funds expended by all units

[11] Public Law 90–351, Title I, § 506, as added Public Law 100–690, Title VI, § 6091(a), Nov. 18, 1988, 102 Stat. 4334, and amended by Public Law 101–162, Title II, § 212, Nov. 21, 1989, 103 Stat. 998, 1006; Public Law 101–302, Title III, § 320(c)(1), May 25, 1990, 104 Stat. 248; Public Law 101–647, Title XVIII, § 1804, Nov. 29, 1990, 104 Stat. 4851; Public Law 103–322, Title XXXIII, § 330001(a), Sept. 13, 1994, 108 Stat. 2138; Public Law 107–273, Div. A, Title II, § 203(a)(2), Nov. 2, 2002, 116 Stat. 1775.

of local government for criminal justice in the preceding fiscal year bears to the aggregate amount of funds expended by the State and all units of local government in such State for criminal justice in such preceding fiscal year.

(2) In distributing funds received under this subchapter among urban, rural, and suburban units of local government and combinations thereof, the State shall give priority to those jurisdictions with the greatest need.

(3) Any funds not distributed to units of local government under paragraph (2) shall be available for expenditure by the State involved.

(4) For purposes of determining the distribution of funds under paragraphs (1) and (2), the most accurate and complete data available for the fiscal year involved shall be used. If data for such fiscal year are not available, then the most accurate and complete data available for the most recent fiscal year preceding such fiscal year shall be used.

(c) Programs eligible

No funds allocated to a State under subsection (a) of this section or received by a State for distribution under subsection (b) of this section may be distributed by the Director or by the State involved for any program other than a program contained in an approved application.

(d) Unneeded State allocated funds distributed to units of local government

If the Director determines, on the basis of information available during any fiscal year, that a portion of the funds allocated to a State for that fiscal year will not be required or that a State will be unable to qualify or receive funds under section 3752 of this title, or that a State chooses not to participate in the program established under such section, then such portion shall be awarded by the Director to urban, rural, and suburban units of local government or combinations thereof within such State giving priority to those jurisdictions with greatest need.

(e) Funds not distributed

Any funds allocated under subsection (a) or (f) of this section that are not distributed under this section shall be available for obligation under part B of this subchapter.

(f) Testing certain sex offenders for human immunodeficiency virus

(1) For any fiscal year beginning more than 2 years after November 29, 1990—

(A) 90 percent of the funds allocated under subsection (a) of this section without regard to this subsection to a State described in paragraph (2) shall be distributed by the Director to such State; and

(B) 10 percent of such funds shall be allocated equally among States that are not affected by the operation of subparagraph (A).

(2) Paragraph (1)(A) refers to a State that does not have in effect, and does not enforce, in such fiscal year, a law that requires the State at the request of the victim of a sexual act—

(A) to administer, to the defendant convicted under State law of such sexual act, a test to detect in such defendant the presence of the etiologic agent for acquired immune deficiency syndrome;

(B) to disclose the results of such test to such defendant and to the victim of such sexual act; and

(C) to provide to the victim of such sexual act counseling regarding HIV disease, HIV testing, in accordance with applicable law, and referral for appropriate health care and support services.

(3) For purposes of this subsection—

(A) the term "convicted" includes adjudicated under juvenile proceedings; and

(B) the term "sexual act" has the meaning given such term in subparagraph (A) or (B) of section 2245(1) of Title 18.

§ 3757. State office [12]

(a) The chief executive of each participating State shall designate a State office for purposes of—

(1) preparing an application to obtain funds under section 3753 of this title;

(2) administering funds received under such section from the Director, including receipt, review, processing, monitoring, progress and financial report review, technical assistance, grant adjustments, accounting, auditing and fund disbursements; and

(3) coordinating the distribution of funds provided under this subchapter with State agencies receiving Federal funds for drug abuse education, prevention, treatment, and research activities and programs.

(b) An office or agency performing other functions within the executive branch of a State may be designated to carry out the functions specified in subsection (a) of this section.

§ 3758. Distribution of grants to local government [13]

(a) Each application made by a local unit of government, or a combination of units of local government, to a State for funds under this part shall be deemed approved, in whole or in part, by the State not later than 45 days after first received unless the State informs the applicant in writing of specific reasons for disapproval. The State shall not finally disapprove any application submitted to the State without first affording the applicant reasonable notice and opportunity for reconsideration.

(b) Each State which receives funds under section 3756 of this title in a fiscal year shall make such funds available to local units of government, or combinations thereof, whose application has been submitted to, approved and awarded by the State, within 45 days after the Bureau has approved the State application and has made

[12] Public Law 90–351, Title I, § 507, as added Public Law 100–690, Title VI, § 6091(a), Nov. 18, 1988, 102 Stat. 4335.

[13] Public Law 90–351, Title I, § 508, as added Public Law 100–690, Title VI, § 6091(a), Nov. 18, 1988, 102 Stat. 4335.

funds available to such State. The Director shall have the authority to waive the 45-day requirement in this section upon a finding that the State cannot satisfy that requirement consistent with State statutes.

§ 3759. Improvement of criminal justice records [14]

(a) Percentage allocation of funds

Subject to subsection (d) of this section, each State which receives funds under section 3756 of this title in a fiscal year shall allocate not less than 5 percent of such funds to the improvement of criminal justice records.

(b) Includible improvements

The improvement referred to in subsection (a) of this section shall include—

(1) the completion of criminal histories to include the final dispositions of all arrests for felony offenses;

(2) the full automation of all criminal justice histories and fingerprint records;

(3) the frequency and quality of criminal history reports to the Federal Bureau of Investigation; and

(4) [15] the improvement of State record systems and the sharing with the Attorney General of all of the records described in paragraphs (1), (2), and (3) of this subsection and the records required by the Attorney General under section 103 of the Brady Handgun Violence Prevention Act, for the purpose of implementing that Act.

(4) [16] the improvement of State record systems and the sharing of all of the records described in paragraphs (1), (2), and (3) and the child abuse crime records required under the National Child Protection Act of 1993 [42 U.S.C. 5119 et seq.] with the Attorney General for the purpose of implementing the National Child Protection Act of 1993.

(c) Guidelines

The Director, in consultation with the Director of the Bureau of Justice Statistics, shall establish guidelines for the fulfillment of the requirements specified in subsections (a) and (b) of this section.

(d) Expenditures unwarranted in light of quality of criminal justice records

In accordance with such guidelines as the Director shall issue and on the request of a State, the Director may—

(1) waive compliance with subsection (a) of this section by such State; or

(2) authorize such State to reduce the minimum amount such State is required to allocate under subsection (a) of this section;

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[14] Public Law 90–351, Title I, § 509, as added Public Law 101–647, Title XVIII, § 1803(a), Nov. 29, 1990, 104 Stat. 4850, and amended by Public Law 103–159, Title I, § 106(a), Nov. 30, 1993, 107 Stat. 1543; Public Law 103–209, § 4(a), Dec. 20, 1993, 107 Stat. 2493.

[15] So in original. Two paragraphs (4) have been enacted.

[16] So in original. Two paragraphs (4) have been enacted.

if the Director, in the discretion of the Director, finds that the quality of the State's criminal justice records does not warrant expending the amount allocated under subsection (a) of this section.

42 U.S.C. §§ 3797u–3797u–8
Omnibus Crime Control and Safe Streets Act, Public Law 90–351, secs. 2951–2959
Drug court grant program

§ 3797u. Grant authority [1]

(a) In general

The Attorney General may make grants to States, State courts, local courts, units of local government, and Indian tribal governments, acting directly or through agreements with other public or private entities, for adult drug courts, juvenile drug courts, family drug courts, and tribal drug courts that involve—

(1) continuing judicial supervision over offenders with substance abuse problems who are not violent offenders;

(2) coordination with the appropriate State or local prosecutor; and

(3) the integrated administration of other sanctions and services, which shall include—

(A) mandatory periodic testing for the use of controlled substances or other addictive substances during any period of supervised release or probation for each participant;

(B) substance abuse treatment for each participant;

(C) diversion, probation, or other supervised release involving the possibility of prosecution, confinement, or incarceration based on noncompliance with program requirements or failure to show satisfactory progress;

(D) offender management, and aftercare services such as relapse prevention, health care, education, vocational training, job placement, housing placement, and child care or other family support services for each participant who requires such services;

(E) payment, in whole or part, by the offender of treatment costs, to the extent practicable, such as costs for urinalysis or counseling; and

(F) payment, in whole or part, by the offender of restitution, to the extent practicable, to either a victim of the offender's offense or to a restitution or similar victim support fund.

(b) Limitation

Economic sanctions imposed on an offender pursuant to this section shall not be at a level that would interfere with the offender's rehabilitation.

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[1] Public Law 90–351, Title I, § 2951, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1795.

§ 3797u–1. Prohibition of participation by violent offenders [2]

The Attorney General shall—

(1) issue regulations or guidelines to ensure that the programs authorized in this subchapter do not permit participation by violent offenders; and

(2) immediately suspend funding for any grant under this subchapter, pending compliance, if the Attorney General finds that violent offenders are participating in any program funded under this subchapter.

§ 3797u–2. Definition [3]

(a) In general

Except as provided in subsection (b) of this section, in this subchapter, the term "violent offender" means a person who—

(1) is charged with or convicted of an offense, during the course of which offense or conduct—

(A) the person carried, possessed, or used a firearm or dangerous weapon;

(B) there occurred the death of or serious bodily injury to any person; or

(C) there occurred the use of force against the person of another, without regard to whether any of the circumstances described in subparagraph (A) or (B) is an element of the offense or conduct of which or for which the person is charged or convicted; or

(2) has 1 or more prior convictions for a felony crime of violence involving the use or attempted use of force against a person with the intent to cause death or serious bodily harm.

(b) Definition for purposes of juvenile drug courts

For purposes of juvenile drug courts, the term "violent offender" means a juvenile who has been convicted of, or adjudicated delinquent for, an offense that—

(1) has as an element, the use, attempted use, or threatened use of physical force against the person or property of another, or the possession or use of a firearm; or

(2) by its nature, involves a substantial risk that physical force against the person or property of another may be used in the course of committing the offense.

§ 3797u–3. Administration [4]

(a) Consultation

The Attorney General shall consult with the Secretary of Health and Human Services and any other appropriate officials in carrying out this subchapter.

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[2] Public Law 90–351, Title I, § 2952, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1795.

[3] Public Law 90–351, Title I, § 2953, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1795.

[4] Public Law 90–351, Title I, § 2954, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1796.

(b) Use of components

The Attorney General may utilize any component or components of the Department of Justice in carrying out this subchapter.

(c) Regulatory authority

The Attorney General may issue regulations and guidelines necessary to carry out this subchapter.

(d) Applications

In addition to any other requirements that may be specified by the Attorney General, an application for a grant under this subchapter shall—

(1) include a long-term strategy and detailed implementation plan that shall provide for the consultation and coordination with appropriate State and local prosecutors, particularly when program participants fail to comply with program requirements;

(2) explain the applicant's inability to fund the program adequately without Federal assistance;

(3) certify that the Federal support provided will be used to supplement, and not supplant, State, Indian tribal, and local sources of funding that would otherwise be available;

(4) identify related governmental or community initiatives which complement or will be coordinated with the proposal;

(5) certify that there has been appropriate consultation with all affected agencies and that there will be appropriate coordination with all affected agencies in the implementation of the program;

(6) certify that participating offenders will be supervised by 1 or more designated judges with responsibility for the drug court program;

(7) specify plans for obtaining necessary support and continuing the proposed program following the conclusion of Federal support; and

(8) describe the methodology that will be used in evaluating the program.

§ 3797u–4. Applications [5]

To request funds under this subchapter, the chief executive or the chief justice of a State or the chief executive or judge of a unit of local government or Indian tribal government, or the chief judge of a State court or the judge of a local court or Indian tribal court shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.

[5] Public Law 90–351, Title I, § 2955, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1797.

§ 3797u–5. Federal share [6]

(a) In general

The Federal share of a grant made under this subchapter may not exceed 75 percent of the total costs of the program described in the application submitted under section 3797u–4 of this title for the fiscal year for which the program receives assistance under this subchapter, unless the Attorney General waives, wholly or in part, the requirement of a matching contribution under this section.

(b) In-kind contributions

In-kind contributions may constitute a portion of the non-Federal share of a grant.

§ 3797u–6. Distribution and allocation [7]

(a) Geographic distribution

The Attorney General shall ensure that, to the extent practicable, an equitable geographic distribution of grant awards is made.

(b) Minimum allocation

Unless all eligible applications submitted by any State or unit of local government within such State for a grant under this subchapter have been funded, such State, together with grantees within the State (other than Indian tribes), shall be allocated in each fiscal year under this subchapter not less than 0.50 percent of the total amount appropriated in the fiscal year for grants pursuant to this subchapter.

§ 3797u–7. Report [8]

A State, Indian tribal government, or unit of local government that receives funds under this subchapter during a fiscal year shall submit to the Attorney General a description and an evaluation report on a date specified by the Attorney General regarding the effectiveness of this subchapter.

§ 3797u–8. Technical assistance, training, and evaluation [9]

(a) Technical assistance and training

The Attorney General may provide technical assistance and training in furtherance of the purposes of this subchapter.

(b) Evaluations

In addition to any evaluation requirements that may be prescribed for grantees (including uniform data collection standards and reporting requirements), the Attorney General shall carry out or make arrangements for evaluations of programs that receive support under this subchapter.

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[6] Public Law 90–351, Title I, § 2956, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1797.
[7] Public Law 90–351, Title I, § 2957, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1797.
[8] Public Law 90–351, Title I, § 2958, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1797.
[9] Public Law 90–351, Title I, § 2959, as added Public Law 107–273, Div. B, Title II, § 2301(a), Nov. 2, 2002, 116 Stat. 1797.

(c) Administration

The technical assistance, training, and evaluations authorized by this section may be carried out directly by the Attorney General, in collaboration with the Secretary of Health and Human Services, or through grants, contracts, or other cooperative arrangements with other entities.

42 U.S.C. § 11152
Health Care Quality Improvement Act, Public Law 99–660, sec. 432
Memorandum between DEA and HHS relating to practitioners whose registration to dispense controlled substances has been revoked

Chapter 117. Encouraging Good Faith Professional Review Activities

§ 11152. Reports and memoranda of understanding [1]

(a) Annual reports to Congress

The Secretary shall report to Congress, annually during the three years after November 14, 1986, on the implementation of this chapter.

(b) Memoranda of understanding

The Secretary of Health and Human Services shall seek to enter into memoranda of understanding with the Secretary of Defense and the Administrator of Veterans' Affairs to apply the provisions of subchapter II of this chapter to hospitals and other facilities and health care providers under the jurisdiction of the Secretary or Administrator, respectively. The Secretary shall report to Congress, not later than two years after November 14, 1986, on any such memoranda and on the cooperation among such officials in establishing such memoranda.

(c) Memorandum of understanding with Drug Enforcement Administration

The Secretary of Health and Human Services shall seek to enter into a memorandum of understanding with the Administrator of Drug Enforcement relating to providing for the reporting by the Administrator to the Secretary of information respecting physicians and other practitioners whose registration to dispense controlled substances has been suspended or revoked under section 824 of Title 21. The Secretary shall report to Congress, not later than two years after November 14, 1986, on any such memorandum and on the cooperation between the Secretary and the Administrator in establishing such a memorandum.

[1] Public Law 99–660, Title IV, § 432, Nov. 14, 1986, 100 Stat. 3794.

42 U.S.C. §§ 11901–11925
Drug-Free Public Housing Act, Public Law 100–690, secs. 5122–5146
Public housing drug elimination

Chapter 124. Public Housing Drug Elimination

§ 11901. Congressional findings [1]

The Congress finds that—

(1) the Federal Government has a duty to provide public and other federally assisted low-income housing that is decent, safe, and free from illegal drugs;

(2) public and other federally assisted low-income housing in many areas suffers from rampant drug-related or violent crime;

(3) drug dealers are increasingly imposing a reign of terror on public and other federally assisted low-income housing tenants;

(4) the increase in drug-related and violent crime not only leads to murders, muggings, and other forms of violence against tenants, but also to a deterioration of the physical environment that requires substantial government expenditures;

(5) local law enforcement authorities often lack the resources to deal with the drug problem in public and other federally assisted low-income housing, particularly in light of the recent reductions in Federal aid to cities;

(6) the Federal Government should provide support for effective safety and security measures to combat drug-related and violent crime, primarily in and around public housing projects with severe crime problems;

(7) closer cooperation should be encouraged between public and assisted housing managers, local law enforcement agencies, and residents in developing and implementing anti-crime programs; and

(8) anti-crime strategies should be improved through the expansion of community-oriented policing initiatives.

§ 11902. Authority to make grants [2]

(a) In general

The Secretary of Housing and Urban Development, in accordance with the provisions of this subchapter, may make grants to public

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[1] Public Law 100–690, Title V, § 5122, Nov. 18, 1988, 102 Stat. 4301; Public Law 101–625, Title V, § 581(a), Nov. 28, 1990, 104 Stat. 4245; Public Law 105–276, Title V, § 586(b), Oct. 21, 1998, 112 Stat. 2646.

[2] Public Law 100–690, Title V, § 5123, Nov. 18, 1988, 102 Stat. 4301; Public Law 101–625, Title V, § 581(a), Nov. 28, 1990, 104 Stat. 4246; Public Law 102–550, Title I, § 161(d)(1), Oct.

Continued

housing agencies, public housing resident management corporations that are principally managing, as determined by the Secretary, public housing projects owned by public housing agencies, recipients of assistance under the Native American Housing Assistance and Self-Determination Act of 1996 [25 U.S.C. 4101 et seq.], Indian tribes [3] and private, for-profit and nonprofit owners of federally assisted low-income housing for use in eliminating drug-related and violent crime.

(b) Consortia

Subject to terms and conditions established by the Secretary, public housing agencies may form consortia for purposes of applying for grants under this subchapter.

§ 11903. Eligible activities [4]

(a) Public and assisted housing

Grants under this subchapter may be used in public housing or other federally assisted low-income housing projects for—

(1) the employment of security personnel;

(2) reimbursement of local law enforcement agencies for additional security and protective services;

(3) physical improvements which are specifically designed to enhance security;

(4) the employment of one or more individuals—

(A) to investigate drug-related or violent crime in and around the real property comprising any public or other federally assisted low-income housing project; and

(B) to provide evidence relating to such crime in any administrative or judicial proceeding;

(5) the provision of training, communications equipment, and other related equipment for use by voluntary tenant patrols acting in cooperation with local law enforcement officials;

(6) programs designed to reduce use of drugs in and around public or other federally assisted low-income housing projects, including drug-abuse prevention, intervention, referral, and treatment programs;

(7) where a public housing agency, an Indian tribe, or recipient of assistance under the Native American Housing Assistance and Self-Determination Act of 1996 [25 U.S.C. 4101 et seq.] receives a grant, providing funding to nonprofit resident management corporations and resident councils to develop security and drug abuse prevention programs involving site residents; and

(8) sports programs and sports activities that serve primarily youths from public or other federally assisted low-income housing projects and are operated in conjunction with, or in furtherance of, an organized program or plan designed to reduce

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28, 1992, 106 Stat. 3719; Public Law 104–330, Title VII, § 704(1), Oct. 26, 1996, 110 Stat. 4051; Public Law 105–276, Title II, § 220(1), Title V, § 586(c), Oct. 21, 1998, 112 Stat. 2488, 2647.

[3] So in original. Probably should be followed by a comma.

[4] Public Law 100–690, Title V, § 5124, Nov. 18, 1988, 102 Stat. 4301; Public Law 101–625, Title V, § 581(a), Nov. 28, 1990, 104 Stat. 4246; Public Law 102–550, Title I, § 161(c), (d)(2), Oct. 28, 1992, 106 Stat. 3718, 3719; Public Law 104–330, Title VII, § 704(2), Oct. 26, 1996, 110 Stat. 4051; Public Law 105–276, Title II, § 220(2), Title V, § 586(d), Oct. 21, 1998, 112 Stat. 2488, 2647.

or eliminate drugs and drug-related problems in and around such projects.

(b) Other PHA-owned housing

Notwithstanding any other provision of this subchapter, grants under this subchapter may be used to eliminate drug-related crime in and around housing owned by public housing agencies that is not public housing assisted under the United States Housing Act of 1937 [42 U.S.C. 1437 et seq.] and is not otherwise federally assisted, for the activities described in paragraphs (1) through (7) of subsection (a) of this section, but only if—

(1) the housing is located in a high intensity drug trafficking area designated pursuant to section 1504 of Title 21; and

(2) the public housing agency owning the housing demonstrates, to the satisfaction of the Secretary, that drug-related or violent activity in or around the housing has a detrimental effect on or about the real property comprising any public or other federally assisted low-income housing.

§ 11904. Applications [5]

(a) In general

To receive a grant under this subchapter, a public housing agency, a public housing resident management corporation, an Indian tribe [6] a recipient of assistance under the Native American Housing Assistance and Self-Determination Act of 1996 [25 U.S.C. 4101 et seq.], or an owner of federally assisted low-income housing shall submit an application to the Secretary, at such time, in such manner, and accompanied by such additional information as the Secretary may reasonably require. Such application shall include a plan for addressing the problem of drug-related or violent crime in and around of [7] the housing administered or owned by the applicant for which the application is being submitted, which plan shall be coordinated with and may be included in the public housing agency plan submitted to the Secretary pursuant to section 1437c–1 of this title.

(b) One-year renewable grants

(1) In general

An eligible applicant that is a public housing agency may apply for a 1-year grant under this subchapter that, subject to the availability of appropriated amounts, shall be renewed annually for a period of not more than 4 additional years, except that such renewal shall be contingent upon the Secretary finding, upon an annual or more frequent review, that the grantee agency is performing under the terms of the grant and applicable laws in a satisfactory manner and meets such other requirements as the Secretary may prescribe. The Secretary may adjust the amount of any grant received or renewed under this

[5] Public Law 100–690, Title V, § 5125, Nov. 18, 1988, 102 Stat. 4302; Public Law 101–625, Title V, § 581(a), Nov. 28, 1990, 104 Stat. 4246; Public Law 102–550, Title I, § 161(d)(3), Oct. 28, 1992, 106 Stat. 3719; Public Law 104–330, Title VII, § 704(3), Oct. 26, 1996, 110 Stat. 4051; Public Law 105–276, Title II, § 220(3), Title V, § 586(e), Oct. 21, 1998, 112 Stat. 2488, 2647.

[6] So in original. A comma probably should follow "an Indian tribe".

[7] So in original. The word "of" probably should have been stricken.

paragraph to take into account increases or decreases in amounts appropriated for these purposes or such other factors as the Secretary determines to be appropriate.

(2) Eligibility and preference

The Secretary may not provide assistance under this subchapter to an applicant that is a public housing agency unless—

(A) the agency will use the grants to continue or expand activities eligible for assistance under this subchapter, as in effect immediately before the effective date under section 503(a) of the Quality Housing and Work Responsibility Act of 1998, in which case the Secretary shall provide preference to such applicant; except that preference under this subparagraph shall not preclude selection by the Secretary of other meritorious applications that address urgent or serious crime problems nor be construed to require continuation of activities determined by the Secretary to be unworthy of continuation; or

(B) the agency is in the class established under paragraph (3).

(3) PHAs having urgent or serious crime problems

The Secretary shall, by regulations issued after notice and opportunity for public comment, set forth criteria for establishing a class of public housing agencies that have urgent or serious crime problems. The Secretary may reserve a portion of the amount appropriated to carry out this subchapter in each fiscal year only for grants for public housing agencies in such class, except that any amounts from such portion reserved that are not obligated to agencies in the class shall be made available only for agencies that are subject to a preference under paragraph (2)(A).

(4) Inapplicability to Federally assisted low-income housing

The provisions of this subsection shall not apply to federally assisted low-income housing.

(c) Criteria

The Secretary shall approve applications under subsection (b) that are not subject to a preference under subsection (b)(2)(A) on the basis of thresholds or criteria such as—

(1) the extent of the drug-related or violent crime problem in and around the public or federally assisted low-income housing project or projects proposed for assistance;

(2) the quality of the plan to address the crime problem in the public or federally assisted low-income housing project or projects proposed for assistance, including the extent to which the plan includes initiatives that can be sustained over a period of several years;

(3) the capability of the applicant to carry out the plan; and

(4) the extent to which tenants, the local government and the local community support and participate in the design and implementation of the activities proposed to be funded under the application.

(d) Federally assisted low-income housing

In addition to the selection criteria specified in subsection (c) of this section, the Secretary may establish other criteria for the evaluation of applications submitted by owners of federally assisted low-income housing, except that such additional criteria shall be designed only to reflect—

(1) relevant differences between the financial resources and other characteristics of public housing authorities and owners of federally assisted low-income housing, or

(2) relevant differences between the problem of drug-related or violent crime in public housing and the problem of drug-related crime or violent in federally assisted low-income housing.

(e) High intensity drug trafficking areas

In evaluating the extent of the drug-related crime problem pursuant to subsection (c) of this section, the Secretary may consider whether housing projects proposed for assistance are located in a high intensity drug trafficking area designated pursuant to section 1504 of Title 21.

§ 11905. Definitions[8]

For the purposes of this subchapter:

(1) Controlled substance

The term "controlled substance" has the meaning given such term in section 802 of Title 21.

(2) Drug-related crime

The term "drug-related crime" means the illegal manufacture, sale, distribution, use, or possession with intent to manufacture, sell, distribute, or use a controlled substance.

(3) Secretary

The term "Secretary" means the Secretary of Housing and Urban Development.

(4) Federally assisted low-income housing

The term "federally assisted low-income housing" means housing assisted under—

(A) section 1715l(d)(3), section 1715l(d)(4), or 1715z–1 of Title 12;

(B) section 1701s of Title 12; or

(C) section 1437f of this title.

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[8] Public Law 100–690, Title V, § 5126, Nov. 18, 1988, 102 Stat. 4302; Public Law 101–625, Title V, § 581(a), Nov. 28, 1990, 104 Stat. 4247; Public Law 104–330, Title VII, § 704(4), Oct. 26, 1996, 110 Stat. 4051; Public Law 105–276, Title II, § 220(4), Title V, § 586(f), Oct. 21, 1998, 112 Stat. 2488, 2649; Public Law 106–74, Title II, § 227(a) as added Public Law 106–113, Div. A, Title I, § 175(d), Nov. 29, 1999, 113 Stat. 1534.

(5) Recipient

The term "recipient", when used in reference to the Native American Housing Assistance and Self-Determination Act of 1996 [25 U.S.C. 4101 et seq.], has the meaning given such term in section 4103 of Title 25 [25 U.S.C. 4103].

(6) Indian tribe

The term "Indian tribe" has the meaning given the term in section 4(12) of the Native American Housing Assistance and Self Determination Act of 1996, 25 U.S.C. 4103(12).

§ 11906. Reports[9]

(a) Grantee reports

The Secretary shall require grantees under this subchapter to provide periodic reports that include the obligation and expenditure of grant funds, the progress made by the grantee in implementing the plan described in section 11904(a) of this title, and any change in the incidence of drug-related crime in projects assisted under this subchapter.

(b) HUD reports

The Secretary shall submit a report to the Congress not later than 18 months after October 21, 1998 describing the system used to distribute funding to grantees under this section, which shall include descriptions of—

(1) the methodology used to distribute amounts made available under this subchapter among public housing agencies, including provisions used to provide for renewals of ongoing programs funded under this subchapter; and

(2) actions taken by the Secretary to ensure that amounts made available under this subchapter are not used to fund baseline local government services, as described in section 11907(b) of this title.

(c) Notice of funding awards

The Secretary shall cause to be published in the Federal Register notice of all grant awards made pursuant to this subchapter, which shall identify the grantees and the amount of the grants. Such notice shall be published not less frequently than annually.

§ 11907. Monitoring[10]

(a) In general

The Secretary shall audit and monitor the programs funded under this subchapter to ensure that assistance provided under this subchapter is administered in accordance with the provisions of this subchapter.

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[9] Public Law 100–690, Title V, § 5127, as added Public Law 105–276, Title V, § 586(g), Oct. 21, 1998, 112 Stat. 2649.

[10] Public Law 100–690, Title V, § 5128, as added Public Law 105–276, Title V, § 586(g), Oct. 21, 1998, 112 Stat. 2649.

(b) Prohibition of funding baseline services

(1) In general

Amounts provided under this subchapter may not be used to reimburse or support any local law enforcement agency or unit of general local government for the provision of services that are included in the baseline of services required to be provided by any such entity pursuant to a local cooperation agreement under section 1437c(e)(2) of this title or any provision of an annual contributions contract for payments in lieu of taxation pursuant to section 1437d(d) of this title.

(2) Description

Each public housing agency that receives grant amounts under this subchapter shall describe, in the report under section 11906(a) of this title, such baseline of services for the unit of general local government in which the jurisdiction of the agency is located.

(c) Enforcement

The Secretary shall provide for the effective enforcement of this section, which may include the use of on-site monitoring, independent public audit requirements, certification by local law enforcement or local government officials regarding the performance of baseline services referred to in subsection (b), and entering into agreements with the Attorney General to achieve compliance, and verification of compliance, with the provisions of this subchapter.

§ 11908. Authorization of appropriations [11]

(a) In general

There are authorized to be appropriated to carry out this subchapter $310,000,000 for fiscal year 1999, and such sums as may be necessary for fiscal years 2000, 2001, 2002, and 2003.

(b) Set-aside for Federally assisted low-income housing

Of any amounts made available in any fiscal year to carry out this subchapter not more than 6.25 percent shall be available for grants for federally assisted low-income housing.

(c) Set-aside for technical assistance and program oversight

Of any amounts appropriated in any fiscal year to carry out this subchapter, amounts shall be available to the extent provided in appropriations Acts to provide training, technical assistance, contract expertise, program oversight, program assessment, execution, and other assistance for or on behalf of public housing agencies, recipients of assistance under the Native American Housing Assistance and Self-Determination Act of 1996 [25 U.S.C. 4101 et seq.], resident organizations, and officials and employees of the Department (including training and the cost of necessary travel for participants in such training, by or to officials and employees of the Department and of public housing agencies, and to residents and

[11] Public Law 100–690, Title V, § 5129, as added Public Law 105–276, Title V, § 586(g), Oct. 21, 1998, 112 Stat. 2650.

to other eligible grantees). Assistance and other activities carried out using amounts made available under this subsection may be provided directly or indirectly by grants, contracts, or cooperative agreements.

§ 11921. Statement of purpose [12]

The purpose of this subchapter is to reaffirm the principle that decent affordable shelter is a basic necessity, and the general welfare of the Nation and the health and living standards of its people require better coordination and training in drug prevention programs among the public officials and agencies responsible for administering the public housing programs of the Nation.

§ 11922. Clearinghouse on drug abuse in public housing [13]

(a) Establishment

The Secretary of Housing and Urban Development shall establish, in the Office of Public Housing in the Department of Housing and Urban Development, a clearinghouse to receive, collect, process, and assemble information regarding the abuse of controlled substances in public housing projects.

(b) Functions

The clearinghouse established under subsection (a) of this section shall—

(1) respond to inquiries by members of the public requesting assistance in investigating, studying, and working on the problem of the abuse of controlled substances; and

(2) receive, collect, process, assemble, and provide information on programs, authorities, institutions, and agencies, that may further assist members of the public requesting information from the clearinghouse.

§ 11923. Regional training program on drug abuse in public housing [14]

(a) Establishment

The Secretary shall establish a regional training program for the training of public housing officials, to better prepare and educate the officials to confront the widespread abuse of controlled substances in the communities in which the officials work.

(b) Operation

The regional training program established under subsection (a) of this section shall be conducted within 12 months after November 18, 1988, by a national training unit established by the Secretary.

§ 11924. Definitions [15]

For purposes of this subchapter:

(1) Controlled substance

The term "controlled substance" has the meaning given such term in section 802 of Title 21.

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[12] Public Law 100–690, Title V, § 5142, Nov. 18, 1988, 102 Stat. 4303.
[13] Public Law 100–690, Title V, § 5143, Nov. 18, 1988, 102 Stat. 4303.
[14] Public Law 100–690, Title V, § 5144, Nov. 18, 1988, 102 Stat. 4303.
[15] Public Law 100–690, Title V, § 5145, Nov. 18, 1988, 102 Stat. 4304.

(2) Secretary

The term "Secretary" means the Secretary of Housing and Urban Development.

§ 11925. Regulations [16]

Not later than 6 months after November 18, 1988, the Secretary shall issue any regulations necessary to carry out this subchapter.

[16] Public Law 100–690, Title V, § 5146, Nov. 18, 1988, 102 Stat. 4304.

Chapter 126. Equal Opportunity for Individuals with Disabilities

§ 12114. Illegal use of drugs and alcohol[1]

(a) Qualified individual with a disability

For purposes of this subchapter, the term "qualified individual with a disability" shall not include any employee or applicant who is currently engaging in the illegal use of drugs, when the covered entity acts on the basis of such use.

(b) Rules of construction

Nothing in subsection (a) of this section shall be construed to exclude as a qualified individual with a disability an individual who—

(1) has successfully completed a supervised drug rehabilitation program and is no longer engaging in the illegal use of drugs, or has otherwise been rehabilitated successfully and is no longer engaging in such use;

(2) is participating in a supervised rehabilitation program and is no longer engaging in such use; or

(3) is erroneously regarded as engaging in such use, but is not engaging in such use;

except that it shall not be a violation of this chapter for a covered entity to adopt or administer reasonable policies or procedures, including but not limited to drug testing, designed to ensure that an individual described in paragraph (1) or (2) is no longer engaging in the illegal use of drugs.

(c) Authority of covered entity

A covered entity—

(1) may prohibit the illegal use of drugs and the use of alcohol at the workplace by all employees;

(2) may require that employees shall not be under the influence of alcohol or be engaging in the illegal use of drugs at the workplace;

(3) may require that employees behave in conformance with the requirements established under the Drug-Free Workplace Act of 1988 (41 U.S.C. 701 et seq.);

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[1] Public Law 101–336, Title I, § 104, July 26, 1990, 104 Stat. 334.

(4) may hold an employee who engages in the illegal use of drugs or who is an alcoholic to the same qualification standards for employment or job performance and behavior that such entity holds other employees, even if any unsatisfactory performance or behavior is related to the drug use or alcoholism of such employee; and

(5) may, with respect to Federal regulations regarding alcohol and the illegal use of drugs, require that—

(A) employees comply with the standards established in such regulations of the Department of Defense, if the employees of the covered entity are employed in an industry subject to such regulations, including complying with regulations (if any) that apply to employment in sensitive positions in such an industry, in the case of employees of the covered entity who are employed in such positions (as defined in the regulations of the Department of Defense);

(B) employees comply with the standards established in such regulations of the Nuclear Regulatory Commission, if the employees of the covered entity are employed in an industry subject to such regulations, including complying with regulations (if any) that apply to employment in sensitive positions in such an industry, in the case of employees of the covered entity who are employed in such positions (as defined in the regulations of the Nuclear Regulatory Commission); and

(C) employees comply with the standards established in such regulations of the Department of Transportation, if the employees of the covered entity are employed in a transportation industry subject to such regulations, including complying with such regulations (if any) that apply to employment in sensitive positions in such an industry, in the case of employees of the covered entity who are employed in such positions (as defined in the regulations of the Department of Transportation).

(d) Drug testing

(1) In general

For purposes of this subchapter, a test to determine the illegal use of drugs shall not be considered a medical examination.

(2) Construction

Nothing in this subchapter shall be construed to encourage, prohibit, or authorize the conducting of drug testing for the illegal use of drugs by job applicants or employees or making employment decisions based on such test results.

(e) Transportation employees

Nothing in this subchapter shall be construed to encourage, prohibit, restrict, or authorize the otherwise lawful exercise by entities subject to the jurisdiction of the Department of Transportation of authority to—

(1) test employees of such entities in, and applicants for, positions involving safety-sensitive duties for the illegal use of drugs and for on-duty impairment by alcohol; and

(2) remove such persons who test positive for illegal use of drugs and on-duty impairment by alcohol pursuant to paragraph (1) from safety-sensitive duties in implementing subsection (c) of this section.

42 U.S.C. § 12210
Americans with Disabilities Act, Public Law 101–336, sec. 510
Illegal use of drugs and alcohol: public accommodation

§ 12210. Illegal use of drugs [1]

(a) In general

For purposes of this chapter, the term "individual with a disability" does not include an individual who is currently engaging in the illegal use of drugs, when the covered entity acts on the basis of such use.

(b) Rules of construction

Nothing in subsection (a) of this section shall be construed to exclude as an individual with a disability an individual who—

(1) has successfully completed a supervised drug rehabilitation program and is no longer engaging in the illegal use of drugs, or has otherwise been rehabilitated successfully and is no longer engaging in such use;

(2) is participating in a supervised rehabilitation program and is no longer engaging in such use; or

(3) is erroneously regarded as engaging in such use, but is not engaging in such use;

except that it shall not be a violation of this chapter for a covered entity to adopt or administer reasonable policies or procedures, including but not limited to drug testing, designed to ensure that an individual described in paragraph (1) or (2) is no longer engaging in the illegal use of drugs; however, nothing in this section shall be construed to encourage, prohibit, restrict, or authorize the conducting of testing for the illegal use of drugs.

(c) Health and other services

Notwithstanding subsection (a) of this section and section 12211(b)(3) of this title, an individual shall not be denied health services, or services provided in connection with drug rehabilitation, on the basis of the current illegal use of drugs if the individual is otherwise entitled to such services.

(d) "Illegal use of drugs" defined

(1) In general

The term "illegal use of drugs" means the use of drugs, the possession or distribution of which is unlawful under the Controlled Substances Act [21 U.S.C. 801 et seq.]. Such term does not include the use of a drug taken under supervision by a licensed health care professional, or other uses authorized by

[1] Public Law 101–336, Title V, § 510, July 26, 1990, 104 Stat. 375.

the Controlled Substances Act or other provisions of Federal law.

(2) Drugs

The term "drug" means a controlled substance, as defined in schedules I through V of section 202 of the Controlled Substances Act [21 U.S.C. 812].

Chapter 129. National and Community Service

§ 12602. Individuals eligible to receive a national service educational award from the Trust[1]

(a) Eligible individuals

An individual shall receive a national service educational award from the National Service Trust if the individual—

(1) successfully completes the required term of service described in subsection (b) of this section in an approved national service position;

(2) was 17 years of age or older at the time the individual began serving in the approved national service position or was an out-of-school youth serving in an approved national service position with a youth corps program described in section 12572(a)(2) of this title or a program described in section 12572(a)(9) of this title;

(3) at the time the individual uses the national service educational award—

(A) has received a high school diploma, or the equivalent of such diploma;

(B) is enrolled at an institution of higher education on the basis of meeting the standard described in paragraph (1) or (2) of subsection (a) of section 1091 of title 20 and meets the requirements of subsection (a) of such section; or

(C) has received a waiver described in section 12591(c) of this title; and

(4) is a citizen or national of the United States or lawful permanent resident alien of the United States.

(b) Term of service

The term of service for an approved national service position shall not be less than the full-or part-time term of service specified in section 12593(b) of this title.

(c) Limitation on number of terms of service for awards

Although an individual may serve more than 2 terms of service described in subsection (b) of this section in an approved national

[1] Public Law 101–610, Title I, § 146, as added Public Law 103–82, Title I, § 102(a), Sept. 21, 1993, 107 Stat. 818, and amended by Public Law 103–304, § 3(b)(4), Aug. 23, 1994, 108 Stat. 1567.

service position, the individual shall receive a national service educational award from the National Service Trust only on the basis of the first and second of such terms of service.

(d) Time for use of educational award

(1) Seven-year requirement

An individual eligible to receive a national service educational award under this section may not use such award after the end of the 7-year period beginning on the date the individual completes the term of service in an approved national service position that is the basis of the award.

(2) Exception

The Corporation may extend the period within which an individual may use a national service educational award if the Corporation determines that the individual—

(A) was unavoidably prevented from using the national service educational award during the original 7-year period; or

(B) performed another term of service in an approved national service position during that period.

(e) Suspension of eligibility for drug-related offenses

(1) In general

An individual who, after qualifying under this section as an eligible individual, has been convicted under any Federal or State law of the possession or sale of a controlled substance shall not be eligible to receive a national service educational award during the period beginning on the date of such conviction and ending after the interval specified in the following table:

If convicted of:	Ineligibility period is:
The possession of a controlled substance:	
1st conviction	1 year
2nd conviction	2 years
3rd conviction	indefinite
The sale of a controlled substance:	
1st conviction	2 years
2nd conviction	indefinite

(2) Rehabilitation

An individual whose eligibility has been suspended under paragraph (1) shall resume eligibility before the end of the period determined under such paragraph if the individual satisfactorily completes a drug rehabilitation program that complies with such criteria as the Corporation shall prescribe for purposes of this paragraph.

(3) First convictions

An individual whose eligibility has been suspended under paragraph (1) and is convicted of a first offense may resume

eligibility before the end of the period determined under such paragraph if the individual demonstrates that he or she has enrolled or been accepted for enrollment in a drug rehabilitation program described in paragraph (2).

(4) "Controlled substance" defined

As used in this subsection, the term "controlled substance" has the meaning given in section 802(6) of title 21.

(5) Effective date

This subsection shall be effective upon publication by the Corporation in the Federal Register of criteria prescribed under paragraph (2).

(f) Authority to establish demonstration programs

The Corporation may establish by regulation demonstration programs for the creation and evaluation of innovative volunteer and community service programs.

42 U.S.C. §§ 13661–13664
Veterans Affairs and HUD Appropriations Act, 1999, Public Law 105–276, secs. 576–579
Safety and security in public and assisted housing

Chapter 135. Residency and Service Requirements in Federally Assisted Housing

§ 13661. Screening of applicants for Federally assisted housing [1]

(a) Ineligibility because of eviction for drug crimes

Any tenant evicted from federally assisted housing by reason of drug-related criminal activity (as such term is defined in section 3(b) of the United States Housing Act of 1937 (42 U.S.C. 1437a(b)) shall not be eligible for federally assisted housing during the 3-year period beginning on the date of such eviction, unless the evicted tenant successfully completes a rehabilitation program approved by the public housing agency (which shall include a waiver of this subsection if the circumstances leading to eviction no longer exist).

(b) Ineligibility of illegal drug users and alcohol abusers

(1) In general

Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing, as determined by the Secretary, shall establish standards that prohibit admission to the program or admission to federally assisted housing for any household with a member—

(A) who the public housing agency or owner determines is illegally using a controlled substance; or

(B) with respect to whom the public housing agency or owner determines that it has reasonable cause to believe that such household member's illegal use (or pattern of illegal use) of a controlled substance, or abuse (or pattern of abuse) of alcohol, may interfere with the health, safety, or right to peaceful enjoyment of the premises by other residents.

(2) Consideration of rehabilitation

In determining whether, pursuant to paragraph (1)(B), to deny admission to the program or federally assisted housing to any household based on a pattern of illegal use of a controlled substance or a pattern of abuse of alcohol by a household member, a public housing agency or an owner may consider whether such household member—

[1] Public Law 105–276, Title V, § 576, Oct. 21, 1998, 112 Stat. 2639.

(A) has successfully completed a supervised drug or alcohol rehabilitation program (as applicable) and is no longer engaging in the illegal use of a controlled substance or abuse of alcohol (as applicable);

(B) has otherwise been rehabilitated successfully and is no longer engaging in the illegal use of a controlled substance or abuse of alcohol (as applicable); or

(C) is participating in a supervised drug or alcohol rehabilitation program (as applicable) and is no longer engaging in the illegal use of a controlled substance or abuse of alcohol (as applicable).

(c) Authority to deny admission to criminal offenders

Except as provided in subsections (a) and (b) of this section and in addition to any other authority to screen applicants, in selecting among applicants for admission to the program or to federally assisted housing, if the public housing agency or owner of such housing (as applicable) determines that an applicant or any member of the applicant's household is or was, during a reasonable time preceding the date when the applicant household would otherwise be selected for admission, engaged in any drug-related or violent criminal activity or other criminal activity which would adversely affect the health, safety, or right to peaceful enjoyment of the premises by other residents, the owner, or public housing agency employees, the public housing agency or owner may—

(1) deny such applicant admission to the program or to federally assisted housing; and

(2) after the expiration of the reasonable period beginning upon such activity, require the applicant, as a condition of admission to the program or to federally assisted housing, to submit to the public housing agency or owner evidence sufficient (as the Secretary shall by regulation provide) to ensure that the individual or individuals in the applicant's household who engaged in criminal activity for which denial was made under paragraph (1) have not engaged in any criminal activity during such reasonable period.

§ 13662. Termination of tenancy and assistance for illegal drug users and alcohol abusers in Federally assisted housing[2]

(a) In general

Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing (as applicable), shall establish standards or lease provisions for continued assistance or occupancy in federally assisted housing that allow the agency or owner (as applicable) to terminate the tenancy or assistance for any household with a member—

(1) who the public housing agency or owner determines is illegally using a controlled substance; or

(2) whose illegal use (or pattern of illegal use) of a controlled substance, or whose abuse (or pattern of abuse) of alcohol, is determined by the public housing agency or owner to interfere

[2] Public Law 105–276, Title V, § 577, Oct. 21, 1998, 112 Stat. 2640.

with the health, safety, or right to peaceful enjoyment of the premises by other residents.

(b) Consideration of rehabilitation

In determining whether, pursuant to subsection (a)(2) of this section, to terminate tenancy or assistance to any household based on a pattern of illegal use of a controlled substance or a pattern of abuse of alcohol by a household member, a public housing agency or an owner may consider whether such household member—

(1) has successfully completed a supervised drug or alcohol rehabilitation program (as applicable) and is no longer engaging in the illegal use of a controlled substance or abuse of alcohol (as applicable);

(2) has otherwise been rehabilitated successfully and is no longer engaging in the illegal use of a controlled substance or abuse of alcohol (as applicable); or

(3) is participating in a supervised drug or alcohol rehabilitation program (as applicable) and is no longer engaging in the illegal use of a controlled substance or abuse of alcohol (as applicable).

§ 13663. Ineligibility of dangerous sex offenders for admission to public housing[3]

(a) In general

Notwithstanding any other provision of law, an owner of federally assisted housing shall prohibit admission to such housing for any household that includes any individual who is subject to a lifetime registration requirement under a State sex offender registration program.

(b) Obtaining information

As provided in regulations issued by the Secretary to carry out this section—

(1) a public housing agency shall carry out criminal history background checks on applicants for federally assisted housing and make further inquiry with State and local agencies as necessary to determine whether an applicant for federally assisted housing is subject to a lifetime registration requirement under a State sex offender registration program; and

(2) State and local agencies responsible for the collection or maintenance of criminal history record information or information on persons required to register as sex offenders shall comply with requests of public housing agencies for information pursuant to this section.

(c) Requests by owners for PHAs to obtain information

A public housing agency may take any action under subsection (b) of this section regarding applicants for, or tenants of, federally assisted housing other than federally assisted housing described in subparagraph (A) or (B) of section 13664(a)(2) of this title, but only if the housing is located within the jurisdiction of the agency and the owner of such housing has requested that the agency take such

[3] Public Law 105–276, Title V, § 578, Oct. 21, 1998, 112 Stat. 2641.

action on behalf of the owner. Upon such a request by the owner, the agency shall take the action requested under subsection (b) of this section. The agency may not make any information obtained pursuant to the action under subsection (b) of this section available to the owner but shall perform determinations for the owner regarding screening, lease enforcement, and eviction based on criteria supplied by the owner.

(d) Opportunity to dispute

Before an adverse action is taken with respect to an applicant for federally assisted housing on the basis that an individual is subject to a lifetime registration requirement under a State sex offender registration program, the public housing agency obtaining the record shall provide the tenant or applicant with a copy of the registration information and an opportunity to dispute the accuracy and relevance of that information.

(e) Fee

A public housing agency may be charged a reasonable fee for taking actions under subsection (b) of this section. In the case of a public housing agency taking actions on behalf of another owner of federally assisted housing pursuant to subsection (c) of this section, the agency may pass such fee on to the owner making the request and may charge an additional reasonable fee for making the request on behalf of the owner.

(f) Records management

Each public housing agency shall establish and implement a system of records management that ensures that any criminal record or information regarding a lifetime registration requirement under a State sex offender registration program that is obtained under this section by the public housing agency is—

(1) maintained confidentially;

(2) not misused or improperly disseminated; and

(3) destroyed, once the purpose for which the record was requested has been accomplished.

§ 13664. Definitions[4]

(a)[5] Definitions

For purposes of this subchapter [42 U.S.C. 13661 et seq.], the following definitions shall apply:

(1) Drug-related criminal activity

The term "drug-related criminal activity" has the meaning given the term in section 1437a(b) of this title.

(2) Federally assisted housing

The term "federally assisted housing" means a dwelling unit—

(A) in public housing (as such term is defined in section 1437a of this title);

[4] Public Law 105–276, Title V, § 579, Oct. 21, 1998, 112 Stat. 2642.
[5] So in original. No subsection (b) has been enacted.

(B) assisted with tenant-based assistance under section 1437f of this title;

(C) in housing that is provided project-based assistance under section 1437f of this title, including new construction and substantial rehabilitation projects;

(D) in housing that is assisted under section 1701q of Title 12 (as amended by section 801 of the Cranston-Gonzalez National Affordable Housing Act);

(E) in housing that is assisted under section 1701q of Title 12, as such section existed before the enactment of the Cranston-Gonzalez National Affordable Housing Act;

(F) in housing that is assisted under section 8013 of this title;

(G) in housing financed by a loan or mortgage insured under section 1715l(d)(3) of title 12 that bears interest at a rate determined under the proviso of section 1715l(d)(5) of title 12;

(H) in housing insured, assisted, or held by the Secretary or a State or State agency under section 1715z–1 of title 12; or

(I) in housing assisted under section 1484 or 1485 of this title.

(3) Owner

The term "owner" means, with respect to federally assisted housing, the entity or private person (including a cooperative or public housing agency) that has the legal right to lease or sublease dwelling units in such housing.

42 U.S.C. § 14053

Violent Crime Control and Law Enforcement Act of 1994, Public Law 103–322, sec. 90107

President may authorize Federal agency assistance to State and local authorities in violent crime and drug emergency areas

Chapter 136. Violent Crime Control and Law Enforcement

§ 14053. Violent crime and drug emergency areas [1]

(a) Definitions

In this section—

"major violent crime or drug-related emergency" means an occasion or instance in which violent crime, drug smuggling, drug trafficking, or drug abuse violence reaches such levels, as determined by the President, that Federal assistance is needed to supplement State and local efforts and capabilities to save lives, and to protect property and public health and safety.

"State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands.

(b) Declaration of violent crime and drug emergency areas

If a major violent crime or drug-related emergency exists throughout a State or a part of a State, the President may declare the State or part of a State to be a violent crime or drug emergency area and may take appropriate actions authorized by this section.

(c) Procedure

(1) In general

A request for a declaration designating an area to be a violent crime or drug emergency area shall be made, in writing, by the chief executive officer of a State or local government, respectively (or in the case of the District of Columbia, the mayor), and shall be forwarded to the Attorney General in such form as the Attorney General may by regulation require. One or more cities, counties, States, or the District of Columbia may submit a joint request for designation as a major violent crime or drug emergency area under this subsection.

(2) Finding

A request made under paragraph (1) shall be based on a written finding that the major violent crime or drug-related

[1] Public Law 103–322, Title IX, § 90107, Sept. 13, 1994, 108 Stat. 1988.

emergency is of such severity and magnitude that Federal assistance is necessary to ensure an effective response to save lives and to protect property and public health and safety.

(d) Irrelevancy of population density

The President shall not limit declarations made under this section to highly populated centers of violent crime or drug trafficking, drug smuggling, or drug use, but shall also consider applications from governments of less populated areas where the magnitude and severity of such activities is beyond the capability of the State or local government to respond.

(e) Requirements

As part of a request for a declaration under this section, and as a prerequisite to Federal violent crime or drug emergency assistance under this section, the chief executive officer of a State or local government shall—

(1) take appropriate action under State or local law and furnish information on the nature and amount of State and local resources that have been or will be committed to alleviating the major violent crime-or drug-related emergency;

(2) submit a detailed plan outlining that government's short- and long-term plans to respond to the violent crime or drug emergency, specifying the types and levels of Federal assistance requested and including explicit goals (including quantitative goals) and timetables; and

(3) specify how Federal assistance provided under this section is intended to achieve those goals.

(f) Review period

The Attorney General shall review a request submitted pursuant to this section, and the President shall decide whether to declare a violent crime or drug emergency area, within 30 days after receiving the request.

(g) Federal assistance

The President may—

(1) direct any Federal agency, with or without reimbursement, to utilize its authorities and the resources granted to it under Federal law (including personnel, equipment, supplies, facilities, financial assistance, and managerial, technical, and advisory services) in support of State and local assistance efforts; and

(2) provide technical and advisory assistance, including communications support and law enforcement-related intelligence information.

(h) Duration of Federal assistance

(1) In general

Federal assistance under this section shall not be provided to a violent crime or drug emergency area for more than 1 year.

(2) Extension

The chief executive officer of a jurisdiction may apply to the President for an extension of assistance beyond 1 year. The President may extend the provision of Federal assistance for not more than an additional 180 days.

(i) Regulations

Not later than 120 days after September 13, 1994, the Attorney General shall issue regulations to implement this section.

(j) No effect on existing authority

Nothing in this section shall diminish or detract from existing authority possessed by the President or Attorney General.

46 U.S.C. § 2101
Definition of dangerous drugs as controlled substances or controlled substance analogs

Title 46. Shipping

Chapter 21. General

§ 2101. General definitions [1]

In this subtitle—

(1) "associated equipment"—

(A) means—

(i) a system, accessory, component, or appurtenance of a recreational vessel; or

(ii) a marine safety article intended for use on board a recreational vessel; but

(B) does not include radio equipment.

(2) "barge" means a non-self-propelled vessel.

(3) "Boundary Line" means a line established under section 2(b) of the Act of February 19, 1895 (33 U.S.C. 151).

(3a) "citizen of the United States" means a national of the United States as defined in section 101(a)(22) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(22)) or an individual citizen of the Trust Territory of the Pacific Islands who is exclusively domiciled in the Northern Mariana Islands within the meaning of section 1005(e) of the Covenant to establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America (48 U.S.C. 1681 note).

(4) "Coast Guard" means the organization established and continued under section 1 of title 14.

(5) "commercial service" includes any type of trade or business involving the transportation of goods or individuals, except service performed by a combatant vessel.

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[1] Public Law 98–89, Aug. 26, 1983, 97 Stat. 501; Public Law 98–364, Title IV, § 402(1), July 17, 1984, 98 Stat. 445; Public Law 98–454, Title III, § 301(a), Oct. 5, 1984, 98 Stat. 1734; Public Law 98–557, § 34(a), Oct. 30, 1984, 98 Stat. 2876; Public Law 99–307, § 1(1), (2), May 19, 1986, 100 Stat. 444; Public Law 99–509, Title V, § 5102(b)(1), Oct. 8, 1986, 100 Stat. 1926; Public Law 99–514, § 2, Oct. 22, 1986, 100 Stat. 2095; Public Law 99–640, §§ 10(b)(1), 11(a), 13(d), Nov. 11, 1986, 100 Stat. 3549 to 3551; Public Law 100–239, § 6(a)(1), Jan. 11, 1988, 101 Stat. 1781; Public Law 100–424, § 8(c)(1), Sept. 9, 1988, 102 Stat. 1593; Public Law 100–710, Title I, § 104(a)(1), (2), Nov. 23, 1988, 102 Stat. 4749; Public Law 101–225, Title II, § 209, Dec. 12, 1989, 103 Stat. 1913; Public Law 101–380, Title IV, § 4103(a)(2)(A), Aug. 18, 1990, 104 Stat. 511; Public Law 101–595, Title VI, § 603(1), Nov. 16, 1990, 104 Stat. 2993; Public Law 102–587, Title V, § 5208(a), Nov. 4, 1992, 106 Stat. 5075; Public Law 103–206, Title V, §§ 502 to 510, Dec. 20, 1993, 107 Stat. 2439; Public Law 103–272, § 5(l), July 5, 1994, 108 Stat. 1375; Public Law 104–324, Title VII, § 709, Title XI, § 1104(a), Oct. 19, 1996, 110 Stat. 3934, 3966; Public Law 105–383, Title III, § 301(b)(1), Nov. 13, 1998, 112 Stat. 3417; Public Law 107–217, § 3(m)(1), Aug. 21, 2002, 116 Stat. 1302; Public Law 107–295, Title IV, § 419, Nov. 25, 2002, 116 Stat. 2124.

(5a) "consideration" means an economic benefit, inducement, right, or profit including pecuniary payment accruing to an individual, person, or entity, but not including a voluntary sharing of the actual expenses of the voyage, by monetary contribution or donation of fuel, food, beverage, or other supplies.

(6) "consular officer" means an officer or employee of the United States Government designated under regulations to grant visas.

(7) "crude oil" means a liquid hydrocarbon mixture occurring naturally in the earth, whether or not treated to render it suitable for transportation, and includes crude oil from which certain distillate fractions may have been removed, and crude oil to which certain distillate fractions may have been added.

(8) "crude oil tanker" means a tanker engaged in the trade of carrying crude oil.

(8a) "dangerous drug" means a narcotic drug, a controlled substance, or a controlled substance analog (as defined in section 102 of the Comprehensive Drug Abuse[2] and Control Act of 1970 (21 U.S.C. 802)).

(9) "discharge", when referring to a substance discharged from a vessel, includes spilling, leaking, pumping, pouring, emitting, emptying, or dumping, however caused.

(10) "documented vessel" means a vessel for which a certificate of documentation has been issued under chapter 121 of this title.

(10a) "Exclusive Economic Zone" means the zone established by Presidential Proclamation Numbered 5030, dated March 10, 1983.

(11) "fish" means finfish, mollusks, crustaceans, and all other forms of marine animal and plant life, except marine mammals and birds.

(11a) "fishing vessel" means a vessel that commercially engages in the catching, taking, or harvesting of fish or an activity that can reasonably be expected to result in the catching, taking, or harvesting of fish.

(11b) "fish processing vessel" means a vessel that commercially prepares fish or fish products other than by gutting, decapitating, gilling, skinning, shucking, icing, freezing, or brine chilling.

(11c) "fish tender vessel" means a vessel that commercially supplies, stores, refrigerates, or transports fish, fish products, or materials directly related to fishing or the preparation of fish to or from a fishing, fish processing, or fish tender vessel or a fish processing facility.

(12) "foreign vessel" means a vessel of foreign registry or operated under the authority of a country except the United States.

(13) "freight vessel" means a motor vessel of more than 15 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title

[2] So in original. Probably should be "Abuse Prevention".

that carries freight for hire, except an oceanographic research vessel or an offshore supply vessel.

(13a) "Great Lakes barge" means a non-self-propelled vessel of at least 3,500 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title operating on the Great Lakes.

(14) "hazardous material" means a liquid material or substance that is—

(A) flammable or combustible;

(B) designated a hazardous substance under section 311(b) of the Federal Water Pollution Control Act (33 U.S.C. 1321); or

(C) designated a hazardous material under section 5103(a) of title 49;

(14a) "major conversion" means a conversion of a vessel that—

(A) substantially changes the dimensions or carrying capacity of the vessel;

(B) changes the type of the vessel;

(C) substantially prolongs the life of the vessel; or

(D) otherwise so changes the vessel that it is essentially a new vessel, as decided by the Secretary.

(15) "marine environment" means—

(A) the navigable waters of the United States and the land and resources in and under those waters;

(B) the waters and fishery resources of an area over which the United States asserts exclusive fishery management authority;

(C) the seabed and subsoil of the outer Continental Shelf of the United States, the resources of the Shelf, and the waters superjacent to the Shelf; and

(D) the recreational, economic, and scenic values of the waters and resources referred to in subclauses (A)-(C) of this clause.

(15a) "mobile offshore drilling unit" means a vessel capable of engaging in drilling operations for the exploration or exploitation of subsea resources.

(16) "motor vessel" means a vessel propelled by machinery other than steam.

(17) "nautical school vessel" means a vessel operated by or in connection with a nautical school or an educational institution under section 558 of title 40.

(17a) "navigable waters of the United States" includes all waters of the territorial sea of the United States as described in Presidential Proclamation No. 5928 of December 27, 1988.

(17b) "numbered vessel" means a vessel for which a number has been issued under chapter 123 of this title.

(18) "oceanographic research vessel" means a vessel that the Secretary finds is being employed only in instruction in oceanography or limnology, or both, or only in oceanographic or limnological research, including those studies about the sea such as seismic, gravity meter, and magnetic exploration and

other marine geophysical or geological surveys, atmospheric research, and biological research.

(19) "offshore supply vessel" means a motor vessel of more than 15 gross tons but less than 500 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title that regularly carries goods, supplies, individuals in addition to the crew, or equipment in support of exploration, exploitation, or production of offshore mineral or energy resources.

(20) "oil" includes oil of any type or in any form, including petroleum, fuel oil, sludge, oil refuse, and oil mixed with wastes except dredged spoil.

(20a) "oil spill response vessel" means a vessel that is designated in its certificate of inspection as such a vessel, or that is adapted to respond to a discharge of oil or a hazardous material.

(20b) "overall in length" means—

(A) for a foreign vessel or a vessel engaged on a foreign voyage, the greater of—

(i) 96 percent of the length on a waterline at 85 percent of the least molded depth measured from the top of the keel (or on a vessel designed with a rake of keel, on a waterline parallel to the designed waterline); or

(ii) the length from the fore side of the stem to the axis of the rudder stock on that waterline; and

(B) for any other vessel, the horizontal distance of the hull between the foremost part of the stem and the aftermost part of the stern, excluding fittings and attachments.

(21) "passenger"—

(A) means an individual carried on the vessel except—

(i) the owner or an individual representative of the owner or, in the case of a vessel under charter, an individual charterer or individual representative of the charterer;

(ii) the master; or

(iii) a member of the crew engaged in the business of the vessel who has not contributed consideration for carriage and who is paid for on board services;

(B) on an offshore supply vessel, means an individual carried on the vessel except—

(i) an individual included in clause (i), (ii), or (iii) of subparagraph (A) of this paragraph;

(ii) an employee of the owner, or of a subcontractor to the owner, engaged in the business of the owner;

(iii) an employee of the charterer, or of a subcontractor to the charterer, engaged in the business of the charterer; or

(iv) an individual employed in a phase of exploration, exploitation, or production of offshore mineral or energy resources served by the vessel;

(C) on a fishing vessel, fish processing vessel, or fish tender vessel, means an individual carried on the vessel except—

(i) an individual included in clause (i), (ii), or (iii) of subparagraph (A) of this paragraph;

(ii) a managing operator;

(iii) an employee of the owner, or of a subcontractor to the owner, engaged in the business of the owner;

(iv) an employee of the charterer, or of a subcontractor to the charterer, engaged in the business of the charterer; or

(v) an observer or sea sampler on board the vessel pursuant to a requirement of State or Federal law; or

(D) on a sailing school vessel, means an individual carried on the vessel except—

(i) an individual included in clause (i), (ii), or (iii) of subparagraph (A) of this paragraph;

(ii) an employee of the owner of the vessel engaged in the business of the owner, except when the vessel is operating under a demise charter;

(iii) an employee of the demise charterer of the vessel engaged in the business of the demise charterer; or

(iv) a sailing school instructor or sailing school student.

(21a) ''passenger for hire'' means a passenger for whom consideration is contributed as a condition of carriage on the vessel, whether directly or indirectly flowing to the owner, charterer, operator, agent, or any other person having an interest in the vessel.

(22) ''passenger vessel'' means a vessel of at least 100 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title—

(A) carrying more than 12 passengers, including at least one passenger for hire;

(B) that is chartered and carrying more than 12 passengers; or

(C) that is a submersible vessel carrying at least one passenger for hire.

(23) ''product carrier'' means a tanker engaged in the trade of carrying oil except crude oil.

(24) ''public vessel'' means a vessel that—

(A) is owned, or demise chartered, and operated by the United States Government or a government of a foreign country; and

(B) is not engaged in commercial service.

(25) ''recreational vessel'' means a vessel—

(A) being manufactured or operated primarily for pleasure; or

(B) leased, rented, or chartered to another for the latter's pleasure.

(26) ''recreational vessel manufacturer'' means a person engaged in the manufacturing, construction, assembly, or importation of recreational vessels, components, or associated equipment.

(27) "sailing instruction" means teaching, research, and practical experience in operating vessels propelled primarily by sail and may include—

(A) any subject related to that operation and to the sea, including seamanship, navigation, oceanography, other nautical and marine sciences, and maritime history and literature; and

(B) only when in conjunction with a subject referred to in subclause (A) of this clause, instruction in mathematics and language arts skills to sailing school students having learning disabilities.

(28) "sailing school instructor" means an individual who is on board a sailing school vessel to provide sailing instruction, but does not include an operator or crewmember who is among those required to be on board the vessel to meet a requirement established under part F of this subtitle.

(29) "sailing school student" means an individual who is on board a sailing school vessel to receive sailing instruction.

(30) "sailing school vessel" means a vessel—

(A) that is less than 500 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title;

(B) carrying more than 6 individuals who are sailing school instructors or sailing school students;

(C) principally equipped for propulsion by sail, even if the vessel has an auxiliary means of propulsion; and

(D) owned or demise chartered, and operated by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and exempt from tax under section 501(a) of that Code, or by a State or political subdivision of a State, during times that the vessel is operated by the organization, State, or political subdivision only for sailing instruction.

(31) "scientific personnel" means individuals on board an oceanographic research vessel only to engage in scientific research, or to instruct or receive instruction in oceanography or limnology.

(32) "seagoing barge" means a non-self-propelled vessel of at least 100 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title making voyages beyond the Boundary Line.

(33) "seagoing motor vessel" means a motor vessel of at least 300 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title making voyages beyond the Boundary Line.

(34) "Secretary", except in part H, means the head of the department in which the Coast Guard is operating.

(35) "small passenger vessel" means a wing-in-ground craft, regardless of tonnage, carrying at least one passenger for hire, and a vessel of less than 100 gross tons as measured under section 14502 of this title, or an alternate tonnage measured

under section 14302 of this title as prescribed by the Secretary under section 14104 of this title—

(A) carrying more than 6 passengers, including at least one passenger for hire;

(B) that is chartered with the crew provided or specified by the owner or the owner's representative and carrying more than 6 passengers;

(C) that is chartered with no crew provided or specified by the owner or the owner's representative and carrying more than 12 passengers; or

(D) that is a submersible vessel carrying at least one passenger for hire.

(36) "State" means a State of the United States, Guam, Puerto Rico, the Virgin Islands, American Samoa, the District of Columbia, the Northern Mariana Islands, and any other territory or possession of the United States.

(37) "steam vessel" means a vessel propelled in whole or in part by steam, except a recreational vessel of not more than 40 feet in length.

(37a) "submersible vessel" means a vessel that is capable of operating below the surface of the water.

(38) "tanker" means a self-propelled tank vessel constructed or adapted primarily to carry oil or hazardous material in bulk in the cargo spaces.

(39) "tank vessel" means a vessel that is constructed or adapted to carry, or that carries, oil or hazardous material in bulk as cargo or cargo residue, and that—

(A) is a vessel of the United States;

(B) operates on the navigable waters of the United States; or

(C) transfers oil or hazardous material in a port or place subject to the jurisdiction of the United States.

(40) "towing vessel" means a commercial vessel engaged in or intending to engage in the service of pulling, pushing, or hauling along side, or any combination of pulling, pushing, or hauling along side.

(41) "undocumented" means not having and not required to have a document issued under chapter 121 of this title.

(42) "uninspected passenger vessel" means an uninspected vessel—

(A) of at least 100 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title—

(i) carrying not more than 12 passengers, including at least one passenger for hire; or

(ii) that is chartered with the crew provided or specified by the owner or the owner's representative and carrying not more than 12 passengers; and

(B) of less than 100 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title—

(i) carrying not more than 6 passengers, including at least one passenger for hire; or

(ii) that is chartered with the crew provided or specified by the owner or the owner's representative and carrying not more than 6 passengers.

(43) "uninspected vessel" means a vessel not subject to inspection under section 3301 of this title that is not a recreational vessel.

(44) "United States", when used in a geographic sense, means the States of the United States, Guam, Puerto Rico, the Virgin Islands, American Samoa, the District of Columbia, the Northern Mariana Islands, and any other territory or possession of the United States.

(45) "vessel" has the same meaning given that term in section 3 of title 1.

(46) "vessel of the United States" means a vessel documented or numbered under the laws of the United States or titled under the law of a State.

(47) "vessel of war" means a vessel—

(A) belonging to the armed forces of a country;

(B) bearing the external marks distinguishing vessels of war of that country;

(C) under the command of an officer commissioned by the government of that country and whose name appears in the appropriate service list or its equivalent; and

(D) staffed by a crew under regular armed forces discipline.

(48) "wing-in-ground craft" means a vessel that is capable of operating completely above the surface of the water on a dynamic air cushion created by aerodynamic lift due to the ground effect between the vessel and the water's surface.

46 U.S.C. § 2115
Civil penalties to enforce alcohol and dangerous drug testing

§ 2115. Civil penalty to enforce alcohol and dangerous drug testing[1]

Any person who fails to implement or conduct, or who otherwise fails to comply with the requirements prescribed by the Secretary for, chemical testing for dangerous drugs or for evidence of alcohol use, as prescribed under this subtitle or a regulation prescribed by the Secretary to carry out the provisions of this subtitle, is liable to the United States Government for a civil penalty of not more than $5,000 for each violation. Each day of a continuing violation shall constitute a separate violation.

[1] Added by Public Law 104–324, Title III, § 303(a), Oct. 19, 1996, 110 Stat. 3917, and amended by Public Law 105–383, Title III, § 304(b), Nov. 13, 1998., 112 Stat. 3419.

46 U.S.C. § 2302
Penalties for operating a vessel under the influence of alcohol or dangerous drugs

Chapter 23. Operation of Vessels Generally

§ 2302. Penalties for negligent operations and interfering with safe operation [1]

(a) A person operating a vessel in a negligent manner or interfering with the safe operation of a vessel, so as to endanger the life, limb, or property of a person is liable to the United States Government for a civil penalty of not more than $5,000 in the case of a recreational vessel, or $25,000 in the case of any other vessel.

(b) A person operating a vessel in a grossly negligent manner that endangers the life, limb, or property of a person commits a class A misdemeanor.

(c) An individual who is under the influence of alcohol, or a dangerous drug in violation of a law of the United States when operating a vessel, as determined under standards prescribed by the Secretary by regulation—

(1) is liable to the United States Government for a civil penalty of not more than $5,000; or

(2) commits a class A misdemeanor.

(d) For a penalty imposed under this section, the vessel also is liable in rem unless the vessel is—

(1) owned by a State or a political subdivision of a State;

(2) operated principally for governmental purposes; and

(3) identified clearly as a vessel of that State or subdivision.

(e)(1) A vessel may not transport Government-impelled cargoes if—

(A) the vessel has been detained and determined to be substandard by the Secretary for violation of an international safety convention to which the United States is a party, and the Secretary has published notice of that detention and determination in an electronic form, including the name of the owner of the vessel; or

(B) the operator of the vessel has on more than one occasion had a vessel detained and determined to be substandard by the Secretary for violation of an international safety convention to which the United States is a party, and the Secretary has published notice of that detention and determination in an electronic form, including the name of the owner of the vessel.

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[1] Public Law 98–89, Aug. 26, 1983, 97 Stat. 508; Public Law 98–557, § 7(a), Oct. 30, 1984, 98 Stat. 2862; Public Law 101–380, Title IV, §§ 4105(b)(2), 4302(a), Aug. 18, 1990, 104 Stat. 513, 537; Public Law 102–587, Title V, § 5102, Nov. 4, 1992, 106 Stat. 5071; Public Law 105–383, Title III, §§ 302(a), 304(c), Title IV, § 408(a), Nov. 13, 1998, 112 Stat. 3417, 3419, 3430; Public Law 107–295, Title III, § 325, Nov. 25, 2002, 116 Stat. 2105.

(2) The prohibition in paragraph (1) expires for a vessel on the earlier of—

(A) 1 year after the date of the publication in electronic form on which the prohibition is based; or

(B) any date on which the owner or operator of the vessel prevails in an appeal of the violation of the relevant international convention on which the detention is based.

(3) As used in this subsection, the term "Government-impelled cargo" means cargo for which a Federal agency contracts directly for shipping by water or for which (or the freight of which) a Federal agency provides financing, including financing by grant, loan, or loan guarantee, resulting in shipment of the cargo by water.

46 U.S.C. § 7101
Drug testing of applicants for shipping licenses and certificates of registry

Chapter 71. Licenses and Certificates of Registry

§ 7101. Issuing and classifying licenses and certificates of registry [1]

(a) Licenses and certificates of registry are established for individuals who are required to hold licenses or certificates under this subtitle.

(b) Under regulations prescribed by the Secretary, the Secretary—

(1) issues the licenses and certificates of registry; and

(2) may classify the licenses and certificates of registry as provided in subsections (c) and (f) of this section, based on—

(A) the tonnage, means of propulsion, and horsepower of machine-propelled vessels;

(B) the waters on which vessels are to be operated; or

(C) other reasonable standards.

(c) The Secretary may issue licenses in the following classes to applicants found qualified as to age, character, habits of life, experience, professional qualifications, and physical fitness:

(1) masters, mates, and engineers.

(2) pilots.

(3) operators.

(4) radio officers.

(d) In classifying individuals under subsection (c)(1) of this section, the Secretary shall establish, when possible, suitable career patterns and service and other qualifying requirements appropriate to the particular service or industry in which the individuals are engaged.

(e) An individual may be issued a license under subsection (c)(2) of this section only if the applicant—

(1) is at least 21 years of age;

(2) is of sound health and has no physical limitations that would hinder or prevent the performance of a pilot's duties;

(3) has a thorough physical examination each year while holding the license, except that this requirement does not apply to an individual who will serve as a pilot only on a vessel of less than 1,600 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title;

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[1] Public Law 98–89, Aug. 26, 1983, 97 Stat. 539; Public Law 98–557, § 29(a), Oct. 30, 1984, 98 Stat. 2873; Public Law 101–380, Title IV, § 4101(a), Aug. 18, 1990, 104 Stat. 509; Public Law 104–324, Title VII, § 720, Oct. 19, 1996, 110 Stat. 3938.

(4) demonstrates, to the satisfaction of the Secretary, that the applicant has the requisite general knowledge and skill to hold the license;

(5) demonstrates proficiency in the use of electronic aids to navigation;

(6) maintains adequate knowledge of the waters to be navigated and knowledge of regulations for the prevention of collisions in those waters;

(7) has sufficient experience, as decided by the Secretary, to evidence ability to handle any vessel of the type and size which the applicant may be authorized to pilot; and

(8) meets any other requirement the Secretary considers reasonable and necessary.

(f) The Secretary may issue certificates of registry in the following classes to applicants found qualified as to character, knowledge, skill, and experience:

(1) pursers.

(2) medical doctors.

(3) professional nurses.

(g) The Secretary may not issue a license or certificate of registry under this section unless an individual applying for the license or certificate makes available to the Secretary, under section 206(b)(7) of the National Driver Register Act of 1982 (23 U.S.C. 401 note), any information contained in the National Driver Register related to an offense described in section 205(a)(3)(A) or (B) of that Act committed by the individual.

(h) The Secretary may review the criminal record of an individual who applies for a license or certificate of registry under this section.

(i) The Secretary shall require the testing of an individual who applies for issuance or renewal of a license or certificate of registry under this chapter for use of a dangerous drug in violation of law or Federal regulation.

Chapter 73. Merchant Mariners' Documents

§ 7302. Issuing merchant mariners' documents and continuous discharge books[1]

(a) The Secretary shall issue a merchant mariner's document to an individual required to have that document under part F of this subtitle if the individual satisfies the requirements of this part. The document serves as a certificate of identification and as a certificate of service, specifying each rating in which the holder is qualified to serve on board vessels on which that document is required under part F.

(b) The Secretary also may issue a continuous discharge book to an individual issued a merchant mariner's document if the individual requests.

(c) The Secretary may not issue a merchant mariner's document under this chapter unless the individual applying for the document makes available to the Secretary, under section 206(b)(7) of the National Driver Register Act of 1982 (23 U.S.C. 401 note), any information contained in the National Driver Register related to an offense described in section 205(a)(3)(A) or (B) of that Act committed by the individual.

(d) The Secretary may review the criminal record of an individual who applies for a merchant mariner's document under this section.

(e) The Secretary shall require the testing of an individual applying for issuance or renewal of a merchant mariner's document under this chapter for the use of a dangerous drug in violation of law or Federal regulation.

(f) Except as provided in subsection (g), a merchant mariner's document issued under this chapter is valid for 5 years and may be renewed for additional 5-year periods.

(g)(1) The Secretary may, pending receipt and review of information required under subsections (c) and (d), immediately issue an interim merchant mariner's document valid for a period not to exceed 120 days, to—

(A) an individual to be employed as gaming personnel, entertainment personnel, wait staff, or other service personnel on board a passenger vessel not engaged in foreign service, with no duties, including emergency duties, related to the navigation of the vessel or the safety of the vessel, its crew, cargo or passengers; or

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[1] Public Law 98–89, Aug. 26, 1983, 97 Stat. 542; Public Law 101–380, Title IV, §§ 4101(b), 4102(c), Aug. 18, 1990, 104 Stat. 509; Public Law 107–295, Title III, § 324(a), Nov. 25, 2002, 116 Stat. 2104.

(B) an individual seeking renewal of, or qualifying for a supplemental endorsement to, a valid merchant mariner's document issued under this section.

(2) No more than one interim document may be issued to an individual under paragraph (1)(A) of this subsection.

46 U.S.C. § 7503
Denial of licenses, certificates, registrations, and the like related to shipping for conviction of dangerous drug offenses

Chapter 75. General Procedures for Licensing, Certification, and Documentation

§ 7503. Dangerous drugs as grounds for denial[1]

(b)[2] A license, certificate of registry, or merchant mariner's document authorized to be issued under this part may be denied to an individual who—

(1) within 10 years before applying for the license, certificate, or document, has been convicted of violating a dangerous drug law of the United States or of a State; or

(2) when applying, has ever been a user of, or addicted to, a dangerous drug unless the individual provides satisfactory proof that the individual is cured.

[1] Public Law 98–89, Aug. 26, 1983, 97 Stat. 545; Public Law 99–36, § 1(a)(9)(D), May 15, 1985, 99 Stat. 68; Public Law 101–380, Title IV, § 4103(a)(2)(B), Aug. 18, 1990, 104 Stat. 511.

[2] Section (a) was repealed by Public Law 101–380, Title IV, § 4103(a)(2)(B), Aug. 18, 1990, 104 Stat. 511.

Chapter 77. Suspension and Revocation

§ 7701. General [1]

(a) The purpose of suspension and revocation proceedings is to promote safety at sea.

(b) Licenses, certificates of registry, and merchant mariners' documents may be suspended or revoked for acts described in section 7703 of this title.

(c) When a license, certificate of registry, or merchant mariner's document has been revoked under this chapter, the former holder may be issued a new license, certificate of registry, or merchant mariner's document only after—

(1) the Secretary decides, under regulations prescribed by the Secretary, that the issuance is compatible with the requirement of good discipline and safety at sea; and

(2) the former holder provides satisfactory proof that the bases for revocation are no longer valid.

(d) The Secretary may prescribe regulations to carry out this chapter.

§ 7702. Administrative procedure [2]

(a) Sections 551–559 of title 5 apply to each hearing under this chapter about suspending or revoking a license, certificate of registry, or merchant mariner's document.

(b) The individual whose license, certificate of registry, or merchant mariner's document has been suspended or revoked under this chapter may appeal, within 30 days, the suspension or revocation to the Secretary.

(c)(1) The Secretary shall request a holder of a license, certificate of registry, or merchant mariner's document to make available to the Secretary, under section 206(b)(4) of the National Driver Register Act of 1982 (23 U.S.C. 401 note), all information contained in the National Driver Register related to an offense described in section 205(a)(3)(A) or (B) of that Act committed by the individual.

(2) The Secretary shall require the testing of the holder of a license, certificate of registry, or merchant mariner's document for use of alcohol and dangerous drugs in violation of law or Federal regulation. The testing may include preemployment (with respect

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[1] Public Law 98–89, Aug. 26, 1983, 97 Stat. 546; Public Law 101–380, Title IV, § 4103(c), Aug. 18, 1990, 104 Stat. 511.

[2] Public Law 98–89, Aug. 26, 1983, 97 Stat. 546; Public Law 99–36, § 1(a)(3), May 15, 1985, 99 Stat. 67; Public Law 101–380, Title IV, § 4103(a)(1), Aug. 18, 1990, 104 Stat. 510; Public Law 105–383, Title III, § 304(a), Nov. 13, 1998, 112 Stat. 3419; Public Law 108–293, §§ 407, 609(2), Aug. 9, 2004, 118 Stat. 1044, 1058.

to dangerous drugs only), periodic, random, and reasonable cause testing, and shall include post-accident testing.

(d)(1) The Secretary may temporarily, for not more than 45 days, suspend and take possession of the license, certificate of registry, or merchant mariner's document held by an individual if—

(A) that individual performs a safety sensitive function on a vessel, as determined by the Secretary; and

(B) there is probable cause to believe that the individual—

(i) has, while acting under the authority of that license, certificate, or document, performed the safety sensitive function in violation of law or Federal regulation regarding use of alcohol or a dangerous drug;

(ii) has been convicted of an offense that would prevent the issuance or renewal of the license, certificate, or document;

(iii) within the 3-year period preceding the initiation of a suspension proceeding, has been convicted of an offense described in section 30304(a)(3)(A) or (B) of title 49; or

(iv) is a security risk that poses a threat to the safety or security of a vessel or a public or commercial structure located within or adjacent to the marine environment.

(2) If a license, certificate, or document is temporarily suspended under this section, an expedited hearing under subsection (a) of this section shall be held within 30 days after the temporary suspension.

§ 7703. Bases for suspension or revocation[3]

A license, certificate of registry, or merchant mariner's document issued by the Secretary may be suspended or revoked if the holder—

(1) when acting under the authority of that license, certificate, or document—

(A) has violated or fails to comply with this subtitle, a regulation prescribed under this subtitle, or any other law or regulation intended to promote marine safety or to protect navigable waters; or

(B) has committed an act of misconduct or negligence;

(2) is convicted of an offense that would prevent the issuance or renewal of a license, certificate of registry, or merchant mariner's document;

(3) within the 3-year period preceding the initiation of the suspension or revocation proceeding is convicted of an offense described in section 30304(a)(3)(A) or (B) of title 49 (23 U.S.C. 401 note);

(4) has committed an act of incompetence relating to the operation of a vessel; or

(5) is a security risk that poses a threat to the safety or security of a vessel or a public or commercial structure located within or adjacent to the marine environment.

[3] Public Law 98–89, Aug. 26, 1983, 97 Stat. 546; Public Law 99–36, § 1(a)(9)(E), May 15, 1985, 99 Stat. 68; Public Law 101–380, Title IV, § 4103(b), Aug. 18, 1990, 104 Stat. 511; Public Law 108–293, § § 408, 609(3), Aug. 9, 2004, 118 Stat. 1044, 1058.

§ 7704. Dangerous drugs as grounds for revocation [4]

(b) [5] If it is shown at a hearing under this chapter that a holder of a license, certificate of registry, or merchant mariner's document issued under this part, within 10 years before the beginning of the proceedings, has been convicted of violating a dangerous drug law of the United States or of a State, the license, certificate, or document shall be suspended or revoked.

(c) If it is shown that a holder has been a user of, or addicted to, a dangerous drug, the license, certificate of registry, or merchant mariner's document shall be revoked unless the holder provides satisfactory proof that the holder is cured.

§ 7705. Subpenas and oaths [6]

(a) An official designated to investigate or preside at a hearing on matters that are grounds for suspension or revocation of licenses, certificates of registry, and merchant mariners' documents may administer oaths and issue subpenas to compel the attendance and testimony of witnesses and the production of records or other evidence during investigations and at hearings.

(b) The jurisdictional limits of a subpena issued under this section are the same as, and are enforceable in the same manner as, subpenas issued under chapter 63 of this title.

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[4] Public Law 98–89, Aug. 26, 1983, 97 Stat. 546; Public Law 99–36, § 1(a)(9)(F), (G), May 15, 1985, 99 Stat. 68; Public Law 101–380, Title IV, § 4103(a)(2)(B), Aug. 18, 1990, 104 Stat. 511; Public Law 108–293, § 402, Aug. 9, 2004, 118 Stat. 1043.

[5] Subsection (a) was repealed by Public Law 101–380.

[6] Public Law 98–89, Aug. 26, 1983, 97 Stat. 547; Public Law 99–36, § 1(a)(9)(H), May 15, 1985, 99 Stat. 68.

46 U.S.C. § 8101
Relieving the master of vessel under the influence of alcohol or dangerous drugs

Chapter 81. General

§ 8101. Complement of inspected vessels[1]

(a) The certificate of inspection issued to a vessel under part B of this subtitle shall state the complement of licensed individuals and crew (including lifeboatmen) considered by the Secretary to be necessary for safe operation. A manning requirement imposed on—

(1) a sailing school vessel shall consider the participation of sailing school instructors and sailing school students in the operation of that vessel;

(2) a mobile offshore drilling unit shall consider the specialized nature of the unit; and

(3) a tank vessel shall consider the navigation, cargo handling, and maintenance functions of that vessel for protection of life, property, and the environment.

(b) The Secretary may modify the complement, by endorsement on the certificate, for reasons of changed conditions or employment.

(c) A requirement made under this section by an authorized official may be appealed to the Secretary under prescribed regulations.

(d) A vessel to which this section applies may not be operated without having in its service the complement required in the certificate of inspection.

(e) When a vessel is deprived of the service of a member of its complement without the consent, fault, or collusion of the owner, charterer, managing operator, agent, master, or individual in charge of the vessel, the master shall engage, if obtainable, a number of members equal to the number of those of whose services the master has been deprived. The replacements must be of the same or a higher grade or rating than those whose places they fill. If the master finds the vessel is sufficiently manned for the voyage, and replacements are not available to fill all the vacancies, the vessel may proceed on its voyage. Within 12 hours after the vessel arrives at its destination, the master shall report in writing to the Secretary the cause of each deficiency in the complement. A master failing to make the report is liable to the United States Government for a civil penalty of $1,000 for each deficiency.

(f) The owner, charterer, or managing operator of a vessel not manned as required by this section is liable to the Government for a civil penalty of $10,000.

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[1] Public Law 98–89, Aug. 26, 1983, 97 Stat. 547; Public Law 98–557, § 29(b), Oct. 30, 1984, 98 Stat. 2873; Public Law 99–640, § 11(b), Nov. 10, 1986, 100 Stat. 3550; Public Law 101–380, Title IV, §§ 4104, 4114(c), 4302(e), Aug. 18, 1990, 104 Stat. 511, 517, 538; Public Law 104–324, Title VII, § 725, Oct. 19, 1996, 110 Stat. 3939.

(g) A person may not employ an individual as, and an individual may not serve as, a master, mate, engineer, radio officer, or pilot of a vessel to which this part applies or which is subject to inspection under chapter 33 of this title if the individual is not licensed by the Secretary. A person (including an individual) violating this subsection is liable to the Government for a civil penalty of not more than $10,000. Each day of a continuing violation is a separate offense.

(h) The owner, charterer, or managing operator of a freight vessel of less than 100 gross tons as measured under section 14502 of this title, or an alternate tonnage measured under section 14302 of this title as prescribed by the Secretary under section 14104 of this title, a small passenger vessel, or a sailing school vessel not manned as required by this section is liable to the Government for a civil penalty of $1,000. The vessel also is liable in rem for the penalty.

(i) When the 2 next most senior licensed officers on a vessel reasonably believe that the master or individual in charge of the vessel is under the influence of alcohol or a dangerous drug and is incapable of commanding the vessel, the next most senior master, mate, or operator licensed under section 7101(c)(1) or (3) of this title shall—

(1) temporarily relieve the master or individual in charge;

(2) temporarily take command of the vessel;

(3) in the case of a vessel required to have a log under chapter 113 of this title, immediately enter the details of the incident in the log; and

(4) report those details to the Secretary—

(A) by the most expeditious means available; and

(B) in written form transmitted within 12 hours after the vessel arrives at its next port.

Title 46 Appendix. Shipping

Chapter 38. Maritime Drug Law Enforcement

§ 1901. Short title [1]

That this chapter may be cited as the "Maritime Drug Law Enforcement Act".

§ 1902. Congressional declaration of findings [2]

The Congress finds and declares that trafficking in controlled substances aboard vessels is a serious international problem and is universally condemned. Moreover, such trafficking presents a specific threat to the security and societal well-being of the United States.

§ 1903. Manufacture, distribution, or possession with intent to manufacture or distribute controlled substances on board vessels [3]

(a) Vessels of United States or vessels subject to jurisdiction of United States

It is unlawful for any person on board a vessel of the United States, or on board a vessel subject to the jurisdiction of the United States, or who is a citizen of the United States or a resident alien of the United States on board any vessel, to knowingly or intentionally manufacture or distribute, or to possess with intent to manufacture or distribute, a controlled substance.

(b) "Vessel of the United States" defined

For purposes of this section, a "vessel of the United States" means—

(1) a vessel documented under chapter 121 of title 46 or a vessel numbered as provided in chapter 123 of that title;

(2) a vessel owned in whole or part by—

(A) the United States or a territory, commonwealth, or possession of the United States;

(B) a State or political subdivision thereof;

(C) a citizen or national of the United States; or

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[1] Public Law 96–350, § 1, Sept. 15, 1980, 94 Stat. 1159; Public Law 99–570, Title III, § 3202, Oct. 27, 1986, 100 Stat. 3207–95; Public Law 99–640, § 17, Nov. 10, 1986, 100 Stat. 3552.

[2] Public Law 96–350, § 2, Sept. 15, 1980, 94 Stat. 1160; Public Law 99–307, § 7, May 19, 1986, 100 Stat. 447; Public Law 99–570, Title III, § 3202, Oct. 27, 1986, 100 Stat. 3207–95; Public Law 99–640, § 17, Nov. 10, 1986, 100 Stat. 3552.

[3] Public Law 96–350, § 3, Sept. 15, 1980, 94 Stat. 1160; Public Law 99–570, Title III, § 3202, Oct. 27, 1986, 100 Stat. 3207–95; Public Law 99–640, § 17, Nov. 10, 1986, 100 Stat. 3552; Public Law 100–690, Title VII, § 7402, Nov. 18, 1988, 102 Stat. 4483; Public Law 101–647, Title XII, § 1203, Nov. 29, 1990, 104 Stat. 4830; Public Law 104–324, Title XI, § 1138, Oct. 19, 1996, 110 Stat. 3988; Public Law 107–295, Title IV, § 418(a), Nov. 25, 2002, 116 Stat. 2123.

(D) a corporation created under the laws of the United States or any State, the District of Columbia, or any territory, commonwealth, or possession of the United States;

unless the vessel has been granted the nationality of a foreign nation in accordance with article 5 of the 1958 Convention on the High Seas and a claim of nationality or registry for the vessel is made by the master or individual in charge at the time of the enforcement action by an officer or employee of the United States authorized to enforce applicable provisions of the United States law; and

(3) a vessel that was once documented under the laws of the United States and, in violation of the laws of the United States, was either sold to a person not a citizen of the United States or placed under foreign registry or a foreign flag, whether or not the vessel has been granted the nationality of a foreign nation.

(c) "Vessel subject to the jurisdiction of the United States" and "vessel without nationality" defined; claim of nationality or registry

(1) For purposes of this section, a "vessel subject to the jurisdiction of the United States" includes—

(A) a vessel without nationality;

(B) a vessel assimilated to a vessel without nationality, in accordance with paragraph (2) of article 6 of the 1958 Convention on the High Seas;

(C) a vessel registered in a foreign nation where the flag nation has consented or waived objection to the enforcement of United States law by the United States;

(D) a vessel located within the customs waters of the United States;

(E) a vessel located in the territorial waters of another nation, where the nation consents to the enforcement of United States law by the United States; and

(F) a vessel located in the contiguous zone of the United States, as defined in Presidential Proclamation 7219 of September 2, 1999, and (i) is entering the United States, (ii) has departed the United States, or (iii) is a hovering vessel as defined in section 1401 of title 19.

Consent or waiver of objection by a foreign nation to the enforcement of United States law by the United States under subparagraph (C) or (E) of this paragraph may be obtained by radio, telephone, or similar oral or electronic means, and is conclusively proved by certification of the Secretary of State or the Secretary's designee.

(2) For purposes of this section, a "vessel without nationality" includes—

(A) a vessel aboard which the master or person in charge makes a claim of registry, which claim is denied by the flag nation whose registry is claimed;

(B) any vessel aboard which the master or person in charge fails, upon request of an officer of the United States empowered to enforce applicable provisions of United States law, to make a claim of nationality or registry for that vessel; and

(C) a vessel aboard which the master or person in charge makes a claim of registry and the claimed nation of registry does not affirmatively and unequivocally assert that the vessel is of its nationality.

A claim of registry under subparagraph (A) or (C) may be verified or denied by radio, telephone, or similar oral or electronic means. The denial of such claim of registry by the claimed flag and is conclusively proved by certification of the Secretary of State or the Secretary's designee.

(3) For purposes of this section, a claim of nationality or registry only includes:

(A) possession on board the vessel and production of documents evidencing the vessel's nationality in accordance with article 5 of the 1958 Convention on the High Seas;

(B) flying its flag nation's ensign or flag; or

(C) a verbal claim of nationality or registry by the master or person in charge of the vessel.

(d) Claim of failure to comply with international law; jurisdiction of court

Any person charged with a violation of this section shall not have standing to raise the claim of failure to comply with international law as a basis for a defense. A claim of failure to comply with international law in the enforcement of this chapter may be invoked solely by a foreign nation, and a failure to comply with international law shall not divest a court of jurisdiction or otherwise constitute a defense to any proceeding under this chapter.

(e) Exceptions; burden of proof

This section does not apply to a common or contract carrier or an employee thereof, who possesses or distributes a controlled substance in the lawful and usual course of the carrier's business or to a public vessel of the United States, or any person on board such a vessel who possesses or distributes a controlled substance in the lawful course of such person's duties, if the controlled substance is a part of the cargo entered in the vessel's manifest and is intended to be lawfully imported into the country of destination for scientific, medical, or other legitimate purposes. It shall not be necessary for the United States to negative the exception set forth in this subsection in any complaint, information, indictment, or other pleading or in any trial or other proceeding. The burden of going forward with the evidence with respect to this exception is upon the person claiming its benefit.

(f) Jurisdiction and venue

Any person who violates this section shall be tried in the United States district court at the point of entry where that person enters the United States, or in the United States District Court of the District of Columbia. Jurisdiction of the United States with respect to vessels subject to this chapter is not an element of any offense. All jurisdictional issues arising under this chapter are preliminary questions of law to be determined solely by the trial judge.

(g) Penalties

(1) Any person who commits an offense defined in this section shall be punished in accordance with the penalties set forth in section 1010 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 960).

(2) Notwithstanding paragraph (1) of this subsection, any person convicted of an offense under this chapter shall be punished in accordance with the penalties set forth in section 1012 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 962) if such offense is a second or subsequent offense as defined in section 1012(b) of that Act.

(h) Extension beyond territorial jurisdiction of United States

This section is intended to reach acts of possession, manufacture, or distribution committed outside the territorial jurisdiction of the United States.

(i) Definitions

The definitions in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802) apply to terms used in this chapter.

(j) Attempt or conspiracy

Any person who attempts or conspires to commit any offense defined in this chapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

§ 1904. Seizure or forfeiture of property [4]

(a) Any property described in section 881(a) of title 21 that is used or intended for use to commit, or to facilitate the commission of, an offense under this chapter shall be subject to seizure and forfeiture in the same manner as similar property seized or forfeited under section 881 of title 21.

(b) Practices commonly recognized as smuggling tactics may provide prima facie evidence of intent to use a vessel to commit, or to facilitate the commission of, an offense under this chapter, and may support seizure and forfeiture of the vessel, even in the absence of controlled substances aboard the vessel. The following indicia, among others, may be considered, in the totality of the circumstances, to be prima facie evidence that a vessel is intended to be used to commit, or to facilitate the commission of an offense under this chapter:

(1) The construction or adaptation of the vessel in a manner that facilitates smuggling, including—

(A) the configuration of the vessel to ride low in the water or present a low hull profile to avoid being detected visually or by radar;

(B) the presence of any compartment or equipment which is built or fitted out for smuggling, not including

[4] Public Law 96–350, § 4, Sept. 15, 1980, 94 Stat. 1160; Public Law 99–570, Title III, § 3202, Oct. 27, 1986, 100 Stat. 3207–97; Public Law 99–640, § 17, Nov. 10, 1986, 100 Stat. 3552; Public Law 107–295, Title IV, § 418(b), Nov. 25, 2002, 116 Stat. 2123.

items such as a safe or lock-box reasonably used for the storage of personal valuables;

(C) the presence of an auxiliary tank not installed in accordance with applicable law or installed in such a manner as to enhance the vessel's smuggling capability;

(D) the presence of engines that are excessively overpowered in relation to the design and size of the vessel;

(E) the presence of materials used to reduce or alter the heat or radar signature of the vessel and avoid detection;

(F) the presence of a camouflaging paint scheme, or of materials used to camouflage the vessel, to avoid detection; or

(G) the display of false vessel registration numbers, false indicia of vessel nationality, false vessel name, or false vessel homeport.

(2) The presence or absence of equipment, personnel, or cargo inconsistent with the type or declared purpose of the vessel.

(3) The presence of excessive fuel, lube oil, food, water, or spare parts, inconsistent with legitimate vessel operation, inconsistent with the construction or equipment of the vessel, or inconsistent with the character of the vessel's stated purpose.

(4) The operation of the vessel without lights during times lights are required to be displayed under applicable law or regulation and in a manner of navigation consistent with smuggling tactics used to avoid detection by law enforcement authorities.

(5) The failure of the vessel to stop or respond or heave to when hailed by government authority, especially where the vessel conducts evasive maneuvering when hailed.

(6) The declaration to government authority of apparently false information about the vessel, crew, or voyage or the failure to identify the vessel by name or country of registration when requested to do so by government authority.

(7) The presence of controlled substance residue on the vessel, on an item aboard the vessel, or on a person aboard the vessel, of a quantity or other nature which reasonably indicates manufacturing or distribution activity.

(8) The use of petroleum products or other substances on the vessel to foil the detection of controlled substance residue.

(9) The presence of a controlled substance in the water in the vicinity of the vessel, where given the currents, weather conditions, and course and speed of the vessel, the quantity or other nature is such that it reasonably indicates manufacturing or distribution activity.

47 U.S.C. § 312a
Anti-Drug Abuse Act of 1986, Public Law 99–570, sec. 3451
Revocation of private radio operator's license used in unlawful distribution of controlled substances

Title 47. Telegraphs, Telephones, and Radiotelegraphs

Chapter 5. Wire or Radio Communication

§ 312a. Revocation of operator's license used in unlawful distribution of controlled substances [1]

The Federal Communications Commission may revoke any private operator's license issued to any person under the Communications Act of 1934 (47 U.S.C. 151 et seq.) who is found to have willfully used said license for the purpose of distributing, or assisting in the distribution of, any controlled substance in violation of any provision of Federal law. In addition, the Federal Communications Commission may, upon the request of an appropriate Federal law enforcement agency, assist in the enforcement of Federal law prohibiting the use or distribution of any controlled substance where communications equipment within the jurisdiction of the Federal Communications Commission under the Communications Act of 1934 is willfully being used for purposes of distributing, or assisting in the distribution of, any such substance.

[1] Public Law 99–570, Title III, § 3451, Oct. 27, 1986, 100 Stat. 3207–103.

48 U.S.C. §§ 1494–1494c

United States Insular Areas Drug Abuse Act, Public Law 99–570, secs. 5002–5005

Application of the controlled substances laws to U.S. Caribbean and Pacific commonwealths and territories

Title 48. Territories and Insular Possessions

Chapter 10. Territorial Provisions of a General Nature

§ 1494. Purposes [1]

The purposes of sections 1494 to 1494c of this title are to improve enforcement of drug laws and enhance interdiction of illicit drug shipments in the Caribbean and Pacific territories and commonwealths of the United States and the Trust Territory of the Pacific Islands (or successor governments) and to assist public and private sector drug abuse and other substance prevention and treatment programs in United States associated insular areas.

§ 1494a. Annual reports to Congress [2]

(a) In general

The President shall report annually to the Congress as to—

(1) the efforts and success of Federal agencies in preventing the illegal entry into the United States of controlled substances from the insular areas of the United States outside the customs territory of the United States, the Trust Territory of the Pacific Islands, and states freely associated with the United States and the nature and extent of such illegal entry, and

(2) The efforts and success of Federal agencies in preventing the illegal entry from other nations, including states freely associated with the United States, of controlled substances into the United States territories, the Trust Territory of the Pacific Islands, and the commonwealths for use in the territories, the Trust Territory of the Pacific Islands, and commonwealths or for transshipment to the United States and the nature and extent of such illegal entry and use.

(b) Transmission date

The annual reports required by subsection (a) of this section shall be transmitted to the Committee on Natural Resources of the United States House of Representatives and to the Committee on

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[1] Public Law 99–570, Title V, § 5002, Oct. 27, 1986, 100 Stat. 3207–154; Public Law 100–690, Title IX, § 9308, Nov. 18, 1988, 102 Stat. 4538.

[2] Public Law 99–570, Title V, § 5003, Oct. 27, 1986, 100 Stat. 3207–155; Public Law 100–690, Title IX, § 9309, Nov. 18, 1988, 102 Stat. 4539; Public Law 103–437, § 17(a)(3), Nov. 2, 1994, 108 Stat. 4595.

Energy and Natural Resources of the United States Senate not later than the first day of October each year.

§ 1494b. Enforcement and administration in insular areas[3]

(a) American Samoa

(1) With the approval of the Attorney General of the United States or his designee, law enforcement officers of the Government of American Samoa are authorized to—

(A) execute and serve warrants, subpoenas, and summons issued under the authority of the United States;

(B) make arrests without warrant; and

(C) make seizures of property to carry out the purposes of sections 1494 to 1494c of this title, the Controlled Substances Import and Export Act (21 U.S.C. 951–970), and any other applicable narcotics laws of the United States.

(2) The Attorney General and the Secretaries of Education and Health and Human Services of the United States, as appropriate, are authorized to and, upon request of the Government of American Samoa, shall—

(A) train law enforcement officers and other personnel of the Government of American Samoa, and

(B) provide by purchase or lease law enforcement equipment and technical assistance to the Government of American Samoa to carry out the purposes of sections 1494 to 1494c of this title and any other Federal or territorial drug or other substance abuse laws.

(3) There are authorized to be appropriated $350,000 for fiscal year 1989 and annually thereafter for grants to the Government of American Samoa to be expended in accordance with a plan approved by the Secretary of the Interior in consultation with the Attorney General and the Secretaries of Education and Health and Human Services to carry out the purposes of sections 1494 to 1494c of this title, to remain available until expended.

(4) The Secretary of the Treasury in consultation with the Secretary of the Interior shall provide the Government of American Samoa with a vessel to be used in the enforcement of narcotics and other laws. There are authorized to be appropriated $500,000 for this purpose.

(b) Guam

(1) The Attorney General and the Secretaries of Education and Health and Human Services of the United States may provide and, upon request of the Government of Guam, shall provide appropriate training, technical assistance and equipment to the Government of Guam to carry out the purposes of sections 1494 to 1494c of this title and any other Federal or territorial drug or other substance abuse law.

(2) There are authorized to be appropriated $500,000 for fiscal year 1989 and annually thereafter for grants to the Government of Guam to be expended in accordance with a plan approved by the Secretary of the Interior in consultation with the Attorney General

[3] Public Law 99–570, Title V, § 5004, Oct. 27, 1986, 100 Stat. 3207–155; Public Law 100–690, Title IX, §§ 9302, 9303, 9304, 9305, 9306(b), 9307, Nov. 18, 1988, 102 Stat. 4536–4538.

and the Secretaries of Education and Health and Human Services, to carry out the purposes of sections 1494 to 1494c of this title, to remain available until expended.

(3) There are authorized to be appropriated to the Government of Guam $500,000 for grants to be expended in accordance with a plan approved by the Secretary of the Interior in consultation with the Attorney General for drug abuse law enforcement equipment.

(c) Northern Mariana Islands

(1) With the approval of the Attorney General of the United States or his designee, law enforcement officers of the Government of the Northern Mariana Islands are authorized to—

(A) execute and serve warrants, subpoenas, and summons issued under the authority of the United States;

(B) make arrests without warrant; and

(C) make seizures of property to carry out the purposes of sections 1494 to 1494c of this title, the Controlled Substances Import and Export Act (21 U.S.C. 951–970), and any other applicable narcotics laws of the United States.

(2) The Attorney General and the Secretaries of Education and Health and Human Services of the United States, as appropriate, are authorized to and, upon request of the Government of the Northern Mariana Islands, shall—

(A) train law enforcement officers and other personnel of the Government of the Northern Mariana Islands, and

(B) provide, by purchase or lease, law enforcement equipment and technical assistance to the Government of the Northern Mariana Islands to carry out the purposes of sections 1494 to 1494c of this title and any other Federal or commonwealth drug or other substance abuse law.

(3) There are authorized to be appropriated $125,000 for fiscal year 1989 and annually thereafter for grants to the Government of the Northern Mariana Islands to be expended in accordance with a plan approved by the Secretary of the Interior in consultation with the Attorney General and the Secretaries of Education and Health and Human Services to carry out the purposes of sections 1494 to 1494c of this title, to remain available until expended.

(4) Federal personnel and equipment assigned to Guam pursuant to subsection (b) of this section shall also be available to carry out the purposes of sections 1494 to 1494c of this title in the Northern Mariana Islands.

(d) Puerto Rico

(1) There are authorized to be appropriated for grants to the Government of Puerto Rico $7,000,000 for fiscal year 1989 and $2,000,000 annually thereafter for grants to the Government of Puerto Rico to carry out the purposes of Sections 1494 to 1494c of this title to be expended in accordance with a plan approved by the Executive Director of the White House Task Force on Puerto Rico in consultation with the Attorney General and the Secretaries of Education and Health and Human Services, to remain available until expended.

(2) The United States Customs Service should station an aerostat in Puerto Rico.

(3) Equipment provided to the Government of Puerto Rico pursuant to paragraph (1) of this subsection shall be made available upon request to the Federal agencies involved in drug interdiction in Puerto Rico.

(4)(A) The Attorney General and the Secretaries of Education and Health and Human Services of the United States may provide and, upon request of the Government of Puerto Rico, shall provide appropriate training, technical assistance and equipment to the Government of Puerto Rico to carry out the purposes of sections 1494 to 1494c of this title and any other Federal or commonwealth drug or other substance abuse law.

(B) There are authorized to be appropriated such sums as may be necessary to carry out subparagraph (A). Funds appropriated under this subparagraph shall remain available until expended.

(e) Virgin Islands

(1) There are authorized to be appropriated for grants to the Government of the Virgin Islands, $2,000,000 for fiscal year 1990 and annually thereafter to carry out the purposes of Sections 1494 to 1494c of this title to be expended in accordance with a plan approved by the Secretary of the Interior in consultation with the Attorney General and the Secretaries of Education and health and Human Services, to remain available until expended.

(2) The United States Coast Guard shall station a patrol vessel in St. Croix, Virgin Islands.

(3)(A) The Attorney General and the Secretaries of Education and Health and Human Services of the United States may provide and, upon request of the Government of the Virgin Islands, shall provide appropriate training, technical assistance and equipment to the Government of the United States Virgin Islands to carry out the purposes of sections 1494 to 1494c of this title and any other Federal or territorial drug or other substance abuse law.

(B) There are authorized to be appropriated such sums as may be necessary to carry out subparagraph (A). Funds appropriated under this subparagraph shall remain available until expended.

(4) To assist in the prosecution of the violation of the narcotics laws of the United States, the Attorney General of the United States shall assign the necessary personnel to serve in the office of the United States Attorney for the Virgin Islands appointed pursuant to section 1617 of this title.

(5) Effective fiscal year 1989, there are authorized to be appropriated for a grant to the Government of the Virgin Islands $2,500,000 to be expended in accordance with a plan approved by the Secretary of the Interior in consultation with the Secretary of Health and Human Services for a substance abuse facility.

(f) Palau

(1) The Attorney General and the Secretaries of Education and Health and Human Services are authorized to and, upon request of the Government of Palau, shall provide appropriate training, technical assistance, and equipment to carry out the purposes of sections 1494 to 1494c of this title and any other applicable Federal or insular drug or other substance abuse laws.

(2) There are authorized to be appropriated $500,000 for fiscal year 1989 and annually thereafter for grants to the Government of Palau to be expended in accordance with a plan to be approved by the Secretary of the Interior in consultation with the Attorney General and the Secretaries of Education, State, and Health and Human Services to carry out the purposes of sections 1494 to 1494c of this title.

(3) To the extent not prohibited under the Constitution of Palau, upon written request of the President of Palau, the Drug Enforcement Administration, the Federal Bureau of Investigation, the Secret Service, the Immigration and Naturalization Service, and the Customs Service are authorized to investigate any United States criminal laws which are applicable in Palau in cooperation with law enforcement agencies of Palau.

§ 1494c. Drug Enforcement Agency personnel assignments[4]

To assist in the enforcement of the controlled substances laws of the United States in coordination with law enforcement officers in insular areas in the eastern Caribbean and in the central and western Pacific, the Administrator of the Drug Enforcement Administration shall assign appropriate personnel and other resources to the Virgin Islands and Guam.

[4] Public Law 99–570, Title V, § 5005, as added Public Law 100–690, Title IX, § 9310, Nov. 18, 1988, 102 Stat. 4539.

48 U.S.C. § 1902
Compact of Free Association Act, Public Law 99–239, sec. 102
Ensuring that waters and territory of the United States and of Micronesia are not used for controlled substance violations

Chapter 18. Micronesia, Marshall Islands, and Palau

§ 1902. Agreements with Federated States of Micronesia [1]

(a) Law enforcement assistance

(1) Agreement

The President of the United States shall negotiate with the Government of the Federated States of Micronesia an agreement pursuant to section 175 of the Compact which is in addition to the Agreement pursuant to such section dated October 1, 1982, and transmitted to the Congress by the President on February 20, 1985. Such additional agreement shall provide as follows:

(A) Mutual assistance in law enforcement

The law enforcement agencies of the United States and the Federated States of Micronesia shall assist one another, as mutually agreed, in the prevention and investigation of crimes and the enforcement of the laws of the United States and the Federated States of Micronesia specified in subparagraph (C) of this paragraph. The United States and the Federated States of Micronesia will authorize mutual assistance with respect to investigations, inquiries, audits and related activities by the law enforcement agencies of both Governments in the United States and the Federated States of Micronesia. In conducting activities authorized in accordance with this section, the United States and the Federated States of Micronesia will act in accordance with the constitution and laws of the jurisdiction in which such activities are conducted.

(B) Narcotics and control of illegal substances

The United States and the Federated States of Micronesia will take all reasonable and necessary steps, as mutually agreed, based upon consultations in which the Attorney General or other designated official of each Government participates, to prevent the use of the lands, waters, and facilities of the United States or the Federated States of Micronesia for the purposes of cultivation of, production of, smuggling of, trafficking in, and abuse of any controlled

[1] Public Law 99–239, Title I, § 102, Jan. 14, 1986, 99 Stat. 1775.

substance as defined in section 802(6) of title 21 and Schedules I through V of Subchapter II of the Controlled Substances Act of the Federated States of Micronesia, or for the distribution of any such substance to or from the Federated States of Micronesia or to or from the United States or any of its territories or commonwealths.

(C) Other criminal laws

Assistance provided pursuant to this subsection shall also extend to, but not be limited to, prevention and prosecution of violations of the laws of the United States and the laws of the Federated States of Micronesia related to terrorism, espionage, racketeer influenced and corrupt organizations, and financial transactions which advance the interests of any person engaging in unlawful activities, as well as the schedule of offenses set forth in Appendix A of the subsidiary agreement to section 175 of the Compact.

(2) Technical and training assistance

Pursuant to sections 224 and 226 of the Compact, the United States shall provide non-reimbursable technical and training assistance as appropriate, including training and equipment for postal inspection of illicit drugs and other contraband, to enable the Government of the Federated States of Micronesia to develop and adequately enforce laws of the Federated States of Micronesia and to cooperate with the United States in the enforcement of criminal laws of the United States. Funds appropriated pursuant to section 1905(l) of this title may be used to reimburse State or local agencies providing such assistance.

(3) Consultation

Any official, designated by this joint resolution or by the President to negotiate any agreement under this section, shall consult with affected law enforcement agencies prior to entering into such an agreement on behalf of the United States.

(4) Report

The President shall report annually to Congress on the implementation of this subsection. Such report shall provide statistical and other information about the incidence of crimes in the Federated States of Micronesia which have an impact upon United States jurisdictions, and propose measures which the United States and the Federated States of Micronesia should take in order better to prevent and prosecute violations of the laws of the United States and the Federated States of Micronesia. The reports required under section 2291(e) of title 22 shall include relevant information concerning the Federated States of Micronesia.

(b) Economic development plans review process

(1) Submission

Notwithstanding section 211(b) of the Compact, the President may agree to an effective date for the Compact pursuant

to section 1901(a) of this title if the Government of the Federated States of Micronesia agrees to submit economic development plans consistent with section 211(b) of the Compact to the Government of the United States for concurrence at intervals no greater than every 5 years for the duration of the Compact. Any capital construction project and any planned independent purchase of aircraft which is to be financed (directly or indirectly) through the use of funds provided under section 211 of the Compact shall be identified in the economic development plans.

(2) United States Government review

The United States shall not concur in those development plans described in paragraph (1) of this subsection until—

(A) after the President of the United States has conducted a review and reported the findings of the President to the Congress; and

(B) the Congress has had 30 days (excluding days on which both Houses of Congress are not in session) to review the findings of the President.

(3) Report

The President shall complete the review under paragraph (2) and shall report the findings no later than 60 days after the President's receipt of such plans.

(4) Views and comments

The report shall include the views of the Secretary of the Interior, the Administrator of the Agency for International Development, and the heads of such other Executive departments as the President may decide to include in the report, as well as any comments which the Federated States of Micronesia may wish to have included.

(c) Agreement on audits

In accordance with section 233 of the Compact, the President of the United States, in consultation with the Comptroller General of the United States, shall negotiate with the Government of the Federated States of Micronesia modifications to the "Agreement Concerning Procedures for the Implementation of United States Economic Assistance, Programs and Services Provided in the Compact of Free Association", which shall provide as follows:

(1) General authority of the GAO to audit

(A) The Comptroller General of the United States (and his duly authorized representatives) shall have the authority to audit—

(i) all grants, program assistance, and other assistance provided to the Government of the Federated States of Micronesia under Articles I and II of Title Two of the Compact; and

(ii) any other assistance provided by the Government of the United States to the Government of the Federated States of Micronesia.

Such authority shall include authority for the Comptroller General to conduct or cause to be conducted any of the audits provided for in section 233 of the Compact. The authority provided in this paragraph shall continue for at least three years after the last such grant has been made or assistance has been provided.

(B) The Comptroller General (and his duly authorized representatives) shall also have authority to review any audit conducted by or on behalf of the Government of the United States. In this connection, the Comptroller General shall have access to such personnel and to such records, documents, working papers, automated data and files, and other information relevant to such review.

(2) GAO access to records

(A) In carrying out paragraph (1), the Comptroller General (and his duly authorized representatives) shall have such access to the personnel and (without cost) to records, documents, working papers, automated data and files, and other information relevant to such audits. The Comptroller General may duplicate any such records, documents, working papers, automated data and files, or other information relevant to such audits.

(B) Such records, documents, working papers, automated data and files, and other information regarding each such grant or other assistance shall be maintained for at least three years after the date such grant or assistance was provided and in a manner that permits such grants, assistance, and payments to be accounted for distinct from any other funds of the Government of the Federated States of Micronesia.

(3) Representative status for GAO representatives

The Comptroller General and his duly authorized representatives shall be accorded the status set forth in Article V of Title One of the Compact.

(4) Annual financial statements

As part of the annual report submitted by the Government of the Federated States of Micronesia under section 211 of the Compact, the Government shall include annual financial statements which account for the use of all of the funds provided by the Government of the United States to the Government under the Compact or otherwise. Such financial statements shall be prepared in accordance with generally accepted accounting procedures, except as may otherwise be mutually agreed. Not later than 180 days after the end of the United States fiscal year with respect to which such funds were provided, each such statement shall be submitted to the President for audit and transmission to the Congress.

(5) "Audits" defined

As used in this subsection, the term "audits" includes financial, program, and management audits, including determining—

(A) whether the Government of the Federated States of Micronesia has met the requirements set forth in the Compact, or any related agreement entered into under the Compact, regarding the purposes for which such grants and other assistance are to be used; and

(B) the propriety of the financial transactions of the Government of the Federated States of Micronesia pursuant to such grants or assistance.

(6) Cooperation by Federated States of Micronesia

The Government of the Federated States of Micronesia will cooperate fully with the Comptroller General of the United States in the conduct of such audits as the Comptroller General determines necessary to enable the Comptroller General to fully discharge his responsibilities under this joint resolution.

48 U.S.C. § 1903

Compact of Free Association Act, Public Law 99–239, sec. 103

Ensuring that waters and territory of the United States and of the Marshall Islands are not used for controlled substance violations

§ 1903. Agreements with and other provisions related to Marshall Islands [1]

(a) Law enforcement assistance

(1) Agreement

The President of the United States shall negotiate with the Government of the Marshall Islands an agreement pursuant to section 175 of the Compact which is in addition to the Agreement pursuant to such section dated May 30, 1982, and transmitted to the Congress by the President on February 20, 1985. Such additional agreement shall provide as follows:

(A) Mutual assistance in law enforcement

The law enforcement agencies of the United States and the Marshall Islands shall assist one another, as mutually agreed, in the prevention and investigation of crimes and the enforcement of the laws of the United States and the Marshall Islands specified in subparagraph (C) of this paragraph. The United States and the Marshall Islands will authorize mutual assistance with respect to investigations, inquiries, audits and related activities by the law enforcement agencies of both Governments in the United States and the Marshall Islands. In conducting activities authorized in accordance with this section, the United States and the Marshall Islands will act in accordance with the constitution and laws of the jurisdiction in which such activities are conducted.

(B) Narcotics and control of illegal substances

The United States and the Marshall Islands will take all reasonable and necessary steps, as mutually agreed, based upon consultations in which the Attorney General or other designated official of each Government participates, to prevent the use of the lands, waters, and facilities of the United States or the Marshall Islands for the purposes of cultivation of, production of, smuggling of, trafficking in, and abuse of any controlled substance as defined in section 802(6) of Title 21 and Schedules I through V of Subchapter

[1] Public Law 99–239, Title I, § 103, Jan. 14, 1986, 99 Stat. 1778; Public Law 100–446, Title I, § 115, Sept. 27, 1988, 102 Stat. 1802; Public Law 102–247, Title III, § 304, Feb. 24, 1992, 106 Stat. 39; Public Law 105–209, § 2, July 29, 1998., 112 Stat. 880.

II of the Controlled Substances Act of the Marshall Islands, or for the distribution of any such substance to or from the Marshall Islands or to or from the United States or any of its territories or commonwealths.

(C) Other criminal laws

Assistance provided pursuant to this subsection shall also extend to, but not be limited to, prevention and prosecution of violations of the laws of the United States and the laws of the Marshall Islands related to terrorism, espionage, racketeer influenced and corrupt organizations, and financial transactions which advance the interests of any person engaging in unlawful activities, as well as the schedule of offenses set forth in Appendix A of the subsidiary agreement to section 175 of the Compact.

(2) Technical and training assistance

Pursuant to sections 224 and 226 of the Compact, the United States shall provide non-reimbursable technical and training assistance as appropriate, including training and equipment for postal inspection of illicit drugs and other contraband, to enable the Government of the Marshall Islands to develop and adequately enforce laws of the Marshall Islands and to cooperate with the United States in the enforcement of criminal laws of the United States. Funds appropriated pursuant to section 1905(l) of this title may be used to reimburse State or local agencies providing such assistance.

(3) Consultation

Any official, designated by this joint resolution or by the President to negotiate any agreement under this section, shall consult with affected law enforcement agencies prior to entering into such an agreement on behalf of the United States.

(4) Report

The President shall report annually to Congress on the implementation of this subsection. Such report shall provide statistical and other information about the incidence of crimes in the Marshall Islands which have an impact upon United States jurisdictions, and propose measures which the United States and the Marshall Islands should take in order better to prevent and prosecute violations of the laws of the United States and the Marshall Islands. The reports required under section 2291(e) of Title 22 shall include relevant information concerning the Marshall Islands.

(b) Economic development plans review process

(1) Submission

Notwithstanding section 211(b) of the Compact, the President may agree to an effective date for the Compact pursuant to section 1901(b) of this title if the Government of the Marshall Islands agrees to submit economic development plans

consistent with section 211(b) of the Compact to the Government of the United States for concurrence at intervals no greater than every 5 years for the duration of the Compact. Any capital construction project and any planned independent purchase of aircraft which is to be financed (directly or indirectly) through the use of funds provided under section 211 of the Compact shall be identified in the economic development plans.

(2) United States Government review

The United States shall not concur in those development plans described in paragraph (1) of this subsection until—

(A) after the President of the United States has conducted a review and reported the findings of the President to the Congress; and

(B) the Congress has had 30 days (excluding days on which both Houses of Congress are not in session) to review the findings of the President.

(3) Report

The President shall complete the review under paragraph (2) and shall report the findings no later than 60 days after the President's receipt of such plans.

(4) Views and comments

The report shall include the views of the Secretary of the Interior, the Administrator of the Agency for International Development, and the heads of such other Executive departments as the President may decide to include in the report, as well as any comments which the Marshall Islands may wish to have included.

(c) Ejit

(1) The President of the United States shall negotiate with the Government of the Marshall Islands an agreement whereby, without prejudice as to any claims which have been or may be asserted by any party as to rightful title and ownership of any lands on Ejit, the Government of the Marshall Islands shall assure that lands on Ejit used as of January 1, 1985, by the people of Bikini, will continue to be available without charge for their use, until such time as Bikini is restored and inhabitable and the continued use of Ejit is no longer necessary, unless a Marshall Islands court of competent jurisdiction finally determines that there are legal impediments to continued use of Ejit by the people of Bikini.

(2) If the impediments described in paragraph (1) do arise, the United States will cooperate with the Government of the Marshall Islands in assisting any person adversely affected by such judicial determination to remain on Ejit, or in locating suitable and acceptable alternative lands for such person's use.

(3) Paragraph (1) shall not be applied in a manner which would prevent the Government of the Marshall Islands from acting in accordance with its constitutional processes to resolve title and ownership claims with respect to such lands or from taking substitute

or additional measures to meet the needs of the people of Bikini with their democratically expressed consent and approval.

(d) Kwajalein payments

(1) Statement of policy

The Congress of the United States hereby declares that it is the policy of the United States that payment of funds by the Government of the Marshall Islands to the landowners of Kwajalein Atoll in accordance with the land use agreement dated October 19, 1982, and the related allocation agreements, is required in order to ensure that the Government of the United States will be able to fulfill its obligations and responsibilities under Title Three of the Compact and the subsidiary agreements concluded pursuant thereto.

(2) Failure to pay

In the event that the Government of the Marshall Islands fails to make payments in accordance with paragraph (1) of this subsection, the Government of the United States shall initiate procedures under Section 313 of the Compact and consult with the Government of the Marshall Islands with respect to the basis for such non-payment of funds. The United States shall expeditiously resolve the matter of any non-payment of funds as described in paragraph (1) of this subsection pursuant to Section 313 of the Compact and the authority and responsibility of the Government of the United States for security and defense matters in or relating to the Marshall Islands. This paragraph shall be enforced, as may be necessary, in accordance with section 1905(g)(2) of this title.

(3) Assistance

The President is hereby authorized to make loans and grants to the Government of the Marshall Islands for the sole use of the Kwajalein Atoll Development Authority for the benefit of the Kwajalein landowners of amounts sought by such authority for development purposes, pursuant to a development plan for Kwajalein Atoll which such authority has adopted in accordance with applicable laws of the Marshall Islands. Such loans and grants shall be subject to such other terms and conditions as the President, in his discretion, may determine appropriate and necessary.

(e) Section 177 Agreement

(1) In furtherance of the purposes of Article I of the Subsidiary Agreement for Implementation of Section 177 of the Compact, the payment of the amount specified therein shall be made by the United States under Article I of the Agreement between the Government of the United States and the Government of the Marshall Islands for the Implementation of Section 177 of the Compact (hereafter in this subsection referred to as the "Section 177 Agreement") only after the Government of the Marshall Islands has notified the President of the United States as to which investment

management firm has been selected by such Government to act as Fund Manager under Article I of the Section 177 Agreement.

(2) In the event that the President determines that an investment management firm selected by the Government of the Marshall Islands does not meet the requirements specified in Article I of the Section 177 Agreement, the United States shall invoke the conference and dispute resolution procedures of Article II of Title Four of the Compact. Pending the resolution of such a dispute and until a qualified Fund Manager has been designated, the Government of the Marshall Islands shall place the funds paid by the United States pursuant to Article I of the Section 177 Agreement into an interest-bearing escrow account. Upon designation of a qualified Fund Manager, all funds in the escrow account shall be transferred to the control of such Fund Manager for management pursuant to the Section 177 Agreement.

(3) If the Government of the Marshall Islands determines that some other investment firm should act as Fund Manager in place of the firm first (or subsequently) selected by such Government, the Government of the Marshall Islands shall so notify the President of the United States, identifying the firm selected by such Government to become Fund Manager, and the President shall proceed to evaluate the qualifications of such identified firm.

(4) At the end of 15 years after the effective date of the Compact, the firm then acting as Fund Manager shall transfer to the Government of the Marshall Islands, or to such account as such Government shall so notify the Fund Manager, all remaining funds and assets being managed by the Fund Manager under the Section 177 Agreement.

(5) An annual report concerning all actions of the Fund Manager pursuant to the Section 177 Agreement and this joint resolution, including information prepared by the Fund Manager, shall be transmitted by the Government of the Marshall Islands to the Congress. Such report shall include such information (whether received from the Fund Manager or any other source) as relates to the disbursements provided for in Article II of the Section 177 Agreement. Such report shall be made public.

(f) Nuclear test effects

In approving the Compact, the Congress understands and intends that the peoples of Bikini, Enewetak, Rongelap, and Utrik, who were affected by the United States nuclear weapons testing program in the Marshall Islands, will receive the amounts of $75,000,000 (Bikini); $48,750,000 (Enewetak),[2] $37,500,000 (Rongelap); and $22,500,000 (Utrik), respectively, which amounts shall be paid out of proceeds from the fund established under Article I, section 1 of the subsidiary agreement for the implementation of section 177 of the Compact. The amounts specified in this subsection shall be in addition to any amounts which may be awarded to claimants pursuant to Article IV of the subsidiary agreement for the implementation of Section 177 of the Compact.

[2] So in original. The comma probably should be a semicolon.

(g) Espousal provisions

(1) It is the intention of the Congress of the United States that the provisions of section 177 of the Compact of Free Association and the Agreement between the Government of the United States and the Government of the Marshall Islands for the Implementation of Section 177 of the Compact (hereafter in this subsection referred to as the "Section 177 Agreement") constitute a full and final settlement of all claims described in Articles X and XI of the Section 177 Agreement, and that any such claims be terminated and barred except insofar as provided for in the Section 177 Agreement.

(2) In furtherance of the intention of Congress as stated in paragraph (1) of this subsection, the Section 177 Agreement is hereby ratified and approved. It is the explicit understanding and intent of Congress that the jurisdictional limitations set forth in Article XII of such Agreement are enacted solely and exclusively to accomplish the objective of Article X of such Agreement and only as a clarification of the effect of Article X, and are not to be construed or implemented separately from Article X.

(h) DOE radiological health care program; USDA agricultural and food programs

(1) Marshall Islands program

Notwithstanding any other provision of law, upon the request of the Government of the Marshall Islands, the President (either through an appropriate department or agency of the United States or by contract with a United States firm) shall continue to provide special medical care and logistical support thereto for the remaining 174 members of the population of Rongelap and Utrik who were exposed to radiation resulting from the 1954 United States thermonuclear "Bravo" test, pursuant to Public Laws 95–134 and 96–205. Such medical care and its accompanying logistical support shall total $22,500,000 over the first 11 years of the Compact.

(2) Agricultural and food programs

Notwithstanding any other provision of law, upon the request of the Government of the Marshall Islands, for the first fifteen years after the effective date of the Compact, the President (either through an appropriate department or agency of the United States or by contract with a United States firm or by a grant to the Government of the Republic of the Marshall Islands which may further contract only with a United States firm or a Republic of the Marshall Islands firm, the owners, officers and majority of the employees of which are citizens of the United States or the Republic of the Marshall Islands) shall provide technical and other assistance—

(A) without reimbursement, to continue the planting and agricultural maintenance program on Enewetak;

(B) without reimbursement, to continue the food programs of the Bikini, Rongelap, Utrik, and Enewetak people described in section 1(d) of Article II of the Subsidiary Agreement for the Implementation of Section 177 of the Compact and for continued waterborne transportation of

agricultural products to Enewetak including operations and maintenance of the vessel used for such purposes. The President shall ensure the assistance provided under these programs reflects the changes in the population since the inception of such programs.

(3) Payments

Payments under this subsection shall be provided to such extent or in such amounts as are necessary for services and other assistance provided pursuant to this subsection. It is the sense of Congress that after the periods of time specified in paragraphs (1) and (2) of this subsection, consideration will be given to such additional funding for these programs as may be necessary.

(i) Rongelap

(1) Because Rongelap was directly affected by fallout from a 1954 United States thermonuclear test and because the Rongelap people remain unconvinced that it is safe to continue to live on Rongelap Island, it is the intent of Congress to take such steps (if any) as may be necessary to overcome the effects of such fallout on the habitability of Rongelap Island, and to restore Rongelap Island, if necessary, so that it can be safely inhabited. Accordingly, it is the expectation of the Congress that the Government of the Marshall Islands shall use such portion of the funds specified in Article II, section 1(e) of the subsidiary agreement for the implementation of section 177 of the Compact as are necessary for the purpose of contracting with a qualified scientist or group of scientists to review the data collected by the Department of Energy relating to radiation levels and other conditions on Rongelap Island resulting from the thermonuclear test. It is the expectation of the Congress that the Government of the Marshall Islands, after consultation with the people of Rongelap, shall select the party to review such data, and shall contract for such review and for submission of a report to the President of the United States and the Congress as to the results thereof.

(2) The purpose of the review referred to in paragraph (1) of this subsection shall be to establish whether the data cited in support of the conclusions as to the habitability of Rongelap Island, as set forth in the Department of Energy report entitled: "The Meaning of Radiation for Those Atolls in the Northern Part of the Marshall Islands That Were Surveyed in 1978", dated November 1982, are adequate and whether such conclusions are fully supported by the data. If the party reviewing the data concludes that such conclusions as to habitability are fully supported by adequate data, the report to the President of the United States and the Congress shall so state. If the party reviewing the data concludes that the data are inadequate to support such conclusions as to habitability or that such conclusions as to habitability are not fully supported by the data, the Government of the Marshall Islands shall contract with an appropriate scientist or group of scientists to undertake a complete survey of radiation and other effects of the nuclear testing program relating to the habitability of Rongelap Island. Such sums as are necessary for such survey and report concerning the results

thereof and as to steps needed to restore the habitability of Rongelap Island are authorized to be made available to the Government of the Marshall Islands.

(3) It is the intent of Congress that such steps (if any) as are necessary to restore the habitability of Rongelap Island and return the Rongelap people to their homeland will be taken by the United States in consultation with the Government of the Marshall Islands and, in accordance with its authority under the Constitution of the Marshall Islands, the Rongelap local government council.

(j) Four Atoll Health Care Program

(1) Services provided by the United States Public Health Service or any other United States agency pursuant to section 1(a) of Article II of the Agreement for the Implementation of Section 177 of the Compact (hereafter in this subsection referred to as the "Section 177 Agreement") shall be only for services to the people of the Atolls of Bikini, Enewetak, Rongelap, and Utrik who were affected by the consequences of the United States nuclear testing program, pursuant to the program described in Public Law 95–134 and Public Law 96–205 and their descendants (and any other persons identified as having been so affected if such identification occurs in the manner described in such public laws). Nothing in this subsection shall be construed as prejudicial to the views or policies of the Government of the Marshall Islands as to the persons affected by the consequences of the United States nuclear testing program.

(2) At the end of the first year after the effective date of the Compact and at the end of each year thereafter, the providing agency or agencies shall return to the Government of the Marshall Islands any unexpended funds to be returned to the Fund Manager (as described in Article I of the Section 177 Agreement) to be covered into the Fund to be available for future use.

(3) The Fund Manager shall retain the funds returned by the Government of the Marshall Islands pursuant to paragraph (2) of this subsection, shall invest and manage such funds, and at the end of 15 years after the effective date of the Compact, shall make from the total amount so retained and the proceeds thereof annual disbursements sufficient to continue to make payments for the provision of health services as specified in paragraph (1) of this subsection to such extent as may be provided in contracts between the Government of the Marshall Islands and appropriate United States providers of such health services.

(k) Enjebi Community Trust Fund

Notwithstanding any other provision of law, the Secretary of the Treasury shall establish on the books of the Treasury of the United States a fund having the status specified in Article V of the subsidiary agreement for the implementation of Section 177 of the Compact, to be known as the "Enjebi Community Trust Fund" (hereafter in this subsection referred to as the "Fund"), and shall credit to the Fund the amount of $7,500,000. Such amount, which shall be ex gratia, shall be in addition to and not charged against any other funds provided for in the Compact and its subsidiary agreements, this joint resolution, or any other Act. Upon receipt by the President of the United States of the agreement described in

this subsection, the Secretary of the Treasury, upon request of the Government of the Marshall Islands, shall transfer the Fund to the Government of the Marshall Islands, provided that the Government of the Marshall Islands agrees as follows:

(1) Enjebi Trust Agreement

The Government of the Marshall Islands and the Enewetak Local Government Council, in consultation with the people of Enjebi, shall provide for the creation of the Enjebi Community Trust Fund and the employment of the manager of the Enewetak Fund established pursuant to the Section 177 Agreement as trustee and manager of the Enjebi Community Trust Fund, or, should the manager of the Enewetak Fund not be acceptable to the people of Enjebi, another United States investment manager with substantial experience in the administration of trusts and with funds under management in excess of 250 million dollars.

(2) Monitor conditions

Upon the request of the Government of the Marshall Islands, the United States shall monitor the radiation and other conditions on Enjebi and within one year of receiving such a request shall report to the Government of the Marshall Islands when the people of Enjebi may resettle Enjebi under circumstances where the radioactive contamination at Enjebi, including contamination derived from consumption of locally grown food products, can be reduced or otherwise controlled to meet whole body Federal radiation protection standards for the general population, including mean annual dose and mean 30-year cumulative dose standards.

(3) Resettlement of Enjebi

In the event that the United States determines that the people of Enjebi can within 25 years of January 14, 1986, resettle Enjebi under the conditions set forth in paragraph (2) of this subsection, then upon such determination there shall be available to the people of Enjebi from the Fund such amounts as are necessary for the people of Enjebi to do the following, in accordance with a plan developed by the Enewetak Local Government Council and the people of Enjebi, and concurred with by the Government of the Marshall Islands to assure consistency with the government's overall economic development plan:

(A) Establish a community on Enjebi Island for the use of the people of Enjebi.

(B) Replant Enjebi with appropriate food-bearing and other vegetation.

(4) Resettlement of other location

In the event that the United States determines that within 25 years of January 14, 1986, the people of Enjebi cannot resettle Enjebi without exceeding the radiation standards set forth in paragraph (2) of this subsection, then the fund manager shall be directed by the trust instrument to distribute the Fund to the people of Enjebi for their resettlement at some

other location in accordance with a plan, developed by the Enewetak Local Government Council and the people of Enjebi and concurred with by the Government of the Marshall Islands, to assure consistency with the government's overall economic development plan.

(5) Interest from fund

Prior to and during the distribution of the corpus of the Fund pursuant to paragraphs (3) and (4) of this subsection, the people of Enjebi may, if they so request, receive the interest earned by the Fund on no less frequent a basis than quarterly.

(6) Disclaimer of liability

Neither under the laws of the Marshall Islands nor under the laws of the United States, shall the Government of the United States be liable for any loss or damage to person or property in respect to the resettlement of Enjebi by the people of Enjebi, pursuant to the provision of this subsection or otherwise.

(l) Bikini Atoll cleanup

(1) Declaration of policy

The Congress hereby determines and declares that it is the policy of the United States, to be supported by the full faith and credit of the United States, that because the United States, through its nuclear testing and other activities, rendered Bikini Atoll unsafe for habitation by the people of Bikini, the United States will fulfill its responsibility for restoring Bikini Atoll to habitability, as set forth in paragraphs (2) and (3) of this subsection.

(2) Cleanup funds

There are hereby authorized to be appropriated such sums as are necessary to implement the settlement agreement of March 15, 1985, in The People of Bikini, et al. against United States of America, et al., Civ. No. 84–0425 (D. Ha.).

(3) Conditions of funding

The funds referred to in paragraph (2) shall be made available pursuant to Article VI, Section 1 of the Compact Section 177 Agreement upon completion of the events set forth in the settlement agreement referred to in paragraph (2) of this subsection.

(m) Agreement on audits

In accordance with section 233 of the Compact, the President of the United States, in consultation with the Comptroller General of the United States, shall negotiate with the Government of the Marshall Islands an agreement which shall provide as follows:

(1) General authority of GAO to audit

(A) The Comptroller General of the United States (and his duly authorized representatives) shall have the authority to audit—

(i) all grants, program assistance, and other assistance provided to the Government of the Marshall Islands under Articles I and II of Title Two of the Compact; and

(ii) any other assistance provided by the Government of the United States to the Government of the Marshall Islands.

Such authority shall include authority for the Comptroller General to conduct or cause to be conducted any of the audits provided for in section 233 of the Compact. The authority provided in this paragraph shall continue for at least three years after the last such grant has been made or assistance has been provided.

(B) The Comptroller General (and his duly authorized representatives) shall also have authority to review any audit conducted by or on behalf of the Government of the United States. In this connection, the Comptroller General shall have access to such personnel and to such records, documents, working papers, automated data and files, and other information relevant to such review.

(2) GAO access to records

(A) In carrying out paragraph (1), the Comptroller General (and his duly authorized representatives) shall have such access to the personnel and (without cost) to records, documents, working papers, automated data and files, and other information relevant to such audits. The Comptroller General may duplicate any such records, documents, working papers, automated data and files, or other information relevant to such audits.

(B) Such records, documents, working papers, automated data and files, and other information regarding each such grant or other assistance shall be maintained for at least three years after the date such grant or assistance was provided and in a manner that permits such grants, assistance, and payments to be accounted for distinct from any other funds of the Government of the Marshall Islands.

(3) Representative status for GAO representatives

The Comptroller General and his duly authorized representatives shall be accorded the status set forth in Article V of Title One of the Compact.

(4) Annual financial statements

As part of the annual report submitted by the Government of the Marshall Islands under section 211 of the Compact, the Government shall include annual financial statements which account for the use of all of the funds provided by the Government of the United States to the Government under the Compact or otherwise. Such financial statements shall be prepared

in accordance with generally accepted accounting procedures, except as may otherwise be mutually agreed. Not later than 180 days after the end of the United States fiscal year with respect to which such funds were provided, each such statement shall be submitted to the President for audit and transmission to the Congress.

(5) "Audits" defined

As used in this subsection, the term "audits" includes financial, program, and management audits, including determining—

(A) whether the Government of the Marshall Islands has met the requirements set forth in the Compact, or any related agreement entered into under the Compact, regarding the purposes for which such grants and other assistance are to be used; and

(B) the propriety of the financial transactions of the Government of the Marshall Islands pursuant to such grants or assistance.

(6) Cooperation by Marshall Islands

The Government of the Marshall Islands will cooperate fully with the Comptroller General of the United States in the conduct of such audits as the Comptroller General determines necessary to enable the Comptroller General to fully discharge his responsibilities under this joint resolution.

48 U.S.C. § 1972

Compact of Free Association with Palau Act, Public Law 101–219, sec. 201

Authorizing the President to negotiate agreements with Micronesia, the Marshall Islands, and Palau to permit the regulated distribution of controlled substances there

§ 1972. Controlled substances in freely associated states [1]

(a) In general

The President is authorized to negotiate agreements which provide—

(1) that the United States shall carry out the provisions of part C of the Controlled Substances Act (21 U.S.C. 821 et seq.) as necessary to provide for the lawful distribution of controlled substances in the freely associated states; and

(2) that a freely associated state which institutes and maintains a voluntary system to report annual estimates of narcotics needs to the International Narcotics Control Board, and which imposes controls on imports of narcotic drugs consistent with the Single Convention on Narcotic Drugs, 1961, shall be eligible for exports of narcotic drugs from the United States in the same manner as a country meeting the requirements of subsection (a) of section 1003 of the Controlled Substances Act (21 U.S.C. 953).

(b) Effective date

Agreements concluded pursuant to this section shall become effective pursuant to section 1901(f)(5) of this title or section 1931(d)(5) of this title, as may be applicable.

[1] Public Law 101–219, Title II, § 201, Dec. 12, 1989, 103 Stat. 1874.

49 U.S.C. § 5331
Alcohol and controlled substance testing relating to mass transit

Title 49. Transportation

Chapter 53. Mass Transportation

§ 5331. Alcohol and controlled substances testing [1]

(a) DEFINITIONS.—In this section—

(1) "controlled substance" means any substance under section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802) whose use the Secretary of Transportation decides has a risk to transportation safety.

(2) "person" includes any entity organized or existing under the laws of the United States, a State, territory, or possession of the United States, or a foreign country.

(3) "mass transportation" means any form of mass transportation, except a form the Secretary decides is covered adequately, for employee alcohol and controlled substances testing purposes, under section 20140 or 31306 of this title.

(b) TESTING PROGRAM FOR MASS TRANSPORTATION EMPLOYEES.—(1)(A) In the interest of mass transportation safety, the Secretary shall prescribe regulations that establish a program requiring mass transportation operations that receive financial assistance under section 5307, 5309, or 5311 of this title or section 103(e)(4) of title 23 to conduct preemployment, reasonable suspicion, random, and post-accident testing of mass transportation employees responsible for safety-sensitive functions (as decided by the Secretary) for the use of a controlled substance in violation of law or a United States Government regulation, and to conduct reasonable suspicion, random, and post-accident testing of such employees for the use of alcohol in violation of law or a United States Government regulation. The regulations shall permit such operations to conduct preemployment testing of such employees for the use of alcohol.

(B) When the Secretary of Transportation considers it appropriate in the interest of safety, the Secretary may prescribe regulations for conducting periodic recurring testing of mass transportation employees responsible for safety-sensitive functions (as decided by the Secretary) for the use of alcohol or a controlled substance in violation of law or a Government regulation.

(2) In prescribing regulations under this subsection, the Secretary of Transportation—

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[1] Added by Public Law 103–272, § 1(d), July 5, 1994, 108 Stat. 832, and amended by Public Law 103–429, § 6(13), Oct. 31, 1994, 108 Stat. 4379; Public Law 104–59, Title III, § 342(a), Nov. 28, 1995, 109 Stat. 608.

(A) shall require that post-accident testing of such a mass transportation employee be conducted when loss of human life occurs in an accident involving mass transportation; and

(B) may require that post-accident testing of such a mass transportation employee be conducted when bodily injury or significant property damage occurs in any other serious accident involving mass transportation.

(c) DISQUALIFICATIONS FOR USE.—(1) When the Secretary of Transportation considers it appropriate, the Secretary shall require disqualification for an established period of time or dismissal of any employee referred to in subsection (b)(1) of this section who is found—

(A) to have used or been impaired by alcohol when on duty; or

(B) to have used a controlled substance, whether or not on duty, except as allowed for medical purposes by law or regulation.

(2) This section does not supersede any penalty applicable to a mass transportation employee under another law.

(d) TESTING AND LABORATORY REQUIREMENTS.—In carrying out subsection (b) of this section, the Secretary of Transportation shall develop requirements that shall—

(1) promote, to the maximum extent practicable, individual privacy in the collection of specimens;

(2) for laboratories and testing procedures for controlled substances, incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing—

(A) comprehensive standards for every aspect of laboratory controlled substances testing and laboratory procedures to be applied in carrying out this section, including standards requiring the use of the best available technology to ensure the complete reliability and accuracy of controlled substances tests and strict procedures governing the chain of custody of specimens collected for controlled substances testing;

(B) the minimum list of controlled substances for which individuals may be tested; and

(C) appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform controlled substances testing in carrying out this section;

(3) require that a laboratory involved in controlled substances testing under this section have the capability and facility, at the laboratory, of performing screening and confirmation tests;

(4) provide that all tests indicating the use of alcohol or a controlled substance in violation of law or a Government regulation be confirmed by a scientifically recognized method of testing capable of providing quantitative information about alcohol or a controlled substance;

(5) provide that each specimen be subdivided, secured, and labeled in the presence of the tested individual and that a part

of the specimen be retained in a secure manner to prevent the possibility of tampering, so that if the individual's confirmation test results are positive the individual has an opportunity to have the retained part tested by a 2d confirmation test done independently at another certified laboratory if the individual requests the 2d confirmation test not later than 3 days after being advised of the results of the first confirmation test;

(6) ensure appropriate safeguards for testing to detect and quantify alcohol in breath and body fluid samples, including urine and blood, through the development of regulations that may be necessary and in consultation with the Secretary of Health and Human Services;

(7) provide for the confidentiality of test results and medical information (except information about alcohol or a controlled substance) of employees, except that this clause does not prevent the use of test results for the orderly imposition of appropriate sanctions under this section; and

(8) ensure that employees are selected for tests by nondiscriminatory and impartial methods, so that no employee is harassed by being treated differently from other employees in similar circumstances.

(e) REHABILITATION.—The Secretary of Transportation shall prescribe regulations establishing requirements for rehabilitation programs that provide for the identification and opportunity for treatment of any mass transportation employee referred to in subsection (b)(1) of this section who is found to have used alcohol or a controlled substance in violation of law or a Government regulation. The Secretary shall decide on the circumstances under which employees shall be required to participate in a program. This subsection does not prevent a mass transportation operation from establishing a program under this section in cooperation with another mass transportation operation.

(f) RELATIONSHIP TO OTHER LAWS, REGULATIONS, STANDARDS, AND ORDERS.—(1) A State or local government may not prescribe, issue, or continue in effect a law, regulation, standard, or order that is inconsistent with regulations prescribed under this section. However, a regulation prescribed under this section does not preempt a State criminal law that imposes sanctions for reckless conduct leading to loss of life, injury, or damage to property.

(2) In prescribing regulations under this section, the Secretary of Transportation—

(A) shall establish only requirements that are consistent with international obligations of the United States; and

(B) shall consider applicable laws and regulations of foreign countries.

(3) This section does not prevent the Secretary of Transportation from continuing in effect, amending, or further supplementing a regulation prescribed before October 28, 1991, governing the use of alcohol or a controlled substance by mass transportation employees.

(g) INELIGIBILITY FOR ASSISTANCE.—A person is not eligible for financial assistance under section 5307, 5309, or 5311 of this title or section 103(e)(4) of title 23 if the person is required, under regulations the Secretary of Transportation prescribes under this section,

to establish a program of alcohol and controlled substances testing and does not establish the program.

49 U.S.C. § 20135

Following satisfactory completion of a rehabilitation program, an individual may not be denied a locomotive operator's license based solely on an earlier conviction of operating a motor vehicle under the influence of alcohol or controlled substances

Chapter 201. General

§ 20135. Licensing or certification of locomotive operators [1]

(a) GENERAL.—The Secretary of Transportation shall prescribe regulations and issue orders to establish a program requiring the licensing or certification, after one year after the program is established, of any operator of a locomotive.

(b) PROGRAM REQUIREMENTS.—The program established under subsection (a) of this section—

(1) shall be carried out through review and approval of each railroad carrier's operator qualification standards;

(2) shall provide minimum training requirements;

(3) shall require comprehensive knowledge of applicable railroad carrier operating practices and rules;

(4) except as provided in subsection (c)(1) of this section, shall require consideration, to the extent the information is available, of the motor vehicle driving record of each individual seeking licensing or certification, including—

(A) any denial, cancellation, revocation, or suspension of a motor vehicle operator's license by a State for cause within the prior 5 years; and

(B) any conviction within the prior 5 years of an offense described in section 30304(a)(3)(A) or (B) of this title;

(5) may require, based on the individual's driving record, disqualification or the granting of a license or certification conditioned on requirements the Secretary prescribes; and

(6) shall require an individual seeking a license or certification—

(A) to request the chief driver licensing official of each State in which the individual has held a motor vehicle operator's license within the prior 5 years to provide information about the individual's driving record to the individual's employer, prospective employer, or the Secretary, as the Secretary requires; and

(B) to make the request provided for in section 30305(b)(4) of this title for information to be sent to the individual's employer, prospective employer, or the Secretary, as the Secretary requires.

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 874.

(c) WAIVERS.—(1) The Secretary shall prescribe standards and establish procedures for waiving subsection (b)(4) of this section for an individual or class of individuals who the Secretary decides are not currently unfit to operate a locomotive. However, the Secretary may waive subsection (b)(4) for an individual or class of individuals with a conviction, cancellation, revocation, or suspension described in paragraph (2)(A) or (B) of this subsection only if the individual or class, after the conviction, cancellation, revocation, or suspension, successfully completes a rehabilitation program established by a railroad carrier or approved by the Secretary.

(2) If an individual, after the conviction, cancellation, revocation, or suspension, successfully completes a rehabilitation program established by a railroad carrier or approved by the Secretary, the individual may not be denied a license or certification under subsection (b)(4) of this section because of—

(A) a conviction for operating a motor vehicle when under the influence of, or impaired by, alcohol or a controlled substance; or

(B) the cancellation, revocation, or suspension of the individual's motor vehicle operator's license for operating a motor vehicle when under the influence of, or impaired by, alcohol or a controlled substance.

(d) OPPORTUNITY FOR HEARING.—An individual denied a license or certification or whose license or certification is conditioned on requirements prescribed under subsection (b)(4) of this section shall be entitled to a hearing under section 20103(e) of this title to decide whether the license has been properly denied or conditioned.

(e) OPPORTUNITY TO EXAMINE AND COMMENT ON INFORMATION.—The Secretary, employer, or prospective employer, as appropriate, shall make information obtained under subsection (b)(6) of this section available to the individual. The individual shall be given an opportunity to comment in writing about the information. Any comment shall be included in any record or file maintained by the Secretary, employer, or prospective employer that contains information to which the comment is related.

§ 20140. Alcohol and controlled substances testing [1]

(a) DEFINITION.—In this section, "controlled substance" means any substance under section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802) specified by the Secretary of Transportation.

(b) GENERAL.—(1) In the interest of safety, the Secretary of Transportation shall prescribe regulations and issue orders, not later than October 28, 1992, related to alcohol and controlled substances use in railroad operations. The regulations shall establish a program requiring—

(A) a railroad carrier to conduct preemployment, reasonable suspicion, random, and post-accident testing of all railroad employees responsible for safety-sensitive functions (as decided by the Secretary) for the use of a controlled substance in violation of law or a United States Government regulation, and to conduct reasonable suspicion, random, and post-accident testing of such employees for the use of alcohol in violation of law or a United States Government regulation; the regulations shall permit such railroad carriers to conduct preemployment testing of such employees for the use of alcohol; and

(B) when the Secretary considers it appropriate, disqualification for an established period of time or dismissal of any employee found—

(i) to have used or been impaired by alcohol when on duty; or

(ii) to have used a controlled substance, whether or not on duty, except as allowed for medical purposes by law or a regulation or order under this chapter.

(2) When the Secretary of Transportation considers it appropriate in the interest of safety, the Secretary may prescribe regulations and issue orders requiring railroad carriers to conduct periodic recurring testing of railroad employees responsible for safety-sensitive functions (as decided by the Secretary) for the use of alcohol or a controlled substance in violation of law or a Government regulation.

(c) TESTING AND LABORATORY REQUIREMENTS.—In carrying out this section, the Secretary of Transportation shall develop requirements that shall—

(1) promote, to the maximum extent practicable, individual privacy in the collection of specimens;

(2) for laboratories and testing procedures for controlled substances, incorporate the Department of Health and Human

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 876, and amended by Public Law 104–59, Title III, § 342(b), Nov. 28, 1995, 109 Stat. 609.

Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing—

(A) comprehensive standards for every aspect of laboratory controlled substances testing and laboratory procedures to be applied in carrying out this section, including standards requiring the use of the best available technology to ensure the complete reliability and accuracy of controlled substances tests and strict procedures governing the chain of custody of specimens collected for controlled substances testing;

(B) the minimum list of controlled substances for which individuals may be tested; and

(C) appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform controlled substances testing in carrying out this section;

(3) require that a laboratory involved in controlled substances testing under this section have the capability and facility, at the laboratory, of performing screening and confirmation tests;

(4) provide that all tests indicating the use of alcohol or a controlled substance in violation of law or a Government regulation be confirmed by a scientifically recognized method of testing capable of providing quantitative information about alcohol or a controlled substance;

(5) provide that each specimen be subdivided, secured, and labeled in the presence of the tested individual and that a part of the specimen be retained in a secure manner to prevent the possibility of tampering, so that if the individual's confirmation test results are positive the individual has an opportunity to have the retained part tested by a 2d confirmation test done independently at another certified laboratory if the individual requests the 2d confirmation test not later than 3 days after being advised of the results of the first confirmation test;

(6) ensure appropriate safeguards for testing to detect and quantify alcohol in breath and body fluid samples, including urine and blood, through the development of regulations that may be necessary and in consultation with the Secretary of Health and Human Services;

(7) provide for the confidentiality of test results and medical information (other than information about alcohol or a controlled substance) of employees, except that this clause does not prevent the use of test results for the orderly imposition of appropriate sanctions under this section; and

(8) ensure that employees are selected for tests by nondiscriminatory and impartial methods, so that no employee is harassed by being treated differently from other employees in similar circumstances.

(d) REHABILITATION.—The Secretary of Transportation shall prescribe regulations or issue orders establishing requirements for rehabilitation programs that at least provide for the identification and opportunity for treatment of railroad employees responsible for safety-sensitive functions (as decided by the Secretary) in need of

assistance in resolving problems with the use of alcohol or a controlled substance in violation of law or a Government regulation. The Secretary shall decide on the circumstances under which employees shall be required to participate in a program. Each railroad carrier is encouraged to make such a program available to all of its employees in addition to employees responsible for safety-sensitive functions. This subsection does not prevent a railroad carrier from establishing a program under this subsection in cooperation with another railroad carrier.

(e) INTERNATIONAL OBLIGATIONS AND FOREIGN LAWS AND REGULATIONS.—In carrying out this section, the Secretary of Transportation—

(1) shall establish only requirements that are consistent with international obligations of the United States; and

(2) shall consider applicable laws and regulations of foreign countries.

(f) OTHER REGULATIONS ALLOWED.—This section does not prevent the Secretary of Transportation from continuing in effect, amending, or further supplementing a regulation prescribed or order issued before October 28, 1991, governing the use of alcohol or a controlled substance in railroad operations.

49 U.S.C. §§ 30301–30308

National driver registration information including that relating to convictions for operating under the influence of a controlled substance

Chapter 303. National Driver Register

§ 30301. Definitions [1]

In this chapter—

(1) "alcohol" has the same meaning given that term in regulations prescribed by the Secretary of Transportation.

(2) "chief driver licensing official" means the official in a State who is authorized to—

(A) maintain a record about a motor vehicle operator's license issued by the State; and

(B) issue, deny, revoke, suspend, or cancel a motor vehicle operator's license issued by the State.

(3) "controlled substance" has the same meaning given that term in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802).

(4) "motor vehicle" means a vehicle, machine, tractor, trailer, or semitrailer propelled or drawn by mechanical power and used on public streets, roads, or highways, but does not include a vehicle operated only on a rail line.

(5) "motor vehicle operator's license" means a license issued by a State authorizing an individual to operate a motor vehicle on public streets, roads, or highways.

(6) "participating State" means a State that has notified the Secretary under section 30303 of this title of its participation in the National Driver Register.

(7) "State" means a State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States.

(8) "State of record" means a State that has given the Secretary a report under section 30304 of this title about an individual who is the subject of a request for information made under section 30305 of this title.

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 973.

§ 30302. National Driver Register[2]

(a) ESTABLISHMENT AND CONTENTS.—The Secretary of Transportation shall establish as soon as practicable and maintain a National Driver Register to assist chief driver licensing officials of participating States in exchanging information about the motor vehicle driving records of individuals. The Register shall contain an index of the information reported to the Secretary under section 30304 of this title. The Register shall enable the Secretary (electronically or, until all States can participate electronically, by United States mail)—

(1) to receive information submitted under section 30304 of this title by the chief driver licensing official of a State of record;

(2) to receive a request for information made by the chief driver licensing official of a participating State under section 30305 of this title;

(3) to refer the request to the chief driver licensing official of a State of record; and

(4) in response to the request, to relay information provided by a chief driver licensing official of a State of record to the chief driver licensing official of a participating State, without interception of the information.

(b) ACCURACY OF INFORMATION.—The Secretary is not responsible for the accuracy of information relayed to the chief driver licensing official of a participating State. However, the Secretary shall maintain the Register in a way that ensures against inadvertent alteration of information during a relay.

(c) TRANSITION FROM PRIOR REGISTER.—(1) The Secretary shall provide by regulation for the orderly transition from the register maintained under the Act of July 14, 1960 (Public Law 86–660, 74 Stat. 526), as restated by section 401 of the National Traffic and Motor Vehicle Safety Act of 1966 (Public Law 89–563, 80 Stat. 730), to the Register maintained under this chapter.

(2)(A) The Secretary shall delete from the Register a report or information that was compiled under the Act of July 14, 1960 (Public Law 86–660, 74 Stat. 526), as restated by section 401 of the National Traffic and Motor Vehicle Safety Act of 1966 (Public Law 89–563, 80 Stat. 730), and transferred to the Register, after the earlier of—

(i) the date the State of record removes it from the State's file;

(ii) 7 years after the date the report or information is entered in the Register; or

(iii) the date a fully electronic Register system is established.

(B) The report or information shall be disposed of under chapter 33 of title 44.

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[2] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 973, and amended by Public Law 105–178, Title II, § 2006(a), June 9, 1998, 112 Stat. 335.

(3) If the chief driver licensing official of a participating State finds that information provided for inclusion in the Register is erroneous or is related to a conviction of a traffic offense that subsequently is reversed, the official immediately shall notify the Secretary. The Secretary shall provide for the immediate deletion of the information from the Register.

(d) ASSIGNMENT OF PERSONNEL.—In carrying out this chapter, the Secretary shall assign personnel necessary to ensure the effective operation of the Register.

(e) TRANSFER OF SELECTED FUNCTIONS TO NON-FEDERAL MANAGEMENT.—

(1) AGREEMENT.— The Secretary may enter into an agreement with an organization that represents the interests of the States to manage, administer, and operate the National Driver Register's computer timeshare and user assistance functions. If the Secretary decides to enter into such an agreement, the Secretary shall ensure that the management of these functions is compatible with this chapter and the regulations issued to implement this chapter.

(2) REQUIRED DEMONSTRATION.— Any transfer of the National Driver Register's computer timeshare and user assistance functions to an organization that represents the interests of the States shall begin only after a determination is made by the Secretary that all States are participating in the National Driver Register's "Problem Driver Pointer System" (the system used by the Register to effect the exchange of motor vehicle driving records) and that the system is functioning properly.

(3) TRANSITION PERIOD.— Any agreement entered into under this subsection shall include a provision for a transition period sufficient to allow the States to make the budgetary and legislative changes the States may need to pay fees charged by the organization representing their interests for their use of the National Driver Register's computer timeshare and user assistance functions. During this transition period, the Secretary shall continue to fund these transferred functions.

(4) FEES.— The total of the fees charged by the organization representing the interests of the States in any fiscal year for the use of the National Driver Register's computer timeshare and user assistance functions shall not exceed the total cost to the organization of performing these functions in such fiscal year.

(5) LIMITATION ON STATUTORY CONSTRUCTION.— Nothing in this subsection may be construed to diminish, limit, or otherwise affect the authority of the Secretary to carry out this chapter.

§ 30303. State participation [3]

(a) NOTIFICATION.—A State may become a participating State under this chapter by notifying the Secretary of Transportation of its intention to be bound by section 30304 of this title.

(b) WITHDRAWAL.—A participating State may end its status as a participating State by notifying the Secretary of its withdrawal from participation in the National Driver Register.

[3] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 974.

(c) FORM AND WAY OF NOTIFICATION.—Notification by a State under this section shall be made in the form and way the Secretary prescribes by regulation.

§ 30304. Reports by chief driver licensing officials[4]

(a) INDIVIDUALS COVERED.—As soon as practicable, the chief driver licensing official of each participating State shall submit to the Secretary of Transportation a report containing the information specified by subsection (b) of this section for each individual—

(1) who is denied a motor vehicle operator's license by that State for cause;

(2) whose motor vehicle operator's license is revoked, suspended, or canceled by that State for cause; or

(3) who is convicted under the laws of that State of any of the following motor vehicle-related offenses or comparable offenses:

(A) operating a motor vehicle while under the influence of, or impaired by, alcohol or a controlled substance.

(B) a traffic violation arising in connection with a fatal traffic accident, reckless driving, or racing on the highways.

(C) failing to give aid or provide identification when involved in an accident resulting in death or personal injury.

(D) perjury or knowingly making a false affidavit or statement to officials about activities governed by a law or regulation on the operation of a motor vehicle.

(b) CONTENTS.—(1) Except as provided in paragraph (2) of this subsection, a report under subsection (a) of this section shall contain—

(A) the individual's legal name, date of birth, sex, and, at the Secretary's discretion, height, weight, and eye and hair color;

(B) the name of the State providing the information; and

(C) the social security account number if used by the State for driver record or motor vehicle license purposes, and the motor vehicle operator's license number if different from the social security account number.

(2) A report under subsection (a) of this section about an event that occurs during the 2-year period before the State becomes a participating State is sufficient if the report contains all of the information that is available to the chief driver licensing official when the State becomes a participating State.

(c) TIME FOR FILING.—If a report under subsection (a) of this section is about an event that occurs—

(1) during the 2-year period before the State becomes a participating State, the report shall be submitted not later than 6 months after the State becomes a participating State; or

(2) after the State becomes a participating State, the report shall be submitted not later than 31 days after the motor vehicle department of the State receives any information specified in subsection (b)(1) of this section that is the subject of the report.

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[4] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 975, and amended by Public Law 106–159, Title II, § 204, Dec. 9, 1999, 113 Stat. 1762.

(d) EVENTS OCCURRING BEFORE PARTICIPATION.—This section does not require a State to report information about an event that occurs before the 2-year period before the State becomes a participating State.

(e) DRIVER RECORD INQUIRY.—Before issuing a motor vehicle operator's license to an individual or renewing such a license, a State shall request from the Secretary information from the National Driver Register under section 30302 and the commercial driver's license information system under section 31309 on the individual's driving record.

§ 30305. Access to Register information[5]

(a) REFERRALS OF INFORMATION REQUESTS.—(1) To carry out duties related to driver licensing, driver improvement, or transportation safety, the chief driver licensing official of a participating State may request the Secretary of Transportation to refer, electronically or by United States mail, a request for information about the motor vehicle driving record of an individual to the chief driver licensing official of a State of record.

(2) The Secretary of Transportation shall relay, electronically or by United States mail, information received from the chief driver licensing official of a State of record in response to a request under paragraph (1) of this subsection to the chief driver licensing official of the participating State requesting the information. However, the Secretary may refuse to relay information to the chief driver licensing official of a participating State that does not comply with section 30304 of this title.

(b) REQUESTS TO OBTAIN INFORMATION.—(1) The Chairman of the National Transportation Safety Board and the Administrator of the Federal Highway Administration may request the chief driver licensing official of a State to obtain information under subsection (a) of this section about an individual who is the subject of an accident investigation conducted by the Board or the Administrator. The Chairman and the Administrator may receive the information.

(2) An individual who is employed, or is seeking employment, as a driver of a motor vehicle may request the chief driver licensing official of the State in which the individual is employed or seeks employment to provide information about the individual under subsection (a) of this section to the individual's employer or prospective employer. An employer or prospective employer may receive the information and shall make the information available to the individual. Information may not be obtained from the National Driver Register under this paragraph if the information was entered in the Register more than 3 years before the request, unless the information is about a revocation or suspension still in effect on the date of the request.

(3) An individual who has received, or is applying for, an airman's certificate may request the chief driver licensing official of

[5] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 976, and amended by Public Law 104–264, Title V, § 502(b), Oct. 9, 1996, 110 Stat. 3262; Public Law 104–324, Title II, § 207(b), Oct. 19, 1996, 110 Stat. 3908; Public Law 105–102, § 2(18), Nov. 20, 1997, 111 Stat. 2205; Public Law 105–178, Title II, § 2006(b), June 9, 1998, 112 Stat. 335; Public Law 108–375, § 1061, Oct. 28, 2004, 118 Stat. 2056.

a State to provide information about the individual under subsection (a) of this section to the Administrator of the Federal Aviation Administration. The Administrator may receive the information and shall make the information available to the individual for review and written comment. The Administrator may use the information to verify information required to be reported to the Administrator by an airman applying for an airman medical certificate and to evaluate whether the airman meets the minimum standards prescribed by the Administrator to be issued an airman medical certificate. The Administrator may not otherwise divulge or use the information. Information may not be obtained from the Register under this paragraph if the information was entered in the Register more than 3 years before the request, unless the information is about a revocation or suspension still in effect on the date of the request.

(4) An individual who is employed, or is seeking employment, by a rail carrier as an operator of a locomotive may request the chief driver licensing official of a State to provide information about the individual under subsection (a) of this section to the individual's employer or prospective employer or to the Secretary of Transportation. Information may not be obtained from the Register under this paragraph if the information was entered in the Register more than 3 years before the request, unless the information is about a revocation or suspension still in effect on the date of the request.

(5) An individual who holds, or is applying for, a license or certificate of registry under section 7101 of title 46, or a merchant mariner's document under section 7302 of title 46, may request the chief driver licensing official of a State to provide information about the individual under subsection (a) of this section to the Secretary of the department in which the Coast Guard is operating. The Secretary may receive the information and shall make the information available to the individual for review and written comment before denying, suspending, or revoking the license, certificate, or document of the individual based on the information and before using the information in an action taken under chapter 77 of title 46. The Secretary may not otherwise divulge or use the information, except for purposes of section 7101, 7302, or 7703 of title 46. Information may not be obtained from the Register under this paragraph if the information was entered in the Register more than 3 years before the request, unless the information is about a revocation or suspension still in effect on the date of the request.

(6) The head of a Federal department or agency that issues motor vehicle operator's licenses may request the chief driver licensing official of a State to obtain information under subsection (a) of this section about an individual applicant for a motor vehicle operator's license from such department or agency. The department or agency may receive the information, provided it transmits to the Secretary a report regarding any individual who is denied a motor vehicle operator's license by that department or agency for cause; whose motor vehicle operator's license is revoked, suspended, or canceled by that department or agency for cause; or about whom the department or agency has been notified of a conviction of any of the motor vehicle-related offenses or comparable offenses listed in section 30304(a)(3) and over whom the department or agency

has licensing authority. The report shall contain the information specified in section 30304(b).

(7) An individual who is an officer, chief warrant officer, or enlisted member of the Coast Guard or Coast Guard Reserve (including a cadet or an applicant for appointment or enlistment of any of the foregoing and any member of a uniformed service who is assigned to the Coast Guard) may request the chief driver licensing official of a State to provide information about the individual under subsection (a) of this section to the Commandant of the Coast Guard. The Commandant may receive the information and shall make the information available to the individual. Information may not be obtained from the Register under this paragraph if the information was entered in the Register more than 3 years before the request, unless the information is about a revocation or suspension still in effect on the date of the request.

(8) An individual who is seeking employment by an air carrier as a pilot may request the chief driver licensing official of a State to provide information about the individual under subsection (a) of this section to the prospective employer of the individual or to the Secretary of Transportation. Information may not be obtained from the National Driver Register under this subsection if the information was entered in the Register more than 5 years before the request unless the information is about a revocation or suspension still in effect on the date of the request.

(9) An individual who has or is seeking access to national security information for purposes of Executive Order No. 12968, or any successor Executive order, or an individual who is being investigated for Federal employment under authority of Executive Order No. 10450, or any successor Executive order, may request the chief driver licensing official of a State to provide information about the individual pursuant to subsection (a) of this section to a Federal department or agency that is authorized to investigate the individual for the purpose of assisting in the determination of the eligibility of the individual for access to national security information or for Federal employment in a position requiring access to national security information. A Federal department or agency that receives information about an individual under the preceding sentence may use such information only for purposes of the authorized investigation and only in accordance with applicable law.

(10) A request under this subsection shall be made in the form and way the Secretary of Transportation prescribes by regulation.

(11) An individual may request the chief driver licensing official of a State to obtain information about the individual under subsection (a) of this section—

(A) to learn whether information about the individual is being provided;

(B) to verify the accuracy of the information; or

(C) to obtain a certified copy of the information.

(12) The head of a Federal department or agency authorized to receive information regarding an individual from the Register under this section may request and receive such information from the Secretary.

(c) RELATIONSHIP TO OTHER LAWS.—A request for, or receipt of, information from the Register is subject to sections 552 and 552a

of title 5, and other applicable laws of the United States or a State, except that—

(1) the Secretary of Transportation may not relay or otherwise provide information specified in section 30304(b)(1)(A) or (C) of this title to a person not authorized by this section to receive the information;

(2) a request for, or receipt of, information by a chief driver licensing official, or by a person authorized by subsection (b) of this section to request and receive the information, is deemed to be a routine use under section 552a(b) of title 5; and

(3) receipt of information by a person authorized by this section to receive the information is deemed to be a disclosure under section 552a(c) of title 5, except that the Secretary of Transportation is not required to retain the accounting made under section 552a(c)(1) for more than 7 years after the disclosure.

(d) AVAILABILITY OF INFORMATION PROVIDED UNDER PRIOR LAW.—Information provided by a State under the Act of July 14, 1960 (Public Law 86–660, 74 Stat. 526), as restated by section 401 of the National Traffic and Motor Vehicle Safety Act of 1966 (Public Law 89–563, 80 Stat. 730), and under this chapter, shall be available under this section during the transition from the register maintained under that Act to the Register maintained under this chapter.

§ 30306. National Driver Register Advisory Committee[6]

(a) ORGANIZATION.—There is a National Driver Register Advisory Committee.

(b) DUTIES.—The Committee shall advise the Secretary of Transportation on—

(1) the efficiency of the maintenance and operation of the National Driver Register; and

(2) the effectiveness of the Register in assisting States in exchanging information about motor vehicle driving records.

(c) COMPOSITION AND APPOINTMENT.—The Committee is composed of 15 members appointed by the Secretary as follows:

(1) 3 members appointed from among individuals who are specially qualified to serve on the Committee because of their education, training, or experience, and who are not officers or employees of the United States Government or a State.

(2) 3 members appointed from among groups outside the Government that represent the interests of bus and trucking organizations, enforcement officials, labor, or safety organizations.

(3) 9 members, geographically representative of the participating States, appointed from among individuals who are chief driver licensing officials of participating States.

(d) TERMS.—(1) Except as provided in paragraph (2) of this subsection, the term of each member is 3 years.

(2) A vacancy on the Committee shall be filled in the same way as an original appointment. A member appointed to fill a vacancy serves for the remainder of the term of that member's predecessor.

[6] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 978.

After a member's term ends, the member may continue to serve until a successor takes office.

(e) PAY AND EXPENSES.—Members of the Committee serve without pay. However, the Secretary may reimburse a member for reasonable travel expenses incurred by the member in attending meetings of the Committee.

(f) MEETINGS, CHAIRMAN, VICE CHAIRMAN, AND QUORUM.—(1) The Committee shall meet at least once a year.

(2) The Committee shall elect a Chairman and a Vice Chairman from among its members.

(3) Eight members are a quorum.

(4) The Committee shall meet at the call of the Chairman or a majority of the members.

(g) PERSONNEL AND SERVICES.—The Secretary may provide the Committee with personnel, penalty mail privileges, and similar services the Secretary considers necessary to assist the Committee in carrying out its duties and powers under this section.

(h) REPORTS.—At least once a year, the Committee shall submit to the Secretary a report on the matters specified in subsection (b) of this section. The report shall include any recommendations of the Committee for changes in the Register.

(i) RELATIONSHIP TO OTHER LAWS.—The Committee is exempt from sections 10(e) and (f) and 14 of the Federal Advisory Committee Act (5 App. U.S.C.).

§ 30307. Criminal penalties[7]

(a) GENERAL PENALTY.—A person (except an individual described in section 30305(b)(6) of this title) shall be fined under title 18, imprisoned for not more than one year, or both, if—

(1) the person receives under section 30305 of this title information specified in section 30304(b)(1)(A) or (C) of this title;

(2) disclosure of the information is not authorized by section 30305 of this title; and

(3) the person willfully discloses the information knowing that disclosure is not authorized.

(b) INFORMATION PENALTY.—A person knowingly and willfully requesting, or under false pretenses obtaining, information specified in section 30304(b)(1)(A) or (C) of this title from a person receiving the information under section 30305 of this title shall be fined under title 18, imprisoned for not more than one year, or both.

§ 30308. Authorization of appropriations[8]

(a) GENERAL.—The Secretary of Transportation shall make available from amounts made available to carry out section 402 of title 23 $4,000,000 for each of the fiscal years ending September 30, 1993, and September 30, 1994, $2,550,000 for each of fiscal years 1995, 1996, and 1997, and $1,855,000 for the period of October 1, 1997, through March 31, 1998 to carry out this chapter.

(b) AVAILABILITY OF AMOUNTS.—Amounts authorized under this section remain available until expended.

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[7] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 979.

[8] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 979, and amended by Public Law 103–331, Title III, § 343, Sept. 30, 1994, 108 Stat. 2496; Public Law 103–429, § 6(25), Oct. 31, 1994, 108 Stat. 4380; Public Law 104–59, Title III, § 343, Nov. 28, 1995, 109 Stat. 610; Public Law 104–287, § 5(59), Oct. 11, 1996, 110 Stat. 3394; Public Law 105–18, Title II, § 8004, June 12, 1997, 111 Stat. 195; Public Law 105–130, § 6(c), Dec. 1, 1997, 111 Stat. 2559.

49 U.S.C. § 31136

Waivers and exemptions for commercial motor vehicle operators in municipalities and commercial zones are not available to those with a medical or physical condition involving alcohol and drug abuse

§ 31136. United States Government regulations[1]

(a) MINIMUM SAFETY STANDARDS.—Subject to section 30103(a) of this title, the Secretary of Transportation shall prescribe regulations on commercial motor vehicle safety. The regulations shall prescribe minimum safety standards for commercial motor vehicles. At a minimum, the regulations shall ensure that—

(1) commercial motor vehicles are maintained, equipped, loaded, and operated safely;

(2) the responsibilities imposed on operators of commercial motor vehicles do not impair their ability to operate the vehicles safely;

(3) the physical condition of operators of commercial motor vehicles is adequate to enable them to operate the vehicles safely; and

(4) the operation of commercial motor vehicles does not have a deleterious effect on the physical condition of the operators.

(b) ELIMINATING AND AMENDING EXISTING REGULATIONS.—The Secretary may not eliminate or amend an existing motor carrier safety regulation related only to the maintenance, equipment, loading, or operation (including routing) of vehicles carrying material found to be hazardous under section 5103 of this title until an equivalent or more stringent regulation has been prescribed under section 5103.

(c) PROCEDURES AND CONSIDERATIONS.—(1) A regulation under this section shall be prescribed under section 553 of title 5 (without regard to sections 556 and 557 of title 5).

(2) Before prescribing regulations under this section, the Secretary shall consider, to the extent practicable and consistent with the purposes of this chapter—

(A) costs and benefits; and

(B) State laws and regulations on commercial motor vehicle safety, to minimize their unnecessary preemption.

(d) EFFECT OF EXISTING REGULATIONS.—If the Secretary does not prescribe regulations on commercial motor vehicle safety under this section, regulations on commercial motor vehicle safety prescribed by the Secretary before October 30, 1984, and in effect on October

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1003, and amended by Public Law 104–59, Title III, § 344, Nov. 28, 1995, 109 Stat. 610, as amended Public Law 104–287, § 5(60), Oct. 11, 1996, 110 Stat. 3394; Public Law 105–178, Title IV, § 4007(c), June 9, 1998, 112 Stat. 403.

30, 1984, shall be deemed in this subchapter to be regulations prescribed by the Secretary under this section.

(e) EXEMPTIONS.—The Secretary may grant in accordance with section 31315 waivers and exemptions from, or conduct pilot programs with respect to, any regulations prescribed under this section.

(f) LIMITATIONS ON MUNICIPALITY AND COMMERCIAL ZONE EXEMPTIONS AND WAIVERS.—(1) The Secretary may not—

(A) exempt a person or commercial motor vehicle from a regulation related to commercial motor vehicle safety only because the operations of the person or vehicle are entirely in a municipality or commercial zone of a municipality; or

(B) waive application to a person or commercial motor vehicle of a regulation related to commercial motor vehicle safety only because the operations of the person or vehicle are entirely in a municipality or commercial zone of a municipality.

(2) If a person was authorized to operate a commercial motor vehicle in a municipality or commercial zone of a municipality in the United States for the entire period from November 19, 1987, through November 18, 1988, and if the person is otherwise qualified to operate a commercial motor vehicle, the person may operate a commercial motor vehicle entirely in a municipality or commercial zone of a municipality notwithstanding—

(A) paragraph (1) of this subsection;

(B) a minimum age requirement of the United States Government for operation of the vehicle; and

(C) a medical or physical condition that—

(i) would prevent an operator from operating a commercial motor vehicle under the commercial motor vehicle safety regulations in title 49, Code of Federal Regulations;

(ii) existed on July 1, 1988;

(iii) has not substantially worsened; and

(iv) does not involve alcohol or drug abuse.

(3) This subsection does not affect a State commercial motor vehicle safety law applicable to intrastate commerce.

49 U.S.C. § 31306
Alcohol and controlled substance testing for commercial motor vehicle operators

Chapter 313. Commercial Motor Vehicle Operators

§ 31306. Alcohol and controlled substances testing [1]

(a) DEFINITION.—In this section, "controlled substance" means any substance under section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802) specified by the Secretary of Transportation.

(b) TESTING PROGRAM FOR OPERATORS OF COMMERCIAL MOTOR VEHICLES.—(1)(A) In the interest of commercial motor vehicle safety, the Secretary of Transportation shall prescribe regulations that establish a program requiring motor carriers to conduct preemployment, reasonable suspicion, random, and post-accident testing of operators of commercial motor vehicles for the use of a controlled substance in violation of law or a United States Government regulation and to conduct reasonable suspicion, random, and post-accident testing of such operators for the use of alcohol in violation of law or a United States Government regulation. The regulations shall permit such motor carriers to conduct preemployment testing of such employees for the use of alcohol.

(B) When the Secretary of Transportation considers it appropriate in the interest of safety, the Secretary may prescribe regulations for conducting periodic recurring testing of operators of commercial motor vehicles for the use of alcohol or a controlled substance in violation of law or a Government regulation.

(2) In prescribing regulations under this subsection, the Secretary of Transportation—

(A) shall require that post-accident testing of an operator of a commercial motor vehicle be conducted when loss of human life occurs in an accident involving a commercial motor vehicle; and

(B) may require that post-accident testing of such an operator be conducted when bodily injury or significant property damage occurs in any other serious accident involving a commercial motor vehicle.

(c) TESTING AND LABORATORY REQUIREMENTS.—In carrying out subsection (b) of this section, the Secretary of Transportation shall develop requirements that shall—

(1) promote, to the maximum extent practicable, individual privacy in the collection of specimens;

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[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1017, and amended by Public Law 104–59, Title III, § 342(c), Nov. 28, 1995, 109 Stat. 609.

(2) for laboratories and testing procedures for controlled substances, incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing—

(A) comprehensive standards for every aspect of laboratory controlled substances testing and laboratory procedures to be applied in carrying out this section, including standards requiring the use of the best available technology to ensure the complete reliability and accuracy of controlled substances tests and strict procedures governing the chain of custody of specimens collected for controlled substances testing;

(B) the minimum list of controlled substances for which individuals may be tested; and

(C) appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform controlled substances testing in carrying out this section;

(3) require that a laboratory involved in testing under this section have the capability and facility, at the laboratory, of performing screening and confirmation tests;

(4) provide that any test indicating the use of alcohol or a controlled substance in violation of law or a Government regulation be confirmed by a scientifically recognized method of testing capable of providing quantitative information about alcohol or a controlled substance;

(5) provide that each specimen be subdivided, secured, and labeled in the presence of the tested individual and that a part of the specimen be retained in a secure manner to prevent the possibility of tampering, so that if the individual's confirmation test results are positive the individual has an opportunity to have the retained part tested by a 2d confirmation test done independently at another certified laboratory if the individual requests the 2d confirmation test not later than 3 days after being advised of the results of the first confirmation test;

(6) ensure appropriate safeguards for testing to detect and quantify alcohol in breath and body fluid samples, including urine and blood, through the development of regulations that may be necessary and in consultation with the Secretary of Health and Human Services;

(7) provide for the confidentiality of test results and medical information (except information about alcohol or a controlled substance) of employees, except that this clause does not prevent the use of test results for the orderly imposition of appropriate sanctions under this section; and

(8) ensure that employees are selected for tests by nondiscriminatory and impartial methods, so that no employee is harassed by being treated differently from other employees in similar circumstances.

(d) TESTING AS PART OF MEDICAL EXAMINATION.—The Secretary of Transportation may provide that testing under subsection (a) of this section for operators subject to subpart E of part 391 of title

49, Code of Federal Regulations, be conducted as part of the medical examination required under that subpart.

(e) REHABILITATION.—The Secretary of Transportation shall prescribe regulations establishing requirements for rehabilitation programs that provide for the identification and opportunity for treatment of operators of commercial motor vehicles who are found to have used alcohol or a controlled substance in violation of law or a Government regulation. The Secretary shall decide on the circumstances under which those operators shall be required to participate in a program. This section does not prevent a motor carrier from establishing a program under this section in cooperation with another motor carrier.

(f) SANCTIONS.—The Secretary of Transportation shall decide on appropriate sanctions for a commercial motor vehicle operator who is found, based on tests conducted and confirmed under this section, to have used alcohol or a controlled substance in violation of law or a Government regulation but who is not under the influence of alcohol or a controlled substance as provided in this chapter.

(g) EFFECT ON STATE AND LOCAL GOVERNMENT REGULATIONS.—A State or local government may not prescribe or continue in effect a law, regulation, standard, or order that is inconsistent with regulations prescribed under this section. However, a regulation prescribed under this section may not be construed to preempt a State criminal law that imposes sanctions for reckless conduct leading to loss of life, injury, or damage to property.

(h) INTERNATIONAL OBLIGATIONS AND FOREIGN LAWS.—In prescribing regulations under this section, the Secretary of Transportation—

(1) shall establish only requirements that are consistent with international obligations of the United States; and

(2) shall consider applicable laws and regulations of foreign countries.

(i) OTHER REGULATIONS ALLOWED.—This section does not prevent the Secretary of Transportation from continuing in effect, amending, or further supplementing a regulation prescribed before October 28, 1991, governing the use of alcohol or a controlled substance by commercial motor vehicle employees.

(j) APPLICATION OF PENALTIES.—This section does not supersede a penalty applicable to an operator of a commercial motor vehicle under this chapter or another law.

49 U.S.C. § 31310
Commercial motor vehicle license disqualification for certain controlled substance offenses

§ 31310. Disqualifications [1]

(a) BLOOD ALCOHOL CONCENTRATION LEVEL.—In this section, the blood alcohol concentration level at or above which an individual when operating a commercial motor vehicle is deemed to be driving under the influence of alcohol is .04 percent.

(b) FIRST VIOLATION OR COMMITTING FELONY.—(1) Except as provided in paragraph (2) of this subsection and subsection (c) of this section, the Secretary of Transportation shall disqualify from operating a commercial motor vehicle for at least one year an individual—

(A) committing a first violation of driving a commercial motor vehicle under the influence of alcohol or a controlled substance;

(B) committing a first violation of leaving the scene of an accident involving a commercial motor vehicle operated by the individual;

(C) using a commercial motor vehicle in committing a felony (except a felony described in subsection (d) of this section);

(D) committing a first violation of driving a commercial motor vehicle when the individual's commercial driver's license is revoked, suspended, or canceled based on the individual's operation of a commercial motor vehicle or when the individual is disqualified from operating a commercial motor vehicle based on the individual's operation of a commercial motor vehicle; or

(E) convicted of causing a fatality through negligent or criminal operation of a commercial motor vehicle.

(2) If the vehicle involved in a violation referred to in paragraph (1) of this subsection is transporting hazardous material required to be placarded under section 5103 of this title, the Secretary shall disqualify the individual for at least 3 years.

(c) SECOND AND MULTIPLE VIOLATIONS.—(1) Subject to paragraph (2) of this subsection, the Secretary shall disqualify from operating a commercial motor vehicle for life an individual—

(A) committing more than one violation of driving a commercial motor vehicle under the influence of alcohol or a controlled substance;

(B) committing more than one violation of leaving the scene of an accident involving a commercial motor vehicle operated by the individual;

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1022, and amended by Public Law 104–88, Title IV, § 403(a), Dec. 29, 1995, 109 Stat. 956; Public Law 106–159, Title II, § 201(a)(1), (2), (b), Dec. 9, 1999, 113 Stat. 1758, 1759.

(C) using a commercial motor vehicle in committing more than one felony arising out of different criminal episodes;

(D) committing more than one violation of driving a commercial motor vehicle when the individual's commercial driver's license is revoked, suspended, or canceled based on the individual's operation of a commercial motor vehicle or when the individual is disqualified from operating a commercial motor vehicle based on the individual's operation of a commercial motor vehicle;

(E) convicted of more than one offense of causing a fatality through negligent or criminal operation of a commercial motor vehicle; or

(F) committing any combination of single violations or use described in subparagraphs (A) through (E).

(2) The Secretary may prescribe regulations establishing guidelines (including conditions) under which a disqualification for life under paragraph (1) of this subsection may be reduced to a period of not less than 10 years.

(d) CONTROLLED SUBSTANCE VIOLATIONS.—The Secretary shall disqualify from operating a commercial motor vehicle for life an individual who uses a commercial motor vehicle in committing a felony involving manufacturing, distributing, or dispensing a controlled substance, or possession with intent to manufacture, distribute, or dispense a controlled substance.

(e) SERIOUS TRAFFIC VIOLATIONS.—(1) The Secretary shall disqualify from operating a commercial motor vehicle for at least 60 days an individual who, in a 3-year period, commits 2 serious traffic violations involving a commercial motor vehicle operated by the individual.

(2) The Secretary shall disqualify from operating a commercial motor vehicle for at least 120 days an individual who, in a 3-year period, commits 3 serious traffic violations involving a commercial motor vehicle operated by the individual.

(f) EMERGENCY DISQUALIFICATION.—

(1) LIMITED DURATION.—The Secretary shall disqualify an individual from operating a commercial motor vehicle for not to exceed 30 days if the Secretary determines that allowing the individual to continue to operate a commercial motor vehicle would create an imminent hazard (as such term is defined in section 5102).

(2) AFTER NOTICE AND HEARING.—The Secretary shall disqualify an individual from operating a commercial motor vehicle for more than 30 days if the Secretary determines, after notice and an opportunity for a hearing, that allowing the individual to continue to operate a commercial motor vehicle would create an imminent hazard (as such term is defined in section 5102).

(g) NONCOMMERCIAL MOTOR VEHICLE CONVICTIONS.—

(1) ISSUANCE OF REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall issue regulations providing for the disqualification by the Secretary from operating a commercial motor vehicle of an individual who holds a commercial driver's license and who has been convicted of—

(A) a serious offense involving a motor vehicle (other than a commercial motor vehicle) that has resulted in the revocation, cancellation, or suspension of the individual's license; or

(B) a drug or alcohol related offense involving a motor vehicle (other than a commercial motor vehicle).

(2) REQUIREMENTS FOR REGULATIONS.—Regulations issued under paragraph (1) shall establish the minimum periods for which the disqualifications shall be in effect, but in no case shall the time periods for disqualification for noncommercial motor vehicle violations be more stringent than those for offenses or violations involving a commercial motor vehicle. The Secretary shall determine such periods based on the seriousness of the offenses on which the convictions are based.

(h) STATE DISQUALIFICATION.—Notwithstanding subsections (b) through (g) of this section, the Secretary does not have to disqualify an individual from operating a commercial motor vehicle if the State that issued the individual a license authorizing the operation has disqualified the individual from operating a commercial motor vehicle under subsections (b) through (g). Revocation, suspension, or cancellation of the license is deemed to be disqualification under this subsection.

(i) OUT-OF-SERVICE ORDERS.—(1)(A) To enforce section 392.5 of title 49, Code of Federal Regulations, the Secretary shall prescribe regulations establishing and enforcing an out-of-service period of 24 hours for an individual who violates section 392.5. An individual may not violate an out-of-service order issued under those regulations.

(B) The Secretary shall prescribe regulations establishing and enforcing requirements for reporting out-of-service orders issued under regulations prescribed under subparagraph (A) of this paragraph. Regulations prescribed under this subparagraph shall require at least that an operator of a commercial motor vehicle who is issued an out-of-service order to report the issuance to the individual's employer and to the State that issued the operator a driver's license.

(2) Not later than December 18, 1992, the Secretary shall prescribe regulations establishing sanctions and penalties related to violations of out-of-service orders by individuals operating commercial motor vehicles. The regulations shall require at least that—

(A) an operator of a commercial motor vehicle found to have committed a first violation of an out-of-service order shall be disqualified from operating such a vehicle for at least 90 days and liable for a civil penalty of at least $1,000;

(B) an operator of a commercial motor vehicle found to have committed a 2d violation of an out-of-service order shall be disqualified from operating such a vehicle for at least one year and not more than 5 years and liable for a civil penalty of at least $1,000; and

(C) an employer that knowingly allows or requires an employee to operate a commercial motor vehicle in violation of an out-of-service order shall be liable for a civil penalty of not more than $10,000.

(j) GRADE-CROSSING VIOLATIONS.—

(1) SANCTIONS.—The Secretary shall issue regulations establishing sanctions and penalties relating to violations, by persons operating commercial motor vehicles, of laws and regulations pertaining to railroad-highway grade crossings.

(2) MINIMUM REQUIREMENTS.—The regulations issued under paragraph (1) shall, at a minimum, require that—

(A) the penalty for a single violation is not less than a 60-day disqualification of the driver's commercial driver's license; and

(B) any employer that knowingly allows, permits, authorizes, or requires an employee to operate a commercial motor vehicle in violation of such a law or regulation shall be subject to a civil penalty of not more than $10,000.

49 U.S.C. § 40101
Exercise of regulatory authority to insure aviation safety should consider controlled substance law enforcement needs

Chapter 401. General Provisions

§ 40101. Policy [1]

(a) ECONOMIC REGULATION.—In carrying out subpart II of this part and those provisions of subpart IV applicable in carrying out subpart II, the Secretary of Transportation shall consider the following matters, among others, as being in the public interest and consistent with public convenience and necessity:

(1) assigning and maintaining safety as the highest priority in air commerce.

(2) before authorizing new air transportation services, evaluating the safety implications of those services.

(3) preventing deterioration in established safety procedures, recognizing the clear intent, encouragement, and dedication of Congress to further the highest degree of safety in air transportation and air commerce, and to maintain the safety vigilance that has evolved in air transportation and air commerce and has come to be expected by the traveling and shipping public.

(4) the availability of a variety of adequate, economic, efficient, and low-priced services without unreasonable discrimination or unfair or deceptive practices.

(5) coordinating transportation by, and improving relations among, air carriers, and encouraging fair wages and working conditions.

(6) placing maximum reliance on competitive market forces and on actual and potential competition—

(A) to provide the needed air transportation system; and

(B) to encourage efficient and well-managed air carriers to earn adequate profits and attract capital, considering any material differences between interstate air transportation and foreign air transportation.

(7) developing and maintaining a sound regulatory system that is responsive to the needs of the public and in which decisions are reached promptly to make it easier to adapt the air transportation system to the present and future needs of—

(A) the commerce of the United States;

(B) the United States Postal Service; and

(C) the national defense.

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[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1094, and amended by Public Law 104–264, Title IV, § 401(a), Oct. 9, 1996, 110 Stat. 3255; Public Law 106–181, Title II, § 201, Apr. 5, 2000, 114 Stat. 91.

(8) encouraging air transportation at major urban areas through secondary or satellite airports if consistent with regional airport plans of regional and local authorities, and if endorsed by appropriate State authorities—

(A) encouraging the transportation by air carriers that provide, in a specific market, transportation exclusively at those airports; and

(B) fostering an environment that allows those carriers to establish themselves and develop secondary or satellite airport services.

(9) preventing unfair, deceptive, predatory, or anticompetitive practices in air transportation.

(10) avoiding unreasonable industry concentration, excessive market domination, monopoly powers, and other conditions that would tend to allow at least one air carrier or foreign air carrier unreasonably to increase prices, reduce services, or exclude competition in air transportation.

(11) maintaining a complete and convenient system of continuous scheduled interstate air transportation for small communities and isolated areas with direct financial assistance from the United States Government when appropriate.

(12) encouraging, developing, and maintaining an air transportation system relying on actual and potential competition—

(A) to provide efficiency, innovation, and low prices; and

(B) to decide on the variety and quality of, and determine prices for, air transportation services.

(13) encouraging entry into air transportation markets by new and existing air carriers and the continued strengthening of small air carriers to ensure a more effective and competitive airline industry.

(14) promoting, encouraging, and developing civil aeronautics and a viable, privately-owned United States air transport industry.

(15) strengthening the competitive position of air carriers to at least ensure equality with foreign air carriers, including the attainment of the opportunity for air carriers to maintain and increase their profitability in foreign air transportation.

(16) ensuring that consumers in all regions of the United States, including those in small communities and rural and remote areas, have access to affordable, regularly scheduled air service.

(b) ALL-CARGO AIR TRANSPORTATION CONSIDERATIONS.—In carrying out subpart II of this part and those provisions of subpart IV applicable in carrying out subpart II, the Secretary of Transportation shall consider the following matters, among others and in addition to the matters referred to in subsection (a) of this section, as being in the public interest for all-cargo air transportation:

(1) encouraging and developing an expedited all-cargo air transportation system provided by private enterprise and responsive to—

(A) the present and future needs of shippers;

(B) the commerce of the United States; and

(C) the national defense.

(2) encouraging and developing an integrated transportation system relying on competitive market forces to decide the extent, variety, quality, and price of services provided.

(3) providing services without unreasonable discrimination, unfair or deceptive practices, or predatory pricing.

(c) GENERAL SAFETY CONSIDERATIONS.—In carrying out subpart III of this part and those provisions of subpart IV applicable in carrying out subpart III, the Administrator of the Federal Aviation Administration shall consider the following matters:

(1) the requirements of national defense and commercial and general aviation.

(2) the public right of freedom of transit through the navigable airspace.

(d) SAFETY CONSIDERATIONS IN PUBLIC INTEREST.—In carrying out subpart III of this part and those provisions of subpart IV applicable in carrying out subpart III, the Administrator shall consider the following matters, among others, as being in the public interest:

(1) assigning, maintaining, and enhancing safety and security as the highest priorities in air commerce.

(2) regulating air commerce in a way that best promotes safety and fulfills national defense requirements.

(3) encouraging and developing civil aeronautics.

(4) controlling the use of the navigable airspace and regulating civil and military operations in that airspace in the interest of the safety and efficiency of both of those operations.

(5) consolidating research and development for air navigation facilities and the installation and operation of those facilities.

(6) developing and operating a common system of air traffic control and navigation for military and civil aircraft.

(7) providing assistance to law enforcement agencies in the enforcement of laws related to regulation of controlled substances, to the extent consistent with aviation safety.

(e) INTERNATIONAL AIR TRANSPORTATION.—In formulating United States international air transportation policy, the Secretaries of State and Transportation shall develop a negotiating policy emphasizing the greatest degree of competition compatible with a well-functioning international air transportation system, including the following:

(1) strengthening the competitive position of air carriers to ensure at least equality with foreign air carriers, including the attainment of the opportunity for air carriers to maintain and increase their profitability in foreign air transportation.

(2) freedom of air carriers and foreign air carriers to offer prices that correspond to consumer demand.

(3) the fewest possible restrictions on charter air transportation.

(4) the maximum degree of multiple and permissive international authority for air carriers so that they will be able to respond quickly to a shift in market demand.

(5) eliminating operational and marketing restrictions to the greatest extent possible.

(6) integrating domestic and international air transportation.

(7) increasing the number of nonstop United States gateway cities.

(8) opportunities for carriers of foreign countries to increase their access to places in the United States if exchanged for benefits of similar magnitude for air carriers or the traveling public with permanent linkage between rights granted and rights given away.

(9) eliminating discrimination and unfair competitive practices faced by United States airlines in foreign air transportation, including—

(A) excessive landing and user fees;

(B) unreasonable ground handling requirements;

(C) unreasonable restrictions on operations;

(D) prohibitions against change of gauge; and

(E) similar restrictive practices.

(10) promoting, encouraging, and developing civil aeronautics and a viable, privately-owned United States air transport industry.

(f) STRENGTHENING COMPETITION.—In selecting an air carrier to provide foreign air transportation from among competing applicants, the Secretary of Transportation shall consider, in addition to the matters specified in subsections (a) and (b) of this section, the strengthening of competition among air carriers operating in the United States to prevent unreasonable concentration in the air carrier industry.

49 U.S.C. § 41110
Re-examination of air carrier fitness following controlled substance violations

Chapter 411. Air Carrier Certificates

§ 41110. Effective periods and amendments, modifications, suspensions, and revocations of certificates [1]

(a) GENERAL.—(1) Each certificate issued under section 41102 of this title is effective from the date specified in it and remains in effect until—

(A) the Secretary of Transportation suspends or revokes the certificate under this section;

(B) the end of the period the Secretary specifies for an air carrier having a certificate of temporary authority issued under section 41102(a)(2) of this title; or

(C) the Secretary certifies that transportation is no longer being provided under a certificate.

(2) On application or on the initiative of the Secretary and after notice and an opportunity for a hearing or, except as provided in paragraph (4) of this subsection, under section 41111 of this title, the Secretary may—

(A) amend, modify, or suspend any part of a certificate if the Secretary finds the public convenience and necessity require amendment, modification, or suspension; and

(B) revoke any part of a certificate if the Secretary finds that the holder of the certificate intentionally does not comply with this chapter, sections 41308–41310(a), 41501, 41503, 41504, 41506, 41510, 41511, 41701, 41702, 41705–41709, 41711, 41712, and 41731–41742, chapter 419, subchapter II of chapter 421, and section 46301(b) of this title, a regulation or order of the Secretary under any of those provisions, or a term of its certificate.

(3) The Secretary may revoke a certificate under paragraph (2)(B) of this subsection only if the holder of the certificate does not comply, within a reasonable time the Secretary specifies, with an order to the holder requiring compliance.

(4) A certificate to provide foreign air transportation may not be amended, modified, suspended, or revoked under section 41111 of this title if the holder of the certificate requests an oral evidentiary hearing or the Secretary finds, under all the facts and circumstances, that the hearing is required in the public interest.

(b) ALL-CARGO AIR TRANSPORTATION.—The Secretary may order that a certificate issued under section 41103 of this title authorizing all-cargo air transportation is ineffective if, after notice and

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1123, and amended by Public Law 103–429, § 6(50), Oct. 31, 1994, 108 Stat. 4384.

an opportunity for a hearing, the Secretary finds that the transportation is not provided to the minimum extent specified by the Secretary.

(c) FOREIGN AIR TRANSPORTATION.—(1) Notwithstanding subsection (a)(2)–(4) of this section, after notice and a reasonable opportunity for the affected air carrier to present its views, but without a hearing, the Secretary may suspend or revoke the authority of an air carrier to provide foreign air transportation to a place under a certificate issued under section 41102 of this title if the carrier—

(A) notifies the Secretary, under section 41734(a) of this title or a regulation of the Secretary, that it intends to suspend all transportation to that place; or

(B) does not provide regularly scheduled transportation to the place for 90 days immediately before the date the Secretary notifies the carrier of the action the Secretary proposes.

(2) Paragraph (1)(B) of this subsection does not apply to a place provided seasonal transportation comparable to the transportation provided during the prior year.

(d) TEMPORARY CERTIFICATES.—On application or on the initiative of the Secretary, the Secretary may—

(1) review the performance of an air carrier issued a certificate under section 41102(c) of this title on the basis that the air carrier will provide innovative or low-priced air transportation under the certificate; and

(2) amend, modify, suspend, or revoke the certificate or authority under subsection (a)(2) or (c) of this section if the air carrier has not provided, or is not providing, the transportation.

(e) CONTINUING REQUIREMENTS.—(1) To hold a certificate issued under section 41102 of this title, an air carrier must continue to be fit, willing, and able to provide the transportation authorized by the certificate and to comply with this part and regulations of the Secretary.

(2) After notice and an opportunity for a hearing, the Secretary shall amend, modify, suspend, or revoke any part of a certificate issued under section 41102 of this title if the Secretary finds that the air carrier—

(A) is not fit, willing, and able to provide the transportation authorized by the certificate and to comply with this part and regulations of the Secretary; or

(B) does not file reports necessary for the Secretary to decide if the carrier is complying with the requirements of clause (A) of this paragraph.

(f) ILLEGAL IMPORTATION OF CONTROLLED SUBSTANCES.—The Secretary—

(1) in consultation with appropriate departments, agencies, and instrumentalities of the United States Government, shall reexamine immediately the fitness of an air carrier that—

(A) violates the laws and regulations of the United States related to the illegal importation of a controlled substance; or

(B) does not adopt available measures to prevent the illegal importation of a controlled substance into the United States on its aircraft; and

(2) when appropriate, shall amend, modify, suspend, or revoke the certificate of the carrier issued under this chapter.

(g) RESPONSES.—An interested person may file a response with the Secretary opposing or supporting the amendment, modification, suspension, or revocation of a certificate under subsection (a) of this section.

49 U.S.C. § 41304
Re-examination of foreign air carrier permits following controlled substance violations

Chapter 413. Foreign Air Transportation

§ 41304. Effective periods and amendments, modifications, suspensions, and revocations of permits [1]

(a) GENERAL.—The Secretary of Transportation may prescribe the period during which a permit issued under section 41302 of this title is in effect. After notice and an opportunity for a hearing, the Secretary may amend, modify, suspend, or revoke the permit if the Secretary finds that action to be in the public interest.

(b) SUSPENSIONS AND RESTRICTIONS.—Without a hearing, but subject to the approval of the President, the Secretary—

(1) may suspend summarily the permits of foreign air carriers of a foreign country, or amend, modify, or limit the operations of the foreign air carriers under the permits, when the Secretary finds—

(A) the action is in the public interest; and

(B) the government, an aeronautical authority, or a foreign air carrier of the foreign country, over the objection of the United States Government, has—

(i) limited or denied the operating rights of an air carrier; or

(ii) engaged in unfair, discriminatory, or restrictive practices that have a substantial adverse competitive impact on an air carrier related to air transportation to, from, through, or over the territory of the foreign country; and

(2) to make this subsection effective, may restrict operations between the United States and the foreign country by a foreign air carrier of a third country.

(c) ILLEGAL IMPORTATION OF CONTROLLED SUBSTANCES.—The Secretary—

(1) in consultation with appropriate departments, agencies, and instrumentalities of the Government, shall reexamine immediately the fitness of a foreign air carrier that—

(A) violates the laws and regulations of the United States related to the illegal importation of a controlled substance; or

(B) does not adopt available measures to prevent the illegal importation of a controlled substance into the United States on its aircraft; and

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1127.

(2) when appropriate, shall amend, modify, suspend, or revoke the permit of the carrier issued under this chapter.

(d) RESPONSES.—An interested person may file a response with the Secretary opposing or supporting the amendment, modification, suspension, or revocation of a permit under subsection (a) of this section.

49 U.S.C. § 44103
Aircraft certificates may not be issued following revocation of aircraft certificates for controlled substance violations

Chapter 441. Registration and Recordation of Aircraft

§ 44103. Registration of aircraft [1]

(a) GENERAL.—(1) On application of the owner of an aircraft that meets the requirements of section 44102 of this title, the Administrator of the Federal Aviation Administration shall—

(A) register the aircraft; and

(B) issue a certificate of registration to its owner.

(2) The Administrator may prescribe the extent to which an aircraft owned by the holder of a dealer's certificate of registration issued under section 44104(2) of this title also is registered under this section.

(b) CONTROLLED SUBSTANCE VIOLATIONS.—(1) The Administrator may not issue an owner's certificate of registration under subsection (a)(1) of this section to a person whose certificate is revoked under section 44106 of this title during the 5-year period beginning on the date of the revocation, except—

(A) as provided in section 44106(e)(2) of this title; or

(B) that the Administrator may issue the certificate to the person after the one-year period beginning on the date of the revocation if the Administrator decides that the aircraft otherwise meets the requirements of section 44102 of this title and that denial of a certificate for the 5-year period—

(i) would be excessive considering the nature of the offense or the act committed and the burden the denial places on the person; or

(ii) would not be in the public interest.

(2) A decision of the Administrator under paragraph (1)(B)(i) or (ii) of this subsection is within the discretion of the Administrator. That decision or failure to make a decision is not subject to administrative or judicial review.

(c) CERTIFICATES AS EVIDENCE.—A certificate of registration issued under this section is—

(1) conclusive evidence of the nationality of an aircraft for international purposes, but not conclusive evidence in a proceeding under the laws of the United States; and

(2) not evidence of ownership of an aircraft in a proceeding in which ownership is or may be in issue.

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[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1162.

(d) CERTIFICATES AVAILABLE FOR INSPECTION.—An operator of an aircraft shall make available for inspection a certificate of registration for the aircraft when requested by a United States Government, State, or local law enforcement officer.

§ 44106. Revocation of aircraft certificates for controlled substance violations[1]

(a) DEFINITION.—In this section, "controlled substance" has the same meaning given that term in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802).

(b) REVOCATIONS.—(1) The Administrator of the Federal Aviation Administration shall issue an order revoking the certificate of registration for an aircraft issued to an owner under section 44103 of this title and any other certificate of registration that the owner of the aircraft holds under section 44103, if the Administrator finds that—

(A) the aircraft was used to carry out, or facilitate, an activity that is punishable by death or imprisonment for more than one year under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance); and

(B) the owner of the aircraft permitted the use of the aircraft knowing that the aircraft was to be used for the activity described in clause (A) of this paragraph.

(2) An aircraft owner that is not an individual is deemed to have permitted the use of the aircraft knowing that the aircraft was to be used for the activity described in paragraph (1)(A) of this subsection only if a majority of the individuals who control the owner of the aircraft or who are involved in forming the major policy of the owner permitted the use of the aircraft knowing that the aircraft was to be used for the activity described in paragraph (1)(A).

(c) ADVICE TO HOLDERS AND OPPORTUNITY TO ANSWER.—Before the Administrator revokes a certificate under subsection (b) of this section, the Administrator shall—

(1) advise the holder of the certificate of the charges or reasons on which the Administrator bases the proposed action; and

(2) provide the holder of the certificate an opportunity to answer the charges and state why the certificate should not be revoked.

(d) APPEALS.—(1) A person whose certificate is revoked by the Administrator under subsection (b) of this section may appeal the revocation order to the National Transportation Safety Board. The Board shall affirm or reverse the order after providing notice and a hearing on the record. In conducting the hearing, the Board is not bound by the findings of fact of the Administrator.

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[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1163.

(2) When a person files an appeal with the Board under this subsection, the order of the Administrator revoking the certificate is stayed. However, if the Administrator advises the Board that safety in air transportation or air commerce requires the immediate effectiveness of the order—

(A) the order remains effective; and

(B) the Board shall dispose of the appeal not later than 60 days after notification by the Administrator under this paragraph.

(3) A person substantially affected by an order of the Board under this subsection may seek judicial review of the order under section 46110 of this title. The Administrator shall be made a party to that judicial proceeding.

(e) ACQUITTAL.—(1) The Administrator may not revoke, and the Board may not affirm a revocation of, a certificate of registration under this section on the basis of an activity described in subsection (b)(1)(A) of this section if the holder of the certificate is acquitted of all charges related to a controlled substance in an indictment or information arising from the activity.

(2) If the Administrator has revoked a certificate of registration of a person under this section because of an activity described in subsection (b)(1)(A) of this section, the Administrator shall reissue a certificate to the person if the person—

(A) subsequently is acquitted of all charges related to a controlled substance in an indictment or information arising from the activity; and

(B) otherwise meets the requirements of section 44102 of this title.

49 U.S.C. § 44111
Modification of regulations relating to aircraft registration and recodification to more effectively serve the needs of controlled substance enforcement efforts

§ 44111. Modifications in registration and recordation system for aircraft not providing air transportation [1]

(a) APPLICATION.—This section applies only to aircraft not used to provide air transportation.

(b) AUTHORITY TO MAKE MODIFICATIONS.—The Administrator of the Federal Aviation Administration shall make modifications in the system for registering and recording aircraft necessary to make the system more effective in serving the needs of—

(1) buyers and sellers of aircraft;

(2) officials responsible for enforcing laws related to the regulation of controlled substances (as defined in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)); and

(3) other users of the system.

(c) NATURE OF MODIFICATIONS.—Modifications made under subsection (b) of this section—

(1) may include a system of titling aircraft or registering all aircraft, even aircraft not operated;

(2) shall ensure positive, verifiable, and timely identification of the true owner; and

(3) shall address at least each of the following deficiencies in and abuses of the existing system:

(A) the registration of aircraft to fictitious persons.

(B) the use of false or nonexistent addresses by persons registering aircraft.

(C) the use by a person registering an aircraft of a post office box or ''mail drop'' as a return address to evade identification of the person's address.

(D) the registration of aircraft to entities established to facilitate unlawful activities.

(E) the submission of names of individuals on applications for registration of aircraft that are not identifiable.

(F) the ability to make frequent legal changes in the registration markings assigned to aircraft.

(G) the use of false registration markings on aircraft.

(H) the illegal use of ''reserved'' registration markings on aircraft.

(I) the large number of aircraft classified as being in ''self-reported status''.

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1166.

(J) the lack of a system to ensure timely and adequate notice of the transfer of ownership of aircraft.

(K) the practice of allowing temporary operation and navigation of aircraft without the issuance of a certificate of registration.

(d) REGULATIONS.—(1) The Administrator of the Federal Aviation Administration shall prescribe regulations to carry out this section and provide a written explanation of how the regulations address each of the deficiencies and abuses described in subsection (c) of this section. In prescribing the regulations, the Administrator of the Federal Aviation Administration shall consult with the Administrator of Drug Enforcement, the Commissioner of Customs, other law enforcement officials of the United States Government, representatives of State and local law enforcement officials, representatives of the general aviation aircraft industry, representatives of users of general aviation aircraft, and other interested persons.

(2) Regulations prescribed under this subsection shall require that—

(A) each individual listed in an application for registration of an aircraft provide with the application the individual's driver's license number; and

(B) each person (not an individual) listed in an application for registration of an aircraft provide with the application the person's taxpayer identifying number.

49 U.S.C. § 44703
Airman certifications may not be issued to anyone whose airman certification has been revoked for controlled substance violations

Chapter 447. Safety Regulation

§ 44703. Airman certificates [1]

(a) GENERAL.—The Administrator of the Federal Aviation Administration shall issue an airman certificate to an individual when the Administrator finds, after investigation, that the individual is qualified for, and physically able to perform the duties related to, the position to be authorized by the certificate.

(b) CONTENTS.—(1) An airman certificate shall—

(A) be numbered and recorded by the Administrator of the Federal Aviation Administration;

(B) contain the name, address, and description of the individual to whom the certificate is issued;

(C) contain terms the Administrator decides are necessary to ensure safety in air commerce, including terms on the duration of the certificate, periodic or special examinations, and tests of physical fitness;

(D) specify the capacity in which the holder of the certificate may serve as an airman with respect to an aircraft; and

(E) designate the class the certificate covers.

(2) A certificate issued to a pilot serving in scheduled air transportation shall have the designation "airline transport pilot" of the appropriate class.

(c) PUBLIC INFORMATION.—

(1) IN GENERAL.—Subject to paragraph (2) and notwithstanding any other provision of law, the information contained in the records of contents of any airman certificate issued under this section that is limited to an airman's name, address, and ratings held shall be made available to the public after the 120th day following the date of the enactment of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century.

(2) OPPORTUNITY TO WITHHOLD INFORMATION.—Before making any information concerning an airman available to the public under paragraph (1), the airman shall be given an opportunity to elect that the information not be made available to the public.

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[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1186, and amended by Public Law 106–181, Title VII, § 715, Apr. 5, 2000, 114 Stat. 162; Public Law 107–71, Title I, §§ 129, 138(b), 140(a), Nov. 19, 2001, 115 Stat. 633, 640, 641.

(3) DEVELOPMENT AND IMPLEMENTATION OF PROGRAM.—Not later than 60 days after the date of the enactment of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, the Administrator shall develop and implement, in cooperation with representatives of the aviation industry, a one-time written notification to airmen to set forth the implications of making information concerning an airman available to the public under paragraph (1) and to carry out paragraph (2). The Administrator shall also provide such written notification to each individual who becomes an airman after such date of enactment.

(d) APPEALS.—(1) An individual whose application for the issuance or renewal of an airman certificate has been denied may appeal the denial to the National Transportation Safety Board, except if the individual holds a certificate that—

(A) is suspended at the time of denial; or

(B) was revoked within one year from the date of the denial.

(2) The Board shall conduct a hearing on the appeal at a place convenient to the place of residence or employment of the applicant. The Board is not bound by findings of fact of the Administrator of the Federal Aviation Administration but is bound by all validly adopted interpretations of laws and regulations the Administrator carries out unless the Board finds an interpretation is arbitrary, capricious, or otherwise not according to law. At the end of the hearing, the Board shall decide whether the individual meets the applicable regulations and standards. The Administrator is bound by that decision.

(e) RESTRICTIONS AND PROHIBITIONS.—The Administrator of the Federal Aviation Administration may—

(1) restrict or prohibit issuing an airman certificate to an alien; or

(2) make issuing the certificate to an alien dependent on a reciprocal agreement with the government of a foreign country.

(f) CONTROLLED SUBSTANCE VIOLATIONS.—The Administrator of the Federal Aviation Administration may not issue an airman certificate to an individual whose certificate is revoked under section 44710 of this title except—

(1) when the Administrator decides that issuing the certificate will facilitate law enforcement efforts; and

(2) as provided in section 44710(e)(2) of this title.

(g) MODIFICATIONS IN SYSTEM.—(1) The Administrator of the Federal Aviation Administration shall make modifications in the system for issuing airman certificates necessary to make the system more effective in serving the needs of airmen and officials responsible for enforcing laws related to the regulation of controlled substances (as defined in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)) and related to combating acts of terrorism. The modifications shall ensure positive and verifiable identification of each individual applying for or holding a certificate and shall address at least each of the following deficiencies in, and abuses of, the existing system:

(A) the use of fictitious names and addresses by applicants for those certificates.

(B) the use of stolen or fraudulent identification in applying for those certificates.

(C) the use by an applicant of a post office box or ''mail drop'' as a return address to evade identification of the applicant's address.

(D) the use of counterfeit and stolen airman certificates by pilots.

(E) the absence of information about physical characteristics of holders of those certificates.

(2) The Administrator of the Federal Aviation Administration shall prescribe regulations to carry out paragraph (1) of this subsection and provide a written explanation of how the regulations address each of the deficiencies and abuses described in paragraph (1). In prescribing the regulations, the Administrator of the Federal Aviation Administration shall consult with the Administrator of Drug Enforcement, the Commissioner of Customs, other law enforcement officials of the United States Government, representatives of State and local law enforcement officials, representatives of the general aviation aircraft industry, representatives of users of general aviation aircraft, and other interested persons.

(3) For purposes of this section, the term ''acts of terrorism'' means an activity that involves a violent act or an act dangerous to human life that is a violation of the criminal laws of the United States or of any State, or that would be a criminal violation if committed within the jurisdiction of the United States or of any State, and appears to be intended to intimidate or coerce a civilian population to influence the policy of a government by intimidation or coercion or to affect the conduct of a government by assassination or kidnaping.

(4) The Administrator is authorized and directed to work with State and local authorities, and other Federal agencies, to assist in the identification of individuals applying for or holding airmen certificates.

(h) RECORDS OF EMPLOYMENT OF PILOT APPLICANTS.—

(1) IN GENERAL.—Subject to paragraph (14), before allowing an individual to begin service as a pilot, an air carrier shall request and receive the following information:

(A) FAA RECORDS.—From the Administrator of the Federal Aviation Administration, records pertaining to the individual that are maintained by the Administrator concerning—

(i) current airman certificates (including airman medical certificates) and associated type ratings, including any limitations to those certificates and ratings; and

(ii) summaries of legal enforcement actions resulting in a finding by the Administrator of a violation of this title or a regulation prescribed or order issued under this title that was not subsequently overturned.

(B) AIR CARRIER AND OTHER RECORDS.—From any air carrier or other person (except a branch of the United States Armed Forces, the National Guard, or a reserve component of the United States Armed Forces) that has

employed the individual as a pilot of a civil or public aircraft at any time during the 5-year period preceding the date of the employment application of the individual, or from the trustee in bankruptcy for such air carrier or person—

(i) records pertaining to the individual that are maintained by an air carrier (other than records relating to flight time, duty time, or rest time) under regulations set forth in—

(I) section 121.683 of title 14, Code of Federal Regulations;

(II) paragraph (A) of section VI, appendix I, part 121 of such title;

(III) paragraph (A) of section IV, appendix J, part 121 of such title;

(IV) section 125.401 of such title; and

(V) section 135.63(a)(4) of such title; and

(ii) other records pertaining to the individual's performance as a pilot that are maintained by the air carrier or person concerning—

(I) the training, qualifications, proficiency, or professional competence of the individual, including comments and evaluations made by a check airman designated in accordance with section 121.411, 125.295, or 135.337 of such title;

(II) any disciplinary action taken with respect to the individual that was not subsequently overturned; and

(III) any release from employment or resignation, termination, or disqualification with respect to employment.

(C) NATIONAL DRIVER REGISTER RECORDS.—In accordance with section 30305(b)(8) of this title, from the chief driver licensing official of a State, information concerning the motor vehicle driving record of the individual.

(2) WRITTEN CONSENT; RELEASE FROM LIABILITY.—An air carrier making a request for records under paragraph (1)—

(A) shall be required to obtain written consent to the release of those records from the individual that is the subject of the records requested; and

(B) may, notwithstanding any other provision of law or agreement to the contrary, require the individual who is the subject of the records to request to execute a release from liability for any claim arising from the furnishing of such records to or the use of such records by such air carrier (other than a claim arising from furnishing information known to be false and maintained in violation of a criminal statute).

(3) 5-YEAR REPORTING PERIOD.—A person shall not furnish a record in response to a request made under paragraph (1) if the record was entered more than 5 years before the date of the request, unless the information concerns a revocation or suspension of an airman certificate or motor vehicle license that is in effect on the date of the request.

(4) REQUIREMENT TO MAINTAIN RECORDS.—The Administrator and air carriers shall maintain pilot records described in paragraphs (1)(A) and (1)(B) for a period of at least 5 years.

(5) RECEIPT OF CONSENT; PROVISION OF INFORMATION.—A person shall not furnish a record in response to a request made under paragraph (1) without first obtaining a copy of the written consent of the individual who is the subject of the records requested; except that, for purposes of paragraph (15), the Administrator may allow an individual designated by the Administrator to accept and maintain written consent on behalf of the Administrator for records requested under paragraph (1)(A). A person who receives a request for records under this subsection shall furnish a copy of all of such requested records maintained by the person not later than 30 days after receiving the request.

(6) RIGHT TO RECEIVE NOTICE AND COPY OF ANY RECORD FURNISHED.—A person who receives a request for records under paragraph (1) shall provide to the individual who is the subject of the records—

(A) on or before the 20th day following the date of receipt of the request, written notice of the request and of the individual's right to receive a copy of such records; and

(B) in accordance with paragraph (10), a copy of such records, if requested by the individual.

(7) REASONABLE CHARGES FOR PROCESSING REQUESTS AND FURNISHING COPIES.—A person who receives a request under paragraph (1) or (6) may establish a reasonable charge for the cost of processing the request and furnishing copies of the requested records.

(8) STANDARD FORMS.—The Administrator shall promulgate—

(A) standard forms that may be used by an air carrier to request records under paragraph (1); and

(B) standard forms that may be used by an air carrier to—

(i) obtain the written consent of the individual who is the subject of a request under paragraph (1); and

(ii) inform the individual of—

(I) the request; and

(II) the individual right of that individual to receive a copy of any records furnished in response to the request.

(9) RIGHT TO CORRECT INACCURACIES.—An air carrier that maintains or requests and receives the records of an individual under paragraph (1) shall provide the individual with a reasonable opportunity to submit written comments to correct any inaccuracies contained in the records before making a final hiring decision with respect to the individual.

(10) RIGHT OF PILOT TO REVIEW CERTAIN RECORDS.—Notwithstanding any other provision of law or agreement, an air carrier shall, upon written request from a pilot who is or has been employed by such carrier, make available, within a reasonable time, but not later than 30 days after the date of the request,

to the pilot for review, any and all employment records referred to in paragraph (1)(B) (i) or (ii) pertaining to the employment of the pilot.

(11) PRIVACY PROTECTIONS.—An air carrier that receives the records of an individual under paragraph (1) may use such records only to assess the qualifications of the individual in deciding whether or not to hire the individual as a pilot. The air carrier shall take such actions as may be necessary to protect the privacy of the pilot and the confidentiality of the records, including ensuring that information contained in the records is not divulged to any individual that is not directly involved in the hiring decision.

(12) PERIODIC REVIEW.—Not later than 18 months after the date of the enactment of the Pilot Records Improvement Act of 1996, and at least once every 3 years thereafter, the Administrator shall transmit to Congress a statement that contains, taking into account recent developments in the aviation industry—

(A) recommendations by the Administrator concerning proposed changes to Federal Aviation Administration records, air carrier records, and other records required to be furnished under subparagraphs (A) and (B) of paragraph (1); or

(B) reasons why the Administrator does not recommend any proposed changes to the records referred to in subparagraph (A).

(13) REGULATIONS.—The Administrator shall prescribe such regulations as shall be necessary—

(A) to protect—

(i) the personal privacy of any individual whose records are requested under paragraph (1) and disseminated under paragraph (15); and

(ii) the confidentiality of those records;

(B) to preclude the further dissemination of records received under paragraph (1) by the person who requested those records; and

(C) to ensure prompt compliance with any request made under paragraph (1).

(14) SPECIAL RULES WITH RESPECT TO CERTAIN PILOTS.—

(A) PILOTS OF CERTAIN SMALL AIRCRAFT.—Notwithstanding paragraph (1), an air carrier, before receiving information requested about an individual under paragraph (1), may allow the individual to begin service for a period not to exceed 90 days as a pilot of an aircraft with a maximum payload capacity (as defined in section 119.3 of title 14, Code of Federal Regulations) of 7,500 pounds or less, or a helicopter, on a flight that is not a scheduled operation (as defined in such section). Before the end of the 90-day period, the air carrier shall obtain and evaluate such information. The contract between the carrier and the individual shall contain a term that provides that the continuation of the individual's employment, after the last day of the 90-day period, depends on a satisfactory evaluation.

(B) GOOD FAITH EXCEPTION.—Notwithstanding paragraph (1), an air carrier, without obtaining information about an individual under paragraph (1)(B) from an air carrier or other person that no longer exists or from a foreign government or entity that employed the individual, may allow the individual to begin service as a pilot if the air carrier required to request the information has made a documented good faith attempt to obtain such information.

(15) ELECTRONIC ACCESS TO FAA RECORDS.—For the purpose of increasing timely and efficient access to Federal Aviation Administration records described in paragraph (1), the Administrator may allow, under terms established by the Administrator, an individual designated by the air carrier to have electronic access to a specified database containing information about such records. The terms shall limit such access to instances in which information in the database is required by the designated individual in making a hiring decision concerning a pilot applicant and shall require that the designated individual provide assurances satisfactory to the Administrator that information obtained using such access will not be used for any purpose other than making the hiring decision.

(i) LIMITATION ON LIABILITY; PREEMPTION OF STATE LAW.—

(1) LIMITATION ON LIABILITY.—No action or proceeding may be brought by or on behalf of an individual who has applied for or is seeking a position with an air carrier as a pilot and who has signed a release from liability, as provided for under paragraph (2), against—

(A) the air carrier requesting the records of that individual under subsection (h)(1);

(B) a person who has complied with such request;

(C) a person who has entered information contained in the individual's records; or

(D) an agent or employee of a person described in subparagraph (A) or (B);

in the nature of an action for defamation, invasion of privacy, negligence, interference with contract, or otherwise, or under any Federal or State law with respect to the furnishing or use of such records in accordance with subsection (h).

(2) PREEMPTION.—No State or political subdivision thereof may enact, prescribe, issue, continue in effect, or enforce any law (including any regulation, standard, or other provision having the force and effect of law) that prohibits, penalizes, or imposes liability for furnishing or using records in accordance with subsection (h).

(3) PROVISION OF KNOWINGLY FALSE INFORMATION.—Paragraphs (1) and (2) shall not apply with respect to a person who furnishes information in response to a request made under subsection (h)(1), that—

(A) the person knows is false; and

(B) was maintained in violation of a criminal statute of the United States.

(j) LIMITATION ON STATUTORY CONSTRUCTION.—Nothing in subsection (h) shall be construed as precluding the availability of the

records of a pilot in an investigation or other proceeding concerning an accident or incident conducted by the Administrator, the National Transportation Safety Board, or a court.

49 U.S.C. § 44710
Revocation of airman certifications for controlled substance violations

§ 44710. Revocations of airman certificates for controlled substance violations [1]

(a) DEFINITION.—In this section, "controlled substance" has the same meaning given that term in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802).

(b) REVOCATION.—(1) The Administrator of the Federal Aviation Administration shall issue an order revoking an airman certificate issued an individual under section 44703 of this title after the individual is convicted, under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance), of an offense punishable by death or imprisonment for more than one year if the Administrator finds that—

(A) an aircraft was used to commit, or facilitate the commission of, the offense; and

(B) the individual served as an airman, or was on the aircraft, in connection with committing, or facilitating the commission of, the offense.

(2) The Administrator shall issue an order revoking an airman certificate issued an individual under section 44703 of this title if the Administrator finds that—

(A) the individual knowingly carried out an activity punishable, under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance), by death or imprisonment for more than one year;

(B) an aircraft was used to carry out or facilitate the activity; and

(C) the individual served as an airman, or was on the aircraft, in connection with carrying out, or facilitating the carrying out of, the activity.

(3) The Administrator has no authority under paragraph (1) of this subsection to review whether an airman violated a law of the United States or a State related to a controlled substance.

(c) ADVICE TO HOLDERS AND OPPORTUNITY TO ANSWER.—Before the Administrator revokes a certificate under subsection (b) of this section, the Administrator must—

(1) advise the holder of the certificate of the charges or reasons on which the Administrator relies for the proposed revocation; and

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1191.

(2) provide the holder of the certificate an opportunity to answer the charges and be heard why the certificate should not be revoked.

(d) APPEALS.—(1) An individual whose certificate is revoked by the Administrator under subsection (b) of this section may appeal the revocation order to the National Transportation Safety Board. The Board shall affirm or reverse the order after providing notice and an opportunity for a hearing on the record. When conducting the hearing, the Board is not bound by findings of fact of the Administrator but shall be bound by all validly adopted interpretations of laws and regulations the Administrator carries out and of written agency policy guidance available to the public related to sanctions to be imposed under this section unless the Board finds an interpretation is arbitrary, capricious, or otherwise not according to law.

(2) When an individual files an appeal with the Board under this subsection, the order of the Administrator revoking the certificate is stayed. However, if the Administrator advises the Board that safety in air transportation or air commerce requires the immediate effectiveness of the order—

(A) the order remains effective; and

(B) the Board shall make a final disposition of the appeal not later than 60 days after the Administrator so advises the Board.

(3) An individual substantially affected by an order of the Board under this subsection, or the Administrator when the Administrator decides that an order of the Board will have a significant adverse effect on carrying out this part, may obtain judicial review of the order under section 46110 of this title. The Administrator shall be made a party to the judicial review proceedings. Findings of fact of the Board are conclusive if supported by substantial evidence.

(e) ACQUITTAL.—(1) The Administrator may not revoke, and the Board may not affirm a revocation of, an airman certificate under subsection (b)(2) of this section on the basis of an activity described in subsection (b)(2)(A) if the holder of the certificate is acquitted of all charges related to a controlled substance in an indictment or information arising from the activity.

(2) If the Administrator has revoked an airman certificate under this section because of an activity described in subsection (b)(2)(A) of this section, the Administrator shall reissue a certificate to the individual if—

(A) the individual otherwise satisfies the requirements for a certificate under section 44703 of this title; and

(B)(i) the individual subsequently is acquitted of all charges related to a controlled substance in an indictment or information arising from the activity; or

(ii) the conviction on which a revocation under subsection (b)(1) of this section is based is reversed.

(f) WAIVERS.—The Administrator may waive the requirement of subsection (b) of this section that an airman certificate of an individual be revoked if—

(1) a law enforcement official of the United States Government or of a State requests a waiver; and

(2) the Administrator decides that the waiver will facilitate law enforcement efforts.

49 U.S.C. § 44713

Modification of regulations relating to aircraft fuel tank repair and alteration applications and inspections to more effectively serve the needs of controlled substance enforcement efforts

§ 44713. Inspection and maintenance [1]

(a) GENERAL EQUIPMENT REQUIREMENTS.—An air carrier shall make, or cause to be made, any inspection, repair, or maintenance of equipment used in air transportation as required by this part or regulations prescribed or orders issued by the Administrator of the Federal Aviation Administration under this part. A person operating, inspecting, repairing, or maintaining the equipment shall comply with those requirements, regulations, and orders.

(b) DUTIES OF INSPECTORS.—The Administrator of the Federal Aviation Administration shall employ inspectors who shall—

(1) inspect aircraft, aircraft engines, propellers, and appliances designed for use in air transportation, during manufacture and when in use by an air carrier in air transportation, to enable the Administrator to decide whether the aircraft, aircraft engines, propellers, or appliances are in safe condition and maintained properly; and

(2) advise and cooperate with the air carrier during that inspection and maintenance.

(c) UNSAFE AIRCRAFT, ENGINES, PROPELLERS, AND APPLIANCES.—When an inspector decides that an aircraft, aircraft engine, propeller, or appliance is not in condition for safe operation, the inspector shall notify the air carrier in the form and way prescribed by the Administrator of the Federal Aviation Administration. For 5 days after the carrier is notified, the aircraft, engine, propeller, or appliance may not be used in air transportation or in a way that endangers air transportation unless the Administrator or the inspector decides the aircraft, engine, propeller, or appliance is in condition for safe operation.

(d) MODIFICATIONS IN SYSTEM.—(1) The Administrator of the Federal Aviation Administration shall make modifications in the system for processing forms for major repairs or alterations to fuel tanks and fuel systems of aircraft not used to provide air transportation that are necessary to make the system more effective in serving the needs of users of the system, including officials responsible for enforcing laws related to the regulation of controlled substances (as defined in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)). The modifications shall address at least each of the following deficiencies in, and abuses of, the existing system:

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[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1194, and amended by Public Law 104–264, Title IV, § 407(b), Oct. 9, 1996, 110 Stat. 3258.

(A) the lack of a special identification feature to allow the forms to be distinguished easily from other major repair and alteration forms.

(B) the excessive period of time required to receive the forms at the Airmen and Aircraft Registry of the Administration.

(C) the backlog of forms waiting for processing at the Registry.

(D) the lack of ready access by law enforcement officials to information contained on the forms.

(2) The Administrator of the Federal Aviation Administration shall prescribe regulations to carry out paragraph (1) of this subsection and provide a written explanation of how the regulations address each of the deficiencies and abuses described in paragraph (1). In prescribing the regulations, the Administrator of the Federal Aviation Administration shall consult with the Administrator of Drug Enforcement, the Commissioner of Customs, other law enforcement officials of the United States Government, representatives of State and local law enforcement officials, representatives of the general aviation aircraft industry, representatives of users of general aviation aircraft, and other interested persons.

(e) AUTOMATED SURVEILLANCE TARGETING SYSTEMS.—

(1) IN GENERAL.—The Administrator shall give high priority to developing and deploying a fully enhanced safety performance analysis system that includes automated surveillance to assist the Administrator in prioritizing and targeting surveillance and inspection activities of the Federal Aviation Administration.

(2) DEADLINES FOR DEPLOYMENT.—

(A) INITIAL PHASE.—The initial phase of the operational deployment of the system developed under this subsection shall begin not later than December 31, 1997.

(B) FINAL PHASE.—The final phase of field deployment of the system developed under this subsection shall begin not later than December 31, 1999. By that date, all principal operations and maintenance inspectors of the Administration, and appropriate supervisors and analysts of the Administration shall have been provided access to the necessary information and resources to carry out the system.

(3) INTEGRATION OF INFORMATION.—In developing the system under this section, the Administration shall consider the near-term integration of accident and incident data into the safety performance analysis system under this subsection.

49 U.S.C. § 44936
Aviation security screeners disqualified for certain controlled substance convictions

Chapter 449. Security

§ 44936. Employment investigations and restrictions [1]

(a) EMPLOYMENT INVESTIGATION REQUIREMENT.—(1)(A) The Under Secretary of Transportation for Security shall require by regulation that an employment investigation, including a criminal history record check and a review of available law enforcement data bases and records of other governmental and international agencies to the extent determined practicable by the Under Secretary of Transportation for Transportation Security,,[2] shall be conducted of each individual employed in, or applying for, a position as a security screener under section 44935(e) or a position in which the individual has unescorted access, or may permit other individuals to have unescorted access, to—

(i) aircraft of an air carrier or foreign air carrier; or

(ii) a secured area of an airport in the United States the Under Secretary designates that serves an air carrier or foreign air carrier.

(B) The Under Secretary shall require by regulation that an employment investigation (including a criminal history record check and a review of available law enforcement data bases and records of other governmental and international agencies to the extent determined practicable by the Under Secretary of Transportation for Transportation Security) be conducted for—

(i) individuals who are responsible for screening passengers or property under section 44901 of this title;

(ii) supervisors of the individuals described in clause (i);

(iii) individuals who regularly have escorted access to aircraft of an air carrier or foreign air carrier or a secured area of an airport in the United States the Administrator designates that serves an air carrier or foreign air carrier; and

(iv) such other individuals who exercise security functions associated with baggage or cargo, as the Under Secretary determines is necessary to ensure air transportation security.

(C) BACKGROUND CHECKS OF CURRENT EMPLOYEES.—

(i) A new background check (including a criminal history record check and a review of available law enforcement data

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[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1218, and amended by Public Law 104–264, Title III, §§ 304(a), 306, Title V, § 502(a), Oct. 9, 1996, 110 Stat. 3251, 3252, 3259; Public Law 105–102, § 2(25), Nov. 20, 1997, 111 Stat. 2205; Public Law 105–142, §§ 1, 2(25), Dec. 5, 1997, 111 Stat. 2650; Public Law 106–181, Title V, § 508, Apr. 5, 2000, 114 Stat. 140; Public Law 106–528, § 2(c), (d), Nov. 22, 2000, 114 Stat. 2517; Public Law 107–71, Title I, §§ 101(f)(7), (9), 111(b), 138(a), (b)(1), 140(a)(1), Nov. 19, 2001, 115 Stat. 603, 620, 639, 640, 641.

[2] So in original.

bases and records of other governmental and international agencies to the extent determined practicable by the Under Secretary of Transportation for Transportation Security shall be required for any individual who is employed in a position described in subparagraphs (A) and (B) on the date of enactment of the Aviation and Transportation Security Act.

(ii) The Under Secretary may provide by order (without regard to the provisions of chapter 5 of title 5, United States Code) for a phased-in implementation of the requirements of this subparagraph.

(D) EXEMPTION.— An employment investigation, including a criminal history record check, shall not be required under this subsection for an individual who is exempted under section 107.31(m)(1) or (2) of title 14, Code of Federal Regulations, as in effect on November 22, 2000. The Under Secretary shall work with the International Civil Aviation Organization and with appropriate authorities of foreign countries to ensure that individuals exempted under this subparagraph do not pose a threat to aviation or national security.

(2) An air carrier, foreign air carrier, airport operator, or government that employs, or authorizes or makes a contract for the services of, an individual in a position described in paragraph (1) of this subsection shall ensure that the investigation the Under Secretary requires is conducted.

(3) The Under Secretary shall provide for the periodic audit of the effectiveness of criminal history record checks conducted under paragraph (1) of this subsection.

(b) PROHIBITED EMPLOYMENT.—(1) Except as provided in paragraph (3) of this subsection, an air carrier, foreign air carrier, airport operator, or government may not employ, or authorize or make a contract for the services of, an individual in a position described in subsection (a)(1) of this section if—

(A) the investigation of the individual required under this section has not been conducted; or

(B) the results of that investigation establish that, in the 10-year period ending on the date of the investigation, the individual was convicted (or found not guilty by reason of insanity) of—

(i) a crime referred to in section 46306, 46308, 46312, 46314, or 46315 or chapter 465 of this title or section 32 of title 18;

(ii) murder;

(iii) assault with intent to murder;

(iv) espionage;

(v) sedition;

(vi) treason;

(vii) rape;

(viii) kidnapping;

(ix) unlawful possession, sale, distribution, or manufacture of an explosive or weapon;

(x) extortion;

(xi) armed or felony unarmed robbery;

(xii) distribution of, or intent to distribute, a controlled substance;

(xiii) a felony involving a threat;
(xiv) a felony involving—
(I) willful destruction of property;
(II) importation or manufacture of a controlled substance;
(III) burglary;
(IV) theft;
(V) dishonesty, fraud, or misrepresentation;
(VI) possession or distribution of stolen property;
(VII) aggravated assault;
(VIII) bribery; and
(IX) illegal possession of a controlled substance punishable by a maximum term of imprisonment of more than 1 year, or any other crime classified as a felony that the Under Secretary determines indicates a propensity for placing contraband aboard an aircraft in return for money; or
(xv) conspiracy to commit any of the acts referred to in clauses (i) through (xiv).

(2) The Under Secretary may specify other factors that are sufficient to prohibit the employment of an individual in a position described in subsection (a)(1) of this section.

(3) An air carrier, foreign air carrier, airport operator, or government may employ, or authorize or contract for the services of, an individual in a position described in subsection (a)(1) of this section without carrying out the investigation required under this section, if the Under Secretary approves a plan to employ the individual that provides alternate security arrangements.

(c) FINGERPRINTING AND RECORD CHECK INFORMATION.—(1) If the Under Secretary requires an identification and criminal history record check, to be conducted by the Attorney General, as part of an investigation under this section, the Under Secretary shall designate an individual to obtain fingerprints and submit those fingerprints to the Attorney General. The Attorney General may make the results of a check available to an individual the Under Secretary designates. Before designating an individual to obtain and submit fingerprints or receive results of a check, the Under Secretary shall consult with the Attorney General. All Federal agencies shall cooperate with the Under Secretary and the Under Secretary's designee in the process of collecting and submitting fingerprints.

(2) The Under Secretary shall prescribe regulations on—
(A) procedures for taking fingerprints; and
(B) requirements for using information received from the Attorney General under paragraph (1) of this subsection—
(i) to limit the dissemination of the information; and
(ii) to ensure that the information is used only to carry out this section.

(3) If an identification and criminal history record check is conducted as part of an investigation of an individual under this section, the individual—
(A) shall receive a copy of any record received from the Attorney General; and

(B) may complete and correct the information contained in the check before a final employment decision is made based on the check.

(d) FEES AND CHARGES.—The Under Secretary and the Attorney General shall establish reasonable fees and charges to pay expenses incurred in carrying out this section. The employer of the individual being investigated shall pay the costs of a record check of the individual. Money collected under this section shall be credited to the account in the Treasury from which the expenses were incurred and are available to the Under Secretary and the Attorney General for those expenses.

(e) WHEN INVESTIGATION OR RECORD CHECK NOT REQUIRED.—This section does not require an investigation or record check when the investigation or record check is prohibited by a law of a foreign country.

Chapter 451. Alcohol and Controlled Substances Testing

§ 45101. Definition [1]

In this chapter, "controlled substance" means any substance under section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802) specified by the Administrator of the Federal Aviation Administration.

§ 45102. Alcohol and controlled substances testing programs [2]

(a) PROGRAM FOR EMPLOYEES OF AIR CARRIERS AND FOREIGN AIR CARRIERS.—(1) In the interest of aviation safety, the Administrator of the Federal Aviation Administration shall prescribe regulations that establish a program requiring air carriers and foreign air carriers to conduct preemployment, reasonable suspicion, random, and post-accident testing of airmen, crew members, airport security screening personnel, and other air carrier employees responsible for safety-sensitive functions (as decided by the Administrator) for the use of a controlled substance in violation of law or a United States Government regulation; and to conduct reasonable suspicion, random, and post-accident testing of airmen, crew members, airport security screening personnel, and other air carrier employees responsible for safety-sensitive functions (as decided by the Administrator) for the use of alcohol in violation of law or a United States Government regulation. The regulations shall permit air carriers and foreign air carriers to conduct preemployment testing of airmen, crew members, airport security screening personnel, and other air carrier employees responsible for safety-sensitive functions (as decided by the Administrator) for the use of alcohol.

(2) When the Administrator considers it appropriate in the interest of safety, the Administrator may prescribe regulations for conducting periodic recurring testing of airmen, crewmembers, airport security screening personnel, and other air carrier employees responsible for safety-sensitive functions for the use of alcohol or a controlled substance in violation of law or a Government regulation.

(b) PROGRAM FOR EMPLOYEES OF THE FEDERAL AVIATION ADMINISTRATION.—(1) The Administrator shall establish a program of preemployment, reasonable suspicion, random, and post-accident testing for the use of a controlled substance in violation of law or a United States Government regulation for employees of the Administration whose duties include responsibility for safety-sensitive

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1221.

[2] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1221, and amended by Public Law 104–59, Title III, § 342(d), Nov. 28, 1995, 109 Stat. 609; Public Law 107–71, Title I, § 139(1), Nov. 19, 2001, 115 Stat. 640.

functions and shall establish a program of reasonable suspicion, random, and post-accident testing for the use of alcohol in violation of law or a United States Government regulation for such employees. The Administrator may establish a program of preemployment testing for the use of alcohol for such employees.

(2) When the Administrator considers it appropriate in the interest of safety, the Administrator may prescribe regulations for conducting periodic recurring testing of employees of the Administration responsible for safety-sensitive functions for use of alcohol or a controlled substance in violation of law or a Government regulation.

(c) SANCTIONS.—In prescribing regulations under the programs required by this section, the Administrator shall require, as the Administrator considers appropriate, the suspension or revocation of any certificate issued to an individual referred to in this section, or the disqualification or dismissal of the individual, under this chapter when a test conducted and confirmed under this chapter indicates the individual has used alcohol or a controlled substance in violation of law or a Government regulation.

§ 45103. Prohibited service[3]

(a) USE OF ALCOHOL OR A CONTROLLED SUBSTANCE.—An individual may not use alcohol or a controlled substance after October 28, 1991, in violation of law or a United States Government regulation and serve as an airman, crewmember, airport security screening employee, air carrier employee responsible for safety-sensitive functions (as decided by the Administrator of the Federal Aviation Administration), or employee of the Administration with responsibility for safety-sensitive functions.

(b) REHABILITATION REQUIRED TO RESUME SERVICE.—Notwithstanding subsection (a) of this section, an individual found to have used alcohol or a controlled substance after October 28, 1991, in violation of law or a Government regulation may serve as an airman, crewmember, airport security screening employee, air carrier employee responsible for safety-sensitive functions (as decided by the Administrator), or employee of the Administration with responsibility for safety-sensitive functions only if the individual completes a rehabilitation program described in section 45105 of this title.

(c) PERFORMANCE OF PRIOR DUTIES PROHIBITED.—An individual who served as an airman, crewmember, airport security screening employee, air carrier employee responsible for safety-sensitive functions (as decided by the Administrator), or employee of the Administration with responsibility for safety-sensitive functions and who was found by the Administrator to have used alcohol or a controlled substance after October 28, 1991, in violation of law or a Government regulation may not carry out the duties related to air transportation that the individual carried out before the finding of the Administrator if the individual—

(1) used the alcohol or controlled substance when on duty;

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[3] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1222, and amended by Public Law 107–71, Title I, § 139(2), Nov. 19, 2001, 115 Stat. 640.

(2) began or completed a rehabilitation program described in section 45105 of this title before using the alcohol or controlled substance; or

(3) refuses to begin or complete a rehabilitation program described in section 45105 of this title after a finding by the Administrator under this section.

§ 45104. Testing and laboratory requirements[4]

In carrying out section 45102 of this title, the Administrator of the Federal Aviation Administration shall develop requirements that—

(1) promote, to the maximum extent practicable, individual privacy in the collection of specimens;

(2) for laboratories and testing procedures for controlled substances, incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing—

(A) comprehensive standards for every aspect of laboratory controlled substances testing and laboratory procedures to be applied in carrying out this chapter, including standards requiring the use of the best available technology to ensure the complete reliability and accuracy of controlled substances tests and strict procedures governing the chain of custody of specimens collected for controlled substances testing;

(B) the minimum list of controlled substances for which individuals may be tested; and

(C) appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform controlled substances testing in carrying out this chapter;

(3) require that a laboratory involved in controlled substances testing under this chapter have the capability and facility, at the laboratory, of performing screening and confirmation tests;

(4) provide that all tests indicating the use of alcohol or a controlled substance in violation of law or a United States Government regulation be confirmed by a scientifically recognized method of testing capable of providing quantitative information about alcohol or a controlled substance;

(5) provide that each specimen be subdivided, secured, and labeled in the presence of the tested individual and that a part of the specimen be retained in a secure manner to prevent the possibility of tampering, so that if the individual's confirmation test results are positive the individual has an opportunity to have the retained part tested by a 2d confirmation test done independently at another certified laboratory if the individual requests the 2d confirmation test not later than 3 days after being advised of the results of the first confirmation test;

(6) ensure appropriate safeguards for testing to detect and quantify alcohol in breath and body fluid samples, including urine and blood, through the development of regulations that

[4] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1222.

may be necessary and in consultation with the Secretary of Health and Human Services;

(7) provide for the confidentiality of test results and medical information (except information about alcohol or a controlled substance) of employees, except that this clause does not prevent the use of test results for the orderly imposition of appropriate sanctions under this chapter; and

(8) ensure that employees are selected for tests by nondiscriminatory and impartial methods, so that no employee is harassed by being treated differently from other employees in similar circumstances.

§ 45105. Rehabilitation [5]

(a) PROGRAM FOR EMPLOYEES OF AIR CARRIERS AND FOREIGN AIR CARRIERS.—The Administrator of the Federal Aviation Administration shall prescribe regulations establishing requirements for rehabilitation programs that at least provide for the identification and opportunity for treatment of employees of air carriers and foreign air carriers referred to in section 45102(a)(1) of this title who need assistance in resolving problems with the use of alcohol or a controlled substance in violation of law or a United States Government regulation. Each air carrier and foreign air carrier is encouraged to make such a program available to all its employees in addition to the employees referred to in section 45102(a)(1). The Administrator shall decide on the circumstances under which employees shall be required to participate in a program. This subsection does not prevent an air carrier or foreign air carrier from establishing a program under this subsection in cooperation with another air carrier or foreign air carrier.

(b) PROGRAM FOR EMPLOYEES OF THE FEDERAL AVIATION ADMINISTRATION.—The Administrator shall establish and maintain a rehabilitation program that at least provides for the identification and opportunity for treatment of employees of the Administration whose duties include responsibility for safety-sensitive functions who need assistance in resolving problems with the use of alcohol or a controlled substance.

§ 45106. Relationship to other laws, regulations, standards, and orders [6]

(a) EFFECT ON STATE AND LOCAL GOVERNMENT LAWS, REGULATIONS, STANDARDS, OR ORDERS.—A State or local government may not prescribe, issue, or continue in effect a law, regulation, standard, or order that is inconsistent with regulations prescribed under this chapter. However, a regulation prescribed under this chapter does not preempt a State criminal law that imposes sanctions for reckless conduct leading to loss of life, injury, or damage to property.

(b) INTERNATIONAL OBLIGATIONS AND FOREIGN LAWS.—(1) In prescribing regulations under this chapter, the Administrator of the Federal Aviation Administration—

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[5] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1223, and amended by Public Law 103–429, § 6(58), Oct. 31, 1994, 108 Stat. 4385.

[6] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1224, and amended by Public Law 107–71, Title I, § 139(3), Nov. 19, 2001, 115 Stat. 640.

(A) shall establish only requirements applicable to foreign air carriers that are consistent with international obligations of the United States; and

(B) shall consider applicable laws and regulations of foreign countries.

(2) The Secretaries of State and Transportation jointly shall request the governments of foreign countries that are members of the International Civil Aviation Organization to strengthen and enforce existing standards to prohibit crewmembers in international civil aviation from using alcohol or a controlled substance in violation of law or a United States Government regulation.

(c) OTHER REGULATIONS ALLOWED.—This section does not prevent the Administrator from continuing in effect, amending, or further supplementing a regulation prescribed before October 28, 1991, governing the use of alcohol or a controlled substance by airmen, crewmembers, airport security screening employees, air carrier employees responsible for safety-sensitive functions (as decided by the Administrator), or employees of the Administration with responsibility for safety-sensitive functions.

§ 45107. Transportation Security Administration[7]

(a) TRANSFER OF FUNCTIONS RELATING TO TESTING PROGRAMS WITH RESPECT TO AIRPORT SECURITY SCREENING PERSONNEL.—The authority of the Administrator of the Federal Aviation Administration under this chapter with respect to programs relating to testing of airport security screening personnel are transferred to the Under Secretary of Transportation for Security. Notwithstanding section 45102(a), the regulations prescribed under section 45102(a) shall require testing of such personnel by their employers instead of by air carriers and foreign air carriers.

(b) APPLICABILITY OF CHAPTER WITH RESPECT TO EMPLOYEES OF ADMINISTRATION.—The provisions of this chapter that apply with respect to employees of the Federal Aviation Administration whose duties include responsibility for safety-sensitive functions shall apply with respect to employees of the Transportation Security Administration whose duties include responsibility for security-sensitive functions. The Under Secretary of Transportation for Security, the Transportation Security Administration, and employees of the Transportation Security Administration whose duties include responsibility for security-sensitive functions shall be subject to and comply with such provisions in the same manner and to the same extent as the Administrator of the Federal Aviation Administration, the Federal Aviation Administration, and employees of the Federal Aviation Administration whose duties include responsibility for safety-sensitive functions, respectively.

[7] Added by Public Law 107–71, Title I, § 139(4), Nov. 19, 2001, 115 Stat. 640.

49 U.S.C. § 46306
Registration violations involving aircraft not providing air transportation in furtherance of a controlled substance violation

Chapter 463. Penalties

§ 46306. Registration violations involving aircraft not providing air transportation [1]

(a) APPLICATION.—This section applies only to aircraft not used to provide air transportation.

(b) GENERAL CRIMINAL PENALTY.—Except as provided by subsection (c) of this section, a person shall be fined under title 18, imprisoned for not more than 3 years, or both, if the person—

(1) knowingly and willfully forges or alters a certificate authorized to be issued under this part;

(2) knowingly sells, uses, attempts to use, or possesses with the intent to use, such a certificate;

(3) knowingly and willfully displays or causes to be displayed on an aircraft a mark that is false or misleading about the nationality or registration of the aircraft;

(4) obtains a certificate authorized to be issued under this part by knowingly and willfully falsifying or concealing a material fact, making a false, fictitious, or fraudulent statement, or making or using a false document knowing it contains a false, fictitious, or fraudulent statement or entry;

(5) owns an aircraft eligible for registration under section 44102 of this title and knowingly and willfully operates, attempts to operate, or allows another person to operate the aircraft when—

(A) the aircraft is not registered under section 44103 of this title or the certificate of registration is suspended or revoked; or

(B) the owner knows or has reason to know that the other person does not have proper authorization to operate or navigate the aircraft without registration for a period of time after transfer of ownership;

(6) knowingly and willfully operates or attempts to operate an aircraft eligible for registration under section 44102 of this title knowing that—

(A) the aircraft is not registered under section 44103 of this title;

(B) the certificate of registration is suspended or revoked; or

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1235, and amended by Public Law 104–287, § 5(78), Oct. 11, 1996, 110 Stat. 3397.

(C) the person does not have proper authorization to operate or navigate the aircraft without registration for a period of time after transfer of ownership;

(7) knowingly and willfully serves or attempts to serve in any capacity as an airman without an airman's certificate authorizing the individual to serve in that capacity;

(8) knowingly and willfully employs for service or uses in any capacity as an airman an individual who does not have an airman's certificate authorizing the individual to serve in that capacity; or

(9) operates an aircraft with a fuel tank or fuel system that has been installed or modified knowing that the tank, system, installation, or modification does not comply with regulations and requirements of the Administrator of the Federal Aviation Administration.

(c) CONTROLLED SUBSTANCE CRIMINAL PENALTY.—(1) In this subsection, "controlled substance" has the same meaning given that term in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802).

(2) A person violating subsection (b) of this section shall be fined under title 18, imprisoned for not more than 5 years, or both, if the violation is related to transporting a controlled substance by aircraft or aiding or facilitating a controlled substance violation and the transporting, aiding, or facilitating—

(A) is punishable by death or imprisonment of more than one year under a law of the United States or a State; or

(B) that is provided is related to an act punishable by death or imprisonment for more than one year under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance).

(3) A term of imprisonment imposed under paragraph (2) of this subsection shall be served in addition to, and not concurrently with, any other term of imprisonment imposed on the individual.

(d) SEIZURE AND FORFEITURE.—(1) The Administrator of Drug Enforcement or the Commissioner of Customs may seize and forfeit under the customs laws an aircraft whose use is related to a violation of subsection (b) of this section, or to aid or facilitate a violation, regardless of whether a person is charged with the violation.

(2) An aircraft's use is presumed to have been related to a violation of, or to aid or facilitate a violation of—

(A) subsection (b)(1) of this section if the aircraft certificate of registration has been forged or altered;

(B) subsection (b)(3) of this section if there is an external display of false or misleading registration numbers or country of registration;

(C) subsection (b)(4) of this section if—

(i) the aircraft is registered to a false or fictitious person; or

(ii) the application form used to obtain the aircraft certificate of registration contains a material false statement;

(D) subsection (b)(5) of this section if the aircraft was operated when it was not registered under section 44103 of this title; or

(E) subsection (b)(9) of this section if the aircraft has a fuel tank or fuel system that was installed or altered—

(i) in violation of a regulation or requirement of the Administrator of the Federal Aviation Administration; or

(ii) if a certificate required to be issued for the installation or alteration is not carried on the aircraft.

(3) The Administrator of the Federal Aviation Administration, the Administrator of Drug Enforcement, and the Commissioner shall agree to a memorandum of understanding to establish procedures to carry out this subsection.

(e) RELATIONSHIP TO STATE LAWS.—This part does not prevent a State from establishing a criminal penalty, including providing for forfeiture and seizure of aircraft, for a person that—

(1) knowingly and willfully forges or alters an aircraft certificate of registration;

(2) knowingly sells, uses, attempts to use, or possesses with the intent to use, a fraudulent aircraft certificate of registration;

(3) knowingly and willfully displays or causes to be displayed on an aircraft a mark that is false or misleading about the nationality or registration of the aircraft; or

(4) obtains an aircraft certificate of registration from the Administrator of the Federal Aviation Administration by—

(A) knowingly and willfully falsifying or concealing a material fact;

(B) making a false, fictitious, or fraudulent statement; or

(C) making or using a false document knowing it contains a false, fictitious, or fraudulent statement or entry.

49 U.S.C. § 46315
Lighting violations involving transporting controlled substances by aircraft not providing air transportation

§ 46315. Lighting violations involving transporting controlled substances by aircraft not providing air transportation [1]

(a) APPLICATION.—This section applies only to aircraft not used to provide air transportation.

(b) CRIMINAL PENALTY.—A person shall be fined under title 18, imprisoned for not more than 5 years, or both, if—

(1) the person knowingly and willfully operates an aircraft in violation of a regulation or requirement of the Administrator of the Federal Aviation Administration related to the display of navigation or anticollision lights;

(2) the person is knowingly transporting a controlled substance by aircraft or aiding or facilitating a controlled substance offense; and

(3) the transporting, aiding, or facilitating—

(A) is punishable by death or imprisonment for more than one year under a law of the United States or a State; or

(B) is provided in connection with an act punishable by death or imprisonment for more than one year under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance).

[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1240.

49 U.S.C. § 46317
Operating in air transportation without an airman's certification in furtherance of a controlled substance violation

§ 46317. Criminal penalty for pilots operating in air transportation without an airman's certificate [1]

(a) GENERAL CRIMINAL PENALTY.—An individual shall be fined under title 18 or imprisoned for not more than 3 years, or both, if that individual—

(1) knowingly and willfully serves or attempts to serve in any capacity as an airman operating an aircraft in air transportation without an airman's certificate authorizing the individual to serve in that capacity; or

(2) knowingly and willfully employs for service or uses in any capacity as an airman to operate an aircraft in air transportation an individual who does not have an airman's certificate authorizing the individual to serve in that capacity.

(b) CONTROLLED SUBSTANCE CRIMINAL PENALTY.—

(1) CONTROLLED SUBSTANCES DEFINED.—In this subsection, the term "controlled substance" has the meaning given that term in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802).

(2) CRIMINAL PENALTY.—An individual violating subsection (a) shall be fined under title 18 or imprisoned for not more than 5 years, or both, if the violation is related to transporting a controlled substance by aircraft or aiding or facilitating a controlled substance violation and that transporting, aiding, or facilitating—

(A) is punishable by death or imprisonment of more than 1 year under a Federal or State law; or

(B) is related to an act punishable by death or imprisonment for more than 1 year under a Federal or State law related to a controlled substance (except a law related to simple possession (as that term is used in section 46306(c)) of a controlled substance).

(3) TERMS OF IMPRISONMENT.—A term of imprisonment imposed under paragraph (2) shall be served in addition to, and not concurrently with, any other term of imprisonment imposed on the individual subject to the imprisonment.

[1] Added by Public Law 106–181, Title V, § 509(a), Apr. 5, 2000, 114 Stat. 141.

Chapter 803. Contraband

§ 80301. Definitions [1]

In this chapter—

(1) "aircraft" means a contrivance used, or capable of being used, for transportation in the air.

(2) "vehicle" means a contrivance used, or capable of being used, for transportation on, below, or above land, but does not include aircraft.

(3) "vessel" means a contrivance used, or capable of being used, for transportation in water, but does not include aircraft.

§ 80302. Prohibitions [2]

(a) DEFINITION.—In this section, "contraband" means—

(1) a narcotic drug (as defined in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)), including marihuana (as defined in section 102 of that Act (21 U.S.C. 802)), that—

(A) is possessed with intent to sell or offer for sale in violation of the laws and regulations of the United States;

(B) is acquired, possessed, sold, transferred, or offered for sale in violation of those laws;

(C) is acquired by theft, robbery, or burglary and transported—

(i) in the District of Columbia or a territory or possession of the United States; or

(ii) from a place in a State, the District of Columbia, or a territory or possession of the United States, to a place in another State, the District of Columbia, or a territory or possession; or

(D) does not bear tax-paid internal revenue stamps required by those laws or regulations;

(2) a firearm involved in a violation of chapter 53 of the Internal Revenue Code of 1986 (26 U.S.C. 5801 et seq.);

(3) a forged, altered, or counterfeit—

(A) coin or an obligation or other security of the United States Government (as defined in section 8 of title 18); or

(B) coin, obligation, or other security of the government of a foreign country;

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[1] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1353.

[2] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1353, and amended by Public Law 104–153, § 13, July 2, 1996, 110 Stat. 1389.

(4) material or equipment used, or intended to be used, in making a coin, obligation, or other security referred to in clause (3) of this subsection;

(5) a cigarette involved in a violation of chapter 114 of title 18 or a regulation prescribed under chapter 114; or

(6)(A) a counterfeit label for a phonorecord, copy of a computer program or computer program documentation or packaging, or copy of a motion picture or other audiovisual work (as defined in section 2318 of title 18);

(B) a phonorecord or copy in violation of section 2319 of title 18;

(C) a fixation of a sound recording or music video of a live musical performance in violation of section 2319A of title 18; or

(D) any good bearing a counterfeit mark (as defined in section 2320 of title 18).

(b) PROHIBITIONS.—A person may not—

(1) transport contraband in an aircraft, vehicle, or vessel;

(2) conceal or possess contraband on an aircraft, vehicle, or vessel; or

(3) use an aircraft, vehicle, or vessel to facilitate the transportation, concealment, receipt, possession, purchase, sale, exchange, or giving away of contraband.

§ 80303. Seizure and forfeiture [3]

The Secretary of the Treasury or the Governor of Guam or of the Northern Mariana Islands as provided in section 80304 of this title or, when the violation of this chapter involves contraband described in paragraph (2) or (5) of section 80302(a), the Attorney General, or a person authorized by another law to enforce section 80302 of this title, shall seize an aircraft, vehicle, or vessel involved in a violation of section 80302 and place it in the custody of a person designated by the Secretary, the Attorney General, or appropriate Governor, as the case may be. The seized aircraft, vehicle, or vessel shall be forfeited, except when the owner establishes that a person except the owner committed the violation when the aircraft, vehicle, or vessel was in the possession of a person who got possession by violating a criminal law of the United States or a State. However, an aircraft, vehicle, or vessel used by a common carrier to provide transportation for compensation may be forfeited only when—

(1) the owner, conductor, driver, pilot, or other individual in charge of the aircraft or vehicle (except a rail car or engine) consents to, or knows of, the alleged violation when the violation occurs;

(2) the owner of the rail car or engine consents to, or knows of, the alleged violation when the violation occurs; or

(3) the master or owner of the vessel consents to, or knows of, the alleged violation when the violation occurs.

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[3] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1354, and amended by Public Law 107–296, Title XI, § 1112(q), Nov. 25, 2002, 116 Stat. 2278.

§ 80304. Administrative[4]

(a) GENERAL.—Except as provided in subsections (b), (c), and (d) of this section, the Secretary of the Treasury—

(1) may designate officers, employees, agents, or other persons to carry out this chapter; and

(2) shall prescribe regulations to carry out this chapter.

(b) IN GUAM.—The Governor of Guam—

(1) or officers of the government of Guam designated by the Governor shall carry out this chapter in Guam;

(2) may carry out laws referred to in section 80306(b) of this title with modifications the Governor decides are necessary to meet conditions in Guam; and

(3) may prescribe regulations to carry out this chapter in Guam.

(c) IN NORTHERN MARIANA ISLANDS.—The Governor of the Northern Mariana Islands—

(1) or officers of the government of the Northern Mariana Islands designated by the Governor shall carry out this chapter in the Northern Mariana Islands;

(2) may carry out laws referred to in section 80306(b) of this title with modifications the Governor decides are necessary to meet conditions in the Northern Mariana Islands; and

(3) may prescribe regulations to carry out this chapter in the Northern Mariana Islands.

(d) ATTORNEY GENERAL.—The Attorney General, or officers, employees, or agents of the Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice designated by the Attorney General, shall carry out the laws referred to in section 80306(b) of this title to the extent that the violation of this chapter involves contraband described in section 80302(a)(2) or (a)(5).

(e) CUSTOMS LAWS ON SEIZURE AND FORFEITURE.—The Secretary, or the Governor of Guam or of the Northern Mariana Islands as provided in subsections (b) and (c) of this section, shall carry out the customs laws on the seizure and forfeiture of aircraft, vehicles, and vessels under this chapter.

§ 80305. Availability of certain appropriations[5]

Appropriations for enforcing customs, narcotics, counterfeiting, or internal revenue laws are available to carry out this chapter.

§ 80306. Relationship to other laws[6]

(a) CHAPTER AS ADDITIONAL LAW.—This chapter is in addition to another law—

(1) imposing, or authorizing the compromise of, fines, penalties, or forfeitures; or

(2) providing for seizure, condemnation, or disposition of forfeited property, or the proceeds from the property.

(b) LAWS APPLICABLE TO SEIZURES AND FORFEITURES.—To the extent applicable and consistent with this chapter, the following apply to a seizure or forfeiture under this chapter:

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[4] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1354, and amended by Public Law 107–296, Title XI, § 1112(r), Nov. 25, 2002, 116 Stat. 2278.

[5] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1355.

[6] Added by Public Law 103–272, § 1(e), July 5, 1994, 108 Stat. 1355.

(1) provisions of law related to the seizure, forfeiture, and condemnation of vehicles and vessels violating the customs laws.

(2) provisions of law related to the disposition of those vehicles or vessels or the proceeds from the sale of those vehicles or vessels.

(3) provisions of law related to the compromise of those forfeitures or claims related to those forfeitures.

(4) provisions of law related to the award of compensation to an informer about those forfeitures.

Appendix

Executive Orders

Executive Order No. 13165 of August 9, 2000 [1]

Creation of the White House Task Force on Drug Use in Sports and Authorization for the Director of the Office of National Drug Control Policy To Serve as the United States Government's Representative on the Board of the World Anti-Doping Agency

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Office of National Drug Control Reauthorization Act of 1998, (21 U.S.C. 1701 et seq.), and in order to develop recommendations for Federal agency actions to address the use of drugs in sports, in particular among young people, it is hereby ordered as follows:

Section 1. POLICY. The use of drugs in sports has reached a level that endangers not just the legitimacy of athletic competition but also the lives and health of athletes—from the elite ranks to youth leagues. The National Household Survey on Drug Abuse issued in 1999 found that in just 1 year's time the rate of steroid use among young people rose roughly 50 percent among both sexes and across all age groups. It is the policy of my Administration to take the steps needed to help eliminate illicit or otherwise banned drug use and doping in sports at the State, national, and international level.

Sec. 2. ESTABLISHMENT OF A WHITE HOUSE TASK FORCE ON DRUG USE IN SPORTS. (a) There is established a White House Task Force on Drug Use in Sports (Task Force). The Task Force shall comprise the co-vice chairs of the White House Olympic Task Force (the "Olympic Task Force Vice Chairs"), and representatives designated by the Office of National Drug Control Policy, the Department of Health and Human Services, the Department of Labor, the President's Council on Physical Fitness and Sports, the Office of Management and Budget, the National Security Council, the Department of State, the Department of the Treasury, the Department of Education, the Department of Justice, the Department of Transportation, the Department of Homeland Security, the National Institute on Drug Abuse, and the Substance Abuse and Mental Health Services Administration.

(b) The Task Force shall develop recommendations for the President on further executive and legislative actions that can be undertaken to address the problem of doping and drug use in sports. In developing the recommendations, the Task Force shall consider, among other things: (i) the health and safety of America's athletes,

[1] As amended by Executive Order No. 13286 (Feb. 28, 2003), 21 U.S.C. § 1701 note.

in particular our Nation's young people; (ii) the integrity of honest athletic competition; and (iii) the views and recommendations of State and local governments, the private sector, citizens, community groups, and nonprofit organizations, on actions to address this threat. The Task Force, through its Chairs, shall submit its recommendations to the President.

(c) The Director of the Office of National Drug Control Policy (the Director), the Secretary of the Department of Health and Human Services, and the Olympic Task Force Vice Chairs or their designees shall serve as the Task Force Chairs.

(d) To the extent permitted by law and at the request of the Chairs, agencies shall cooperate with and provide information to the Task Force.

Sec. 3. PARTICIPATION IN THE WORLD ANTI-DOPING AGENCY. (a) As part of my Administration's efforts to address the problem of drug use in sports, the United States has played a leading role in the formation of a World Anti-Doping Agency (WADA) by the Olympic and sports community and the nations of the world. Through these efforts, the United States has been selected to serve as a governmental representative on the board of the WADA. This order will authorize the Director to serve as the United States Government's representative on the WADA board.

(b) Pursuant to 21 U.S.C. 1701 et seq., the Director, or in his absence his designee, is hereby authorized to take all necessary and proper actions to execute his responsibilities as United States representative to the WADA.

(c) To assist the Director in carrying out these responsibilities as the United States Government representative to the WADA and to the extent permitted by law, Federal employees may serve in their official capacity, *inter alia*, on WADA Committees or WADA advisory committees, serving as experts to the WADA.

WILLIAM J. CLINTON

Executive Order No. 12992 of March 15, 1996 [1]

President's Drug Policy Council

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

Section 1. *Establishment.* There is established the President's Drug Policy Council.

Sec. 2. *Membership.* The Council shall comprise the:

(a) President; who shall serve as Chairman of the Council;
(b) Vice President;
(c) Secretary of State;
(d) Secretary of the Treasury;
(e) Secretary of Defense;
(f) Attorney General;
(g) Secretary of the Interior;
(h) Secretary of Agriculture;
(i) Secretary of Health and Human Services;
(j) Secretary of Housing and Urban Development;
(k) Secretary of Transportation;
(l) Secretary of Education;
(m) Secretary of Veterans Affairs;
(n) Secretary of Homeland Security;
(o) Representative of the United States of America to the United Nations;
(p) Director of the Office of Management and Budget;
(q) Chief of Staff to the President;
(r) Director of National Drug Control Policy;
(s) Director of Central Intelligence;
(t) Assistant to the President for National Security Affairs;
(u) Counsel to the President;
(v) Chairman, Joint Chiefs of Staff;
(w) National Security Advisor to the Vice President; and
(x) Assistant to the President for Domestic Policy.

As applicable, the Council shall also comprise such other officials of the departments and agencies as the President may, from time to time, designate.

Sec. 3. *Meetings of the Council.* The President, or upon his direction, the Vice President, may convene meetings of the Council. The President shall preside over meetings of the Council, provided that in his absence, the Vice President will preside. The Council will meet at least quarterly.

Sec. 4. *Functions.* (a) The functions of the Council are to advise and assist the President in: (1) providing direction and oversight

[1] As amended by Executive Order No. 13023 (Nov. 6, 1996), as amended by Executive Order No. 13284, section 8 (Jan. 23, 2003), 21 U.S.C. § 1709 note.

for the national drug control strategy, including relating drug control policy to other national security interests and establishing priorities; and (2) ensuring coordination among departments and agencies concerning implementation of the President's national drug control strategy.

(b) The Director of National Drug Control Policy will continue to be the senior drug control policy official in the executive branch and the President's chief drug control policy spokesman.

(c) In matters affecting national security interests, the Director of National Drug Control Policy shall work in conjunction with the Assistant to the President for National Security Affairs.

Sec. 5. *Administration.* (a) The Council may utilize established or ad hoc committees, task forces, or interagency groups chaired by the Director of National Drug Control Policy or his representative, in carrying out its functions under this order.

(b) The staff of the Office of National Drug Control Policy, in coordination with the staffs of the Vice President and the Assistant to the President for National Security Affairs, shall act as staff for the Council.

(c) All executive departments and agencies shall cooperate with the Council and provide such assistance, information, and advice as the Council may request, to the extent permitted by law.

WILLIAM J. CLINTON

Executive Order No. 12880 of November 16, 1993[1]

National Drug Control Program

The Office of National Drug Control Policy has the lead responsibility within the Executive Office of the President to establish policies, priorities, and objectives for the Nation's drug control program, with the goal of reducing the production, availability, and use of illegal drugs. All lawful and reasonable means must be used to ensure that the United States has a comprehensive and effective National Drug Control Strategy.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, including the National Narcotics Leadership Act of 1988, as amended (21 U.S.C. 1501 *et seq.*), and in order to provide for the effective management of the drug abuse policies of the United States, it is hereby ordered as follows:

Section 1. GENERAL PROVISIONS. (a) Because the United States considers the operations of international criminal narcotics syndicates as a national security threat requiring an extraordinary and coordinated response by civilian and military agencies involved in national security, the Director of the Office of National Drug Control Policy (Director), in his role as the principal adviser to the National Security Council on national drug control policy (50 U.S.C. 402(f)), shall provide drug policy guidance and direction in the development of related national security programs.

(b) The Director shall provide oversight and direction for all international counternarcotics policy development and implementation, in coordination with other concerned Cabinet members, as appropriate.

(c) An Interagency Working Group (IWG) on international counternarcotics policy, chaired by the Office of National Drug Control Policy, shall develop and ensure coordinated implementation of an international counternarcotics policy. The IWG shall report its activities and differences of views among agencies to the Director for review, mediation, and resolution with concerned Cabinet members, and if necessary, by the President.

(d) A coordinator for drug interdiction shall be designated by the Director to ensure that assets dedicated by Federal drug program agencies for interdiction are sufficient and that their use is properly integrated and optimized. The coordinator shall ensure that interdiction efforts and priorities are consistent with overall U.S. international counternarcotics policy.

(e) The Director shall examine the number and structure of command/control and drug intelligence centers operated by drug control program agencies involved in international counter-narcotics

[1] As amended by Executive Order No. 13008 (June 3, 1996), 21 U.S.C. § 1703 note.

[sic] and suggest improvements to the current structure for consideration by the President and concerned members of the Cabinet.

(f) The Director, utilizing the services of the Drugs and Crime Data Center and Department of Justice Clearinghouse, shall assist in coordinating and enhancing the dissemination of statistics and studies relating to anti-drug abuse policy.

(g) The Director shall provide advice to agencies regarding ways to achieve efficiencies in spending and improvements to interagency cooperation that could enhance the delivery of drug control treatment and prevention services to the public. The Director may request agencies to provide studies, information, and analyses in support of this order.

Sec. 2. GOALS, DIRECTION, DUTIES AND RESPONSIBILITIES WITH RESPECT TO THE NATIONAL DRUG CONTROL PROGRAM. (a) BUDGET MATTERS. (1) In addition to the budgetary authorities and responsibilities provided to the Director by statute, 21 U.S.C. 1502, for those agency budget requests that are not certified as adequate to implement the objectives of the National Drug Control Strategy, the Director shall include in such certifications initiatives or funding levels that would make such requests adequate.

(2) The Director shall provide, by July 1 of each year, budget recommendations to the heads of departments and agencies with responsibilities under the National Drug Control Program. The recommendations shall apply to the second following fiscal year and address funding priorities developed in the annual National Drug Control Strategy.

(b) MEASUREMENT OF NATIONAL DRUG CONTROL STRATEGY OUTCOMES. (1) The National Drug Control Strategy shall include long-range goals for reducing drug use and the consequences of drug use in the United States, including burdens on hospital emergency rooms, drug use among arrestees, the extent of drug-related crime, high school dropout rates, the number of infants exposed annually to illicit drugs in utero, national drug abuse treatment capacity, and the annual national health care costs of drug use.

(2) The National Drug Control Strategy shall also include an assessment of the quality of techniques and instruments to measure current drug use and supply and demand reduction activities, and the adequacy of the coverage of existing national drug use instruments and techniques to measure the total illicit drug user population and groups at-risk for drug use.

(3) The Director shall coordinate an effort among the relevant drug control program agencies to assess the quality, access, management, effectiveness, and standards of accountability of drug abuse treatment, prevention, education, and other demand reduction activities.

(c) PROVISION OF REPORTS. To the extent permitted by law, heads of departments and agencies with responsibilities under the National Drug Control Program shall make available to the Office of National Drug Control Policy, appropriate statistics, studies, and reports, pertaining to Federal drug abuse control.

WILLIAM J. CLINTON

Executive Order No. 12564 of September 15, 1986 [1]

Drug-Free Federal Workplace

I, RONALD REAGAN, President of the United States of America, find that:

Drug use is having serious adverse effects upon a significant proportion of the national work force and results in billions of dollars of lost productivity each year;

The Federal government, as an employer, is concerned with the well-being of its employees, the successful accomplishment of agency missions, and the need to maintain employee productivity;

The Federal government, as the largest employer in the Nation, can and should show the way towards achieving drug-free workplaces through a program designed to offer drug users a helping hand and, at the same time, demonstrating to drug users and potential drug users that drugs will not be tolerated in the Federal workplace;

The profits from illegal drugs provide the single greatest source of income for organized crime, fuel violent street crime, and otherwise contribute to the breakdown of our society;

The use of illegal drugs, on or off duty, by Federal employees is inconsistent not only with the law-abiding behavior expected of all citizens, but also with the special trust placed in such employees as servants of the public;

Federal employees who use illegal drugs, on or off duty, tend to be less productive, less reliable, and prone to greater absenteeism than their fellow employees who do not use illegal drugs;

The use of illegal drugs, on or off duty, by Federal employees impairs the efficiency of Federal departments and agencies, undermines public confidence in them, and makes it more difficult for other employees who do not use illegal drugs to perform their jobs effectively. The use of illegal drugs, on or off duty, by Federal employees also can pose a serious health and safety threat to members of the public and to other Federal employees;

The use of illegal drugs, on or off duty, by Federal employees in certain positions evidences less than the complete reliability, stability, and good judgment that is consistent with access to sensitive information and creates the possibility of coercion, influence, and irresponsible action under pressure that may pose a serious risk to national security, the public safety, and the effective enforcement of the law; and

Federal employees who use illegal drugs must themselves be primarily responsible for changing their behavior and, if necessary, begin the process of rehabilitating themselves.

By the authority vested in me as President by the Constitution and laws of the United States of America, including section 3301(2)

[1] 5 U.S.C. § 7301 note.

of Title 5 of the United States Code, section 7301 of Title 5 of the United States Code, section 290ee–1 of Title 42 of the United States Code, deeming such action in the best interests of national security, public health and safety, law enforcement and the efficiency of the Federal service, and in order to establish standards and procedures to ensure fairness in achieving a drug-free Federal workplace and to protect the privacy of Federal employees, it is hereby ordered as follows:

SECTION 1. DRUG-FREE WORKPLACE.

(a) Federal employees are required to refrain from the use of illegal drugs.

(b) The use of illegal drugs by Federal employees, whether on duty or off duty, is contrary to the efficiency of the service.

(c) Persons who use illegal drugs are not suitable for Federal employment.

SEC. 2. AGENCY RESPONSIBILITIES.

(a) The head of each Executive agency shall develop a plan for achieving the objective of a drug-free workplace with due consideration of the rights of the government, the employee, and the general public.

(b) Each agency plan shall include:

(1) A statement of policy setting forth the agency's expectations regarding drug use and the action to be anticipated in response to identified drug use;

(2) Employee Assistance Programs emphasizing high level direction, education, counseling, referral to rehabilitation, and coordination with available community resources;

(3) Supervisory training to assist in identifying and addressing illegal drug use by agency employees;

(4) Provision for self-referrals as well as supervisory referrals to treatment with maximum respect for individual confidentiality consistent with safety and security issues; and

(5) Provision for identifying illegal drug users, including testing on a controlled and carefully monitored basis in accordance with this Order.

SEC. 3. DRUG TESTING PROGRAMS.

(a) The head of each Executive agency shall establish a program to test for the use of illegal drugs by employees in sensitive positions. The extent to which such employees are tested and the criteria for such testing shall be determined by the head of each agency, based upon the nature of the agency's mission and its employees' duties, the efficient use of agency resources, and the danger to the public health and safety or national security that could result from the failure of an employee adequately to discharge his or her position.

(b) The head of each Executive agency shall establish a program for voluntary employee drug testing.

(c) In addition to the testing authorized in subsections (a) and (b) of this section, the head of each Executive agency is authorized to test an employee for illegal drug use under the following circumstances:

(1) When there is a reasonable suspicion that any employee uses illegal drugs;

(2) In an examination authorized by the agency regarding an accident or unsafe practice; or

(3) As part of or as a follow-up to counseling or rehabilitation for illegal drug use through an Employee Assistance Program.

(d) The head of each Executive agency is authorized to test any applicant for illegal drug use.

SEC. 4. DRUG TESTING PROCEDURES.

(a) Sixty days prior to the implementation of a drug testing program pursuant to this Order, agencies shall notify employees that testing for use of illegal drugs is to be conducted and that they may seek counseling and rehabilitation and inform them of the procedures for obtaining such assistance through the agency's Employee Assistance Program. Agency drug testing programs already ongoing are exempted from the 60-day notice requirement. Agencies may take action under section 3(c) of this Order without reference to the 60-day notice period.

(b) Before conducting a drug test, the agency shall inform the employee to be tested of the opportunity to submit medical documentation that may support a legitimate use for a specific drug.

(c) Drug testing programs shall contain procedures for timely submission of requests for retention of records and specimens; procedures for retesting; and procedures, consistent with applicable law, to protect the confidentiality of test results and related medical and rehabilitation records. Procedures for providing urine specimens must allow individual privacy, unless the agency has reason to believe that a particular individual may alter or substitute the specimen to be provided.

(d) The Secretary of Health and Human Services is authorized to promulgate scientific and technical guidelines for drug testing programs, and agencies shall conduct their drug testing programs in accordance with these guidelines once promulgated.

SEC. 5. PERSONNEL ACTIONS.

(a) Agencies shall, in addition to any appropriate personnel actions, refer any employee who is found to use illegal drugs to an Employee Assistance Program for assessment, counseling, and referral for treatment or rehabilitation as appropriate.

(b) Agencies shall initiate action to discipline any employee who is found to use illegal drugs, *provided that* such action is not required for an employee who:

(1) Voluntarily identifies himself as a user of illegal drugs or who volunteers for drug testing pursuant to section 3(b) of this Order, prior to being identified through other means;

(2) Obtains counseling or rehabilitation through an Employee Assistance Program; and

(3) Thereafter refrains from using illegal drugs.

(c) Agencies shall not allow any employee to remain on duty in a sensitive position who is found to use illegal drugs, prior to successful completion of rehabilitation through an Employee Assistance Program. However, as part of a rehabilitation or counseling program, the head of an Executive agency may, in his or her discretion, allow an employee to return to duty in a sensitive position if it is determined that this action would not pose a danger to public health or safety or the national security.

(d) Agencies shall initiate action to remove from the service any employee who is found to use illegal drugs and:

(1) Refuses to obtain counseling or rehabilitation through an Employee Assistance Program; or

(2) Does not thereafter refrain from using illegal drugs.

(e) The results of a drug test and information developed by the agency in the course of the drug testing of the employee may be considered in processing any adverse action against the employee or for other administrative purposes. Preliminary test results may not be used in an administrative proceeding unless they are confirmed by a second analysis of the same sample or unless the employee confirms the accuracy of the initial test by admitting the use of illegal drugs.

(f) The determination of an agency that an employee uses illegal drugs can be made on the basis of any appropriate evidence, including direct observation, a criminal conviction, administrative inquiry, or the results of an authorized testing program. Positive drug test results may be rebutted by other evidence that an employee has not used illegal drugs.

(g) Any action to discipline an employee who is using illegal drugs (including removal from the service, if appropriate) shall be taken in compliance with otherwise applicable procedures, including the Civil Service Reform Act [Civil Service Reform Act of 1978, Public Law 95–454, Oct. 13, 1978, 92 Stat. 1111].

(h) Drug testing shall not be conducted pursuant to this Order for the purpose of gathering evidence for use in criminal proceedings. Agencies are not required to report to the Attorney General for investigation or prosecution any information, allegation, or evidence relating to violations of Title 21 of the United States Code received as a result of the operation of drug testing programs established pursuant to this Order.

SEC. 6. COORDINATION OF AGENCY PROGRAMS.

(a) The Director of the Office of Personnel Management shall:

(1) Issue government-wide guidance to agencies on the implementation of the terms of this Order;

(2) Ensure that appropriate coverage for drug abuse is maintained for employees and their families under the Federal Employees Health Benefits Program;

(3) Develop a model Employee Assistance Program for Federal agencies and assist the agencies in putting programs in place;

(4) In consultation with the Secretary of Health and Human Services, develop and improve training programs for Federal supervisors and managers on illegal drug use; and

(5) In cooperation with the Secretary of Health and Human Services and heads of Executive agencies, mount an intensive drug awareness campaign throughout the Federal work force.

(b) The Attorney General shall render legal advice regarding the implementation of this Order and shall be consulted with regard to all guidelines, regulations, and policies proposed to be adopted pursuant to this Order.

(c) Nothing in this Order shall be deemed to limit the authorities of the Director of Central Intelligence under the National Security Act of 1947, as amended [Act July 26, 1947, c. 343, 61 Stat. 495, 50 U.S.C. 401 et seq.], or the statutory authorities of the National

Security Agency or the Defense Intelligence Agency. Implementation of this Order within the Intelligence Community, as defined in Executive Order No. 12333 [set out as a note under section 401 of Title 50, War and National Defense], shall be subject to the approval of the head of the affected agency.

SEC. 7. DEFINITIONS.

(a) This Order applies to all agencies of the Executive Branch.

(b) For purposes of this Order, the term "agency" means an Executive agency, as defined in 5 U.S.C. 105; the Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the armed forces as defined by 5 U.S.C. 2101(2)); or any other employing unit or authority of the Federal government, except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches.

(c) For purposes of this Order, the term "illegal drugs" means a controlled substance included in Schedule I or II, as defined by section 802(6) of Title 21 of the United States Code, the possession of which is unlawful under chapter 13 of that Title [section 801 et seq. of Title 21]. The term "illegal drugs" does not mean the use of a controlled substance pursuant to a valid prescription or other uses authorized by law.

(d) For purposes of this Order, the term "employee in a sensitive position" refers to:

(1) An employee in a position that an agency head designates Special Sensitive, Critical-Sensitive, or Noncritical-Sensitive under Chapter 731 of the Federal Personnel Manual or an employee in a position that an agency head designates as sensitive in accordance with Executive Order No. 10450, as amended [set out as a note under section 7311 of Title 5, Government Organization and Employees];

(2) An employee who has been granted access to classified information or may be granted access to classified information pursuant to a determination of trustworthiness by an agency head under Section 4 of Executive Order No. 12356 [formerly set out as a note under 50 U.S.C. 435];

(3) Individuals serving under Presidential appointments;

(4) Law enforcement officers as defined in 5 U.S.C. 8331(20); and

(5) Other positions that the agency head determines involve law enforcement, national security, the protection of life and property, public health or safety, or other functions requiring a high degree of trust and confidence.

(e) For purposes of this Order, the term "employee" means all persons appointed in the Civil Service as described in 5 U.S.C. 2105 (but excluding persons appointed in the armed services as defined in 5 U.S.C. 2102(2)).

(f) For purposes of this Order, the term "Employee Assistance Program" means agency-based counseling programs that offer assessment, short-term counseling, and referral services to employees for a wide range of drug, alcohol, and mental health programs that affect employee job performance. Employee Assistance Programs are responsible for referring drug-using employees for rehabilitation and for monitoring employees' progress while in treatment.

SEC. 8. EFFECTIVE DATE. This Order is effective immediately.
RONALD REAGAN

Executive Order No. 11727 of July 6, 1973, 38 F.R. 18357 [1]

Drug Law Enforcement

Reorganization Plan No. 2 of 1973 [set out in the Appendix to Title 5, Government Organization and Employees], which becomes effective on July 1, 1973, among other things establishes a Drug Enforcement Administration in the Department of Justice. In my message to the Congress transmitting that plan, I stated that all functions of the Office for Drug Abuse Law Enforcement (established pursuant to Executive Order No. 11641 of January 28, 1972) and the Office of National Narcotics Intelligence (established pursuant to Executive Order No. 11676 of July 27, 1972) would, together with other related functions, be merged in the new Drug Enforcement Administration.

NOW, THEREFORE, by virtue of the authority vested in me by the Constitution and laws of the United States, including section 5317 of title 5 of the United States Code, as amended [section 5317 of Title 5, Government Organization and Employees], it is hereby ordered as follows:

SECTION 1. The Attorney General, to the extent permitted by law, is authorized to coordinate all activities of executive branch departments and agencies which are directly related to the enforcement of laws respecting narcotics and dangerous drugs. Each department and agency of the Federal Government shall, upon request and to the extent permitted by law, assist the Attorney General in the performance of functions assigned to him pursuant to this order, and the Attorney General may, in carrying out those functions, utilize the services of any other agencies, Federal and State, as may be available and appropriate.

SEC. 2. Executive Order No. 11641 of January 28, 1972, is revoked and the Attorney General shall provide for the reassignment of the functions of the Office for Drug Abuse Law Enforcement and for the abolishment of that Office.

SEC. 3. Executive Order No. 11676 of July 27, 1972, is hereby revoked and the Attorney General shall provide for the reassignment of the functions of the Office of National Narcotics Intelligence and for the abolishment of that Office.

SEC. 4. Section 1 of Executive Order No. 11708 of March 23, 1973, as amended [set out as a note under section 5317 of Title 5, Government Organization and Employees], placing certain positions in level IV of the Executive Schedule is hereby further amended by deleting—

(1) "(6) Director, Office for Drug Abuse Law Enforcement, Department of Justice."; and

(2) "(7) Director, Office of National Narcotics Intelligence, Department of Justice."

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[1] 21 U.S.C. § 801 note.

SEC. 5. The Attorney General shall provide for the winding up of the affairs of the two offices and for the reassignment of their functions.

SEC. 6. This order shall be effective as of July 1, 1973.

RICHARD NIXON

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