



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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Food and Drug Administration

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STATEMENT BY

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U.S. FOOD AND DRUG ADMINISTRATION

BEFORE THE

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SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN  
RESOURCES

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## INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Robert J. Meyer, M.D., Director of the Office of New Drug Evaluation II, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA or the Agency). I oversee CDER's Division of Anesthetic, Critical Care and Addiction Drug Products. I appreciate the opportunity to talk about FDA's drug approval process and role in preventing prescription drug abuse.

Recognized worldwide as the regulatory gold standard for food and drug safety and effectiveness, the mission of FDA is to protect and advance the public health. FDA is strongly committed to promoting and protecting the public health by assuring that safe and effective products reach the market in a timely way and monitoring products for continued safety after they are in use.

FDA is aware of and is concerned about reports of prescription drug abuse, misuse, and diversion. We understand the seriousness of this issue and sympathize with the families and friends of individuals who have lost their lives as a result of prescription drug abuse and misuse. The Agency has taken many steps to prevent abuse and misuse of prescription drugs, while making sure they are available for patients who need them.

## **BACKGROUND**

### **The Need for Effective Pain Relief**

Millions of Americans suffer from chronic pain. The medical and lay literature has documented inadequacies of the treatment of pain, both from cancer and from non-malignant causes. A consensus statement from the National Cancer Institute Workshop on Cancer Pain indicated that the “under-treatment of pain and other symptoms of cancer is a serious and neglected public health problem.”<sup>1</sup> A report by the Agency for Healthcare Research and Quality concluded that, “half of all patients given conventional therapy for their pain...do not get adequate relief.”<sup>2</sup> The Joint Commission on Accreditation of Healthcare Organizations regards the evaluation of pain in hospitalized patients as a routine requirement of proper management, akin to assessing temperature, pulse or blood pressure, stating that, “Unrelieved pain has enormous physiological and psychological effects on patients. The Joint Commission believes the effective management of pain is a crucial component of good care. ...Research clearly shows that unrelieved pain can slow recovery, create burdens for patients and their families, and increase costs to the health care system.”<sup>3</sup>

Pain of moderate to severe intensity impacts many aspects of patients’ lives, including enjoyment, work, mood, activity level, and ability to sleep or even walk. While a variety of drugs are available for the treatment of moderate to severe pain, opiates are an effective class of

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<sup>1</sup> National Cancer Institute, 1990.

<sup>2</sup> Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. Panel Co-chairs: Daniel B. Carr, M.D., Massachusetts General Hospital’s Division of Pain Management, and Ada Jacox, Ph.D., R.N., Johns Hopkins University School of Nursing. Guideline Release Date: March 5, 1992.

<sup>3</sup> Joint Commission Focuses on Pain Management, Press Release, Joint Commission on Accreditation of Healthcare Organizations, August 3, 1999.

medications that is recommended by numerous guidelines and statements for the treatment of pain. For many patients, adequate pain relief will only occur through the proper, informed use of opiates as a part of their treatment.

FDA must assure that patients who require narcotics for pain control maintain full, appropriate access to them through informed providers, while limiting misuse, abuse and diversion of these products. FDA takes its responsibility in meeting this challenge very seriously. Given the broad scope of factors at issue, it is essential that FDA work in concert with other government agencies, professional societies, patient advocacy groups, industry, and others to share information to take steps to prevent abuse and misuse while ensuring that these products are available for patients who need them.

### **The Problem of Prescription Drug Abuse**

FDA is concerned about the rising abuse of prescription drugs. Abuse of opioid analgesics (substances with an addiction potential similar to that of morphine), in particular, has risen steadily over the past five years. By contrast, rates of abuse of illicit drugs have been relatively stable over the same time period.

The Substance Abuse and Mental Health Services Administration (SAMHSA) conducts the National Survey on Drug Use and Health annually on a random sample of U.S. households to determine the prevalence of non-medical use of illicit and prescription drugs. In 2002, an estimated 6.2 million persons in the U.S. over the age of 12 reported having used one or more

psychotherapeutic drugs (stimulants, sedatives, tranquilizers, and analgesics available through prescription) for non-medical purposes at some time in their lives. This represents 2.6 percent of the population aged 12 or older. Stimulants, analgesics, and tranquilizers were the most widely used drugs that fit this category. This is a significant annual increase from 2001 when 3.5 million persons reported non-medical prescription drug use, and from 2000 with an estimate of 1.6 million users.

The consequences of this dramatic rise of prescription drug abuse are great. SAMHSA's Drug Abuse Warning Network (DAWN) surveys a national sample of emergency departments. DAWN captures drug-related visits to emergency departments (ED) contacts for non-medical use of substances for psychic effects, dependence, or suicide attempt. ED contacts increased from 69,011 in 1999 to 119,185 in 2002 for narcotic analgesics, both single and combination products. A subset of these data assessing oxycodone (single and combination products) show that ED contacts increased from 6,429 in 1999 to 22,397 in 2002. Sustained release oxycodone (OxyContin is the sole approved sustained release oxycodone product) contributed to most of the observed increase, with ED mentions increasing from 1,178 in 1999 to 14,087 in 2002.

## **FDA DRUG APPROVAL PROCESS**

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA is responsible for ensuring that all new drugs are safe and effective. Before any drug is approved for marketing in the U.S., FDA must decide whether the studies submitted by the drug's sponsor (usually the manufacturer)

have adequately demonstrated that the drug is safe and effective under the conditions of use in the drug's labeling. It is important to realize, however, that there is always some risk of potential adverse reactions when using prescription drugs. FDA's approval decisions, therefore, always involve an assessment of the benefits and the risks for a particular product. When the benefits of a drug are thought to outweigh the risks, and if the labeling instructions allow for safe and effective use, FDA considers a drug safe for approval and marketing.

During the approval process, FDA assesses a drug product's potential for abuse and misuse. Abuse liability assessments are based on a composite profile of the drug's chemistry, pharmacology, clinical manifestations, similarity to other drugs in a class, and the potential for public health risks following introduction of the drug to the general population. If a potential for abuse exists, the product's sponsor is required to provide FDA with all data pertinent to abuse of the drug, a proposal for scheduling under the Controlled Substances Act (CSA), Title 21, *United States Code* (U.S.C.) §801 et seq., and data on overdoses.

The CSA requires the Secretary of Health and Human Services (HHS) to notify the Attorney General through the Drug Enforcement Administration (DEA) if a "new-drug application is submitted for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system," because it would then appear that the drug had abuse potential (21 U.S.C. §811(f)). HHS has delegated this function to FDA. The Agency assesses preclinical, clinical, and epidemiological data to determine whether a drug under review requires abuse liability studies, scheduling under the CSA, or a risk management program (RMP) designed to reduce abuse, overdose, or diversion.

FDA's job is not over after a drug is approved. The goal of FDA's post-marketing surveillance is to continue to monitor marketed drugs for safety. This is accomplished by reassessing drug risks based on new data obtained after the drug is marketed and recommending ways of trying to most appropriately manage that risk.

### **OxyContin (oxycodone HCl)**

OxyContin is a narcotic drug that was approved by FDA for the treatment of moderate to severe pain on December 12, 1995. OxyContin contains oxycodone HCl (hydrochloride), an opioid agonist with an addiction potential similar to that of morphine. Opioid agonists are substances that act by attaching to specific proteins called opioid receptors, which are found in the brain, spinal cord, and gastrointestinal tract. When these drugs attach to certain opioid receptors in the brain and spinal cord they can effectively block the transmission of pain messages to the brain. OxyContin is formulated to release oxycodone HCl in a slow and steady manner following oral ingestion. OxyContin is the only currently marketed FDA approved controlled-release formulation of oxycodone. The drug substance oxycodone, however, has been marketed in the U.S. for many decades and is available in a wide variety of immediate release and combination dosage forms.

At the time of approval, the abuse potential for OxyContin was considered by FDA to be no greater than for other Schedule II opioid analgesics that were already marketed in the U.S. Schedule II provides the maximum amount of control possible under the CSA for approved drug products. Based on the information available to FDA at the time of its approval, including the record of other modified release Schedule II opioids, the widespread abuse and misuse of

OxyContin that has been reported over the past few years was not predicted. In fact, at the time of its approval, FDA believed that the controlled-release characteristics of the OxyContin formulation would result in less abuse potential since, when taken properly, the drug would be absorbed slowly and there would not be an immediate “rush” or high that would promote abuse. In part, FDA based its judgment of the abuse potential for OxyContin on the prior marketing history of a similar product, MS-Contin, a controlled-release formulation of morphine that had been marketed in the U.S. by Purdue Pharma without significant reports of abuse and misuse for many years. At the time of OxyContin’s approval, FDA was aware that crushing the controlled-release tablet followed by intravenous injection of the tablet’s contents could result in a lethal overdose. A warning against such practice was included in the approved labeling. FDA did not anticipate, however, nor did anyone suggest, that crushing the controlled-release capsule followed by intravenous injection or snorting would become widespread and lead to a high level of abuse.

In response to reports of abuse and misuse of OxyContin, FDA worked with Purdue Pharma to develop a RMP. The program included strengthening OxyContin’s warning label, educating healthcare professionals and Purdue Pharma’s sales staff, and developing a tracking system to identify and monitor abuse. In July 2001, Purdue Pharma, working in cooperation with FDA, significantly strengthened the warning and precaution sections in the labeling for OxyContin. The labeling now includes a “black box” warning, the strongest warning for an FDA approved product, which warns patients and physicians of the potentially lethal consequences of crushing the controlled-release tablets and injecting or snorting the contents. The indication for use was

clarified to reflect that it is approved for the treatment of moderate to severe pain in patients who require around the clock narcotics for an extended period of time.

## **FDA ACTIONS TO PREVENT PRESCRIPTION DRUG ABUSE**

### **Labeling changes**

FDA is responsible for ensuring that drug products are safe and effective for use as directed in the labeling. Part of the labeling for all drugs is the recommended prescribing information derived from the clinical trial data and approved by the scientists who review the products at the Agency. This prescribing information is essential for physicians who will be recommending products to their patients. Labeling can serve as a useful education tool for both physicians and patients. It also importantly serves to define the content of advertising and promotional materials about a drug. Establishing effective, consistent labeling of potent and long-acting opiate products will help assure that their marketing will be appropriate.

Most approved controlled-release, high-strength opiates contain a “black box” warning. Generally, when a serious risk is identified FDA works with the drug’s sponsor to identify methods to manage that risk. The black box warning is one of these methods. FDA works with the sponsor on the specific language to be included in the warning. Boxed warnings are used in labeling to convey serious risks associated with the use of a drug product. The promotional materials of drug products with boxed warnings must present these serious risks in a prominent manner.

Labeling is helping prescribers properly identify patients for whom these products are appropriate. For the extended release products that contain high concentrations of an opioid drug, appropriate patients would have moderate to severe pain (i.e., pain that impacts on a person's ability to function) that requires continuous, around-the-clock therapy for adequate control over an extended period of time. While this description clearly would apply to many patients with cancer pain, it also properly includes many patients with chronic, non-cancer pain, such as those with severe osteoarthritis or many patients with neuropathic pain. Long-acting, controlled-release products are not suitable for patients who only need intermittent analgesia, nor patients for whom only a few days of therapy is thought to be needed (e.g., for wisdom tooth extraction). Such patients can be satisfactorily treated with immediate release opiates, if opiates are even needed. While current labeling for some drugs already stresses this indication (e.g., OxyContin), FDA will work to ensure consistent labeling across agents and that this message is clear and prominent.

Labeling should emphasize that drug treatment for pain should be initiated at a level appropriate to the pain and condition of the patient. Non-steroidal anti-inflammatory drugs are appropriate therapies for patients with lesser degrees of pain and even in more moderate pain, may be a reasonable first-line therapy. If opiates are needed for acute pain, initially or due to inadequate response to non-opiate analgesics, short-acting opiate formulations should be administered. The higher dosage forms (concentrations) of the extended release opiates are only safe and should only be used in patients already undergoing long-term treatment with high dose opiates and who are opiate-tolerant. FDA will work to assure the rational evaluation of pain and analgesia is more clearly delineated and stressed in the labeling of these products.

Finally, labeling should help prescribers properly assess potential patients for the likelihood of abuse. In particular, patients with a personal history of substance abuse or a strong family history of substance abuse should be considered as being at higher risk of abuse. While use of opiates may still be appropriate in such patients when they have conditions requiring effective pain control, these patients deserve even more careful assessment in follow-up for signs of abuse.

### **Monitor Drug Advertising and Promotion**

FDA has regulated the advertising of prescription drugs since 1962, under the FD&C Act and its implementing regulations. The Division of Drug Marketing, Advertising, and Communications (DDMAC), in CDER, is responsible for regulating prescription drug advertising and promotion. DDMAC's mission is to protect the public health by ensuring that prescription drug information is truthful, balanced, and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering optimal communication of labeling and promotional information to health care professionals and consumers. FDA regulates prescription drug advertisements and other promotional materials (called "promotional labeling") disseminated by or on behalf of the advertised product's manufacturer, packer, or distributor to health care professionals and consumers.

FDA continues to monitor promotional materials for controlled substances, particularly for sustained release products, to ensure that false and potentially misleading claims are not tolerated. To date, advertising and marketing for these products has been directed only to health care professionals, although direct-to-consumer marketing is not prohibited by the FD&C Act.

FDA will continue to encourage sponsors, as part of their RMPs, to voluntarily refrain from advertising directly to consumers as a means to avoid excessive or unnecessary use. Also, FDA regulations require that all product promotional materials prominently feature any information in “black box” warnings of a label. For example, the current approved product labeling for OxyContin contains a “black box” to convey serious risks associated with the use of the product. FDA has taken action against sponsors who violate this requirement or otherwise promote their product in a manner that could be considered false or misleading. Purdue Pharma, the sponsor of OxyContin, was cited in May 2000 and January 2003 for advertisements that promoted OxyContin in a manner that was false or misleading. In response, Purdue Pharma agreed to correct the advertisements. We will continue to monitor promotional materials for these products and use our regulatory authority to its fullest extent to ensure that healthcare providers and patients have good medicines available, but are not subjected to false or misleading claims.

### **Strong Risk Management Programs (RMPs)**

FDA’s September 2003 Anesthetic and Life Support Drugs Advisory Committee and a recent General Accounting Office report<sup>4</sup> recommended that the Agency encourage pharmaceutical manufacturers with new drug applications to submit plans for a RMP that contain a strategy for addressing abuse and diversion. The Agency agrees with these recommendations and believes that it is highly desirable for all extended release or high concentration Schedule II opiate drug products to have RMPs in place at the time of approval. FDA defines a RMP as a strategic safety program designed to decrease product risk by using one or more interventions or tools

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<sup>4</sup> GAO Report (GAO-01-110) to Congressional Requesters entitled, “*Prescription Drugs – OxyContin Abuse and Diversion and Efforts to Address the Problem.*”

beyond the package insert. RMPs across individual products would likely vary, depending on the approved indications and product-specific considerations, including the product's safety profiles. However, each RMP would appropriately address such elements as: identification of appropriate patients; assuring the safe and informed use of the product by both practitioners and patients; and monitoring for adverse outcomes, including misuse, overdose, abuse, and diversion. Manufacturers have access to tools that help them effectively monitor for adverse outcomes including: access to drug utilization, distribution, and prescribing data; reports from physicians (manufacturers are required to provide safety reports to FDA); and access to various databases. The development of such programs would provide an added measure of safety in the drug approval process. FDA plans to provide more specific guidance to the pharmaceutical industry on the development, implementation, and evaluation of RMPs this year.

### **Letters to Health Care Professionals**

When significant changes are made to a drug's labeling, FDA encourages the drug's sponsor to notify health care professionals. For example, after reports of OxyContin abuse and diversion, resulting in serious consequences including death were received, Purdue Pharma warned health care providers in the form of a "Dear Healthcare Professional" letter (issued July 18, 2001). The letter was issued to educate health care providers about these serious risks. The "Dear Healthcare Professional" letter was distributed widely to physicians, pharmacists, and other health professionals. The letter explained recent changes to the labeling, including additional prescribing information, and highlighted the problems associated with the abuse and diversion of OxyContin.

## **Patient Information Page on FDA Web Site**

An important component of FDA's strategic plan is to enable consumers to make smarter decisions by getting them better information to weigh the benefits and risks of FDA-regulated products. FDA's website ([www.fda.gov](http://www.fda.gov)) includes information for patients on drug safety and side effects, public health alerts, and general information about major drugs. These web pages provide important information to patients regarding how to safely use their drug products. In an effort to educate health care providers and consumers about the risks associated with OxyContin, FDA has created an OxyContin Drug Information web page ([www.fda.gov/cder/drug/infopage/oxycontin/default.htm](http://www.fda.gov/cder/drug/infopage/oxycontin/default.htm)). This page contains valuable information for consumers including the current approved labeling, approval letter, frequently asked questions, and articles on prescription drug abuse.

## **Advisory Committee Meetings**

FDA routinely convenes panels of non-Agency experts to seek outside advice. Outside experts add a wide spectrum of judgment, outlook, and state-of-the-art experience to drug issues confronting FDA. These expert advisers add to FDA's understanding, so that final Agency decisions will more likely reflect a balanced evaluation. Committee recommendations are not binding on FDA, but the Agency considers them carefully when deciding drug issues.

FDA's Anesthetic and Life Support Drugs Advisory Committee has met twice within the last two years<sup>5</sup> to discuss the medical use of opioid analgesics, appropriate drug development plans to support approval of opioid analgesics, and strategies to communicate and manage the risks associated with opioid analgesics, particularly the risks of abuse of these drugs.

Committee members agreed that opioids are essential for relieving pain. Members suggested that a balanced approach should be taken to relieve pain for patients and to prevent diversion. They noted that imposing restrictions on use of opioids could have substantial likelihood of hurting legitimate patients and reversing the tremendous progress that has been achieved in the appropriate treatment of pain.

### **Collaboration with Other Government Agencies, Professional Groups, and Industry**

FDA has met and continues to meet with DEA, SAMHSA, the National Institute on Drug Abuse (NIDA), the Office of National Drug Control Policy (ONDCP), the Centers for Disease Control and Prevention, the American Medical Association (AMA), and industry to share information and insights needed to address the problem of prescription drug abuse.

FDA and DEA meet regularly to discuss new ways to prevent prescription drug abuse and diversion. A description of joint investigative efforts is discussed later in the enforcement

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<sup>5</sup> Meeting of FDA's Anesthetic and Life Support Drugs Advisory Committee, September 9-10, 2003, Bethesda, Maryland. Transcript located at: <http://www.fda.gov/ohrms/dockets/ac/cder03.html#AnestheticLifeSupport>; Meeting of FDA's Anesthetic and Life Support Drugs Advisory Committee, January 30-31, 2002, Gaithersburg, Maryland. Transcript located at: <http://www.fda.gov/ohrms/dockets/ac/cder02.htm#AnestheticandLifeSupport>.

section of this testimony. In addition to assisting one another with criminal investigations, both agencies are currently working together on the following initiatives:

- *Physician Education* - In order to prescribe controlled substances, including opiate analgesics, physicians must maintain a registration with the DEA, which is renewed on a periodic basis. Currently, there is no requirement for demonstration or attestation of knowledge or training in order to maintain DEA registration. FDA supports linking renewal of DEA registration to up-to-date training and education in the appropriate prescribing of opiate analgesics in some appropriate manner.
- *State Prescription Drug Monitoring Programs* – States that have monitoring programs have shown lower levels of abuse and misuse of scheduled drugs compared to states that do not have such programs. These programs facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled prescription drugs. Approximately 18 states have some kind of monitoring program in effect. While they vary in resources, methods, and data access by health care professionals, the programs share the objective of preventing and reducing inappropriate prescribing and dispensing, drug diversion, and drug abuse. FDA strongly supports state-based prescription drug monitoring programs.
- *Task Force Participation* – FDA Office of Criminal Investigations (OCI) agents frequently participate in and/or assist many DEA led Federal-state task forces throughout the country focusing on the illegal sale of controlled prescription drugs. Examples of

some of the working groups both agencies are members of are: Cross Border Pharmacy Working Group, Permanent Forum on International Pharmaceutical Crime, Interagency Committee on Drug Control, Federal Trade Commission/FDA Health Fraud Working Group, and a working group composed of representatives from HHS (including FDA, NIDA, SAMHSA, National Institutes of Health), DEA, ONDCP and other agencies to address issues of drug abuse and control under the CSA.

- *Assessment of New Products With Abuse Potential* – FDA provides DEA with a scientific assessment of a new drug product’s potential for abuse and misuse. In addition, DEA often participates in FDA public meetings to provide advice and recommendations to the Agency on FDA’s regulatory issues involving scheduled drugs.

In January 2003, FDA and SAMHSA launched a joint prescription drug abuse prevention education effort, with the primary goal of preventing and reducing the abuse of prescription drugs, especially narcotic opiate pain relievers by teens and young adults. This campaign includes brochures and posters, as well as print and television educational advertising highlighting the risks of prescription opiate analgesic abuse. In particular, the campaign highlights the potentially lethal risks of abuse of sustained release opioid analgesics such as OxyContin.

FDA is working with professional societies, including the AMA, to help develop educational programs for physicians regarding sound use of potent opiate analgesics. This includes

education about the risks of overdose, misuse, abuse, and diversion of scheduled substances as well as ways to manage these risks while ensuring proper treatment of patients with pain.

## **Enforcement**

FDA's enforcement efforts to address the problem of diversion and illegal sales of controlled substances, particularly opiates like long-acting oxycodone, have grown in recent years. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA. However, the complexity of the cases and the solutions to the problems of misuse, overdose, and diversion of prescription drugs, especially of high concentration opioid analgesic drugs, requires the collaboration of DEA and FDA as well as state and non-governmental entities.

FDA's OCI is working closely with DEA on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances. For example, in August 2003, as a result of an extensive, cooperative law enforcement effort that involved DEA and FDA, as well as local and state police in Indiana, the U.S. Attorney's Office announced a 24-count indictment against four individuals who allegedly conspired to dispense prescription drugs, including controlled substances, outside the scope of a legitimate professional practice and absent legitimate medical purposes. Another case conducted by FDA, DEA, the Internal Revenue Service, and the U.S. Attorney's Office resulted in a guilty plea by a medical doctor for the role

he played in prescribing prescription drugs via a web-based pharmacy without establishing a patient history or performing a mental/physical exam of patients. The cases cited are just two examples of enforcement actions, which have been taken. FDA, DEA, FBI, and Main Justice have worked together to pursue other significant Internet pharmacy cases involving prescription drugs, and these enforcement efforts will continue.

A subset of the criminal cases investigated by FDA has involved the drug OxyContin. Since 1998, OCI has opened 46 criminal investigations relating to OxyContin. Twenty-four of these cases have successfully been adjudicated, resulting in a variety of criminal penalties. FDA looks forward to continuing our collaboration with DEA to address mutual concerns regarding the abuse, misuse and illegal diversion of OxyContin and other controlled substances; and our efforts to hold those individuals involved in such activities criminally responsible. This relationship will continue to be important as the Federal government addresses the increasing number of websites that offer controlled substances.

## **CONCLUSION**

FDA recognizes the serious problem of prescription drug abuse. The Agency will continue to take steps to curb abuse, misuse, and diversion of prescription drugs. Since this is a problem that is broad in its reach and implications, we are committed to collaborating with our partners – Federal, state and Local officials, professional societies, and industry to prevent abuse and help ensure that these important drugs remain available to appropriate patients.

We share the Subcommittee's interest and concerns regarding prescription drug abuse and would be happy to answer any questions.