

WRITTEN STATEMENT
OF THE
AMERICAN DENTAL ASSOCIATION
TO THE
U.S. HOUSE OF REPRESENTATIVES
GOVERNMENT REFORM
SUBCOMMITTEE ON
HUMAN RIGHTS AND WELLNESS
MAY 8, 2003

The American Dental Association is devoted to improving the oral health of the public. The ADA has achieved considerable success in meeting this goal. In no small part through the efforts of the ADA and its members, Americans today enjoy the best oral health in the world. As the leader of a science-based profession, the ADA is open to new scientific information and welcomes the opportunity to debate it according to the standards that prevail in the scientific community.

As the very event of this hearing proves, dental amalgam remains the subject of debate and controversy. Unfortunately, much of the information we encounter about amalgam and the American Dental Association's positions and policies regarding it are simply wrong. We are grateful that the subcommittee has invited the ADA to appear at its hearing, and we offer this testimony to set the record straight.

The ADA submitted extensive documentation on November 14, 2002, for a hearing before the House Committee on Government Reform, to support our assertion that, according to the best available scientific information, dental amalgam is a safe and effective restorative material, even though mercury is a component of this alloy. As stated in our written testimony last year, "If the Association believed that dental amalgam posed a threat to the health of dental patients, we would advise our members to stop using it. But the best and latest available scientific evidence indicates that it is safe." A copy of that submission, which remains accurate today, is attached (*Attachment 1*).

In fact, the major U.S. and international scientific and health bodies—organizations responsible for protecting the public’s health—have all stated that dental amalgam is a safe restorative material. These bodies include the National Institutes of Health (NIH), the U.S. Public Health Service (PHS), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), among others.

It is not the intent of the ADA to promote amalgam over any other safe and effective material dentists use to restore decayed teeth, but our organization believes very strongly that Americans should not be deprived of this valued—and in some instances—irreplaceable treatment option. For instance, in large cavities in the rear teeth, where chewing forces are the greatest, or in cavities below the gum line, amalgam is used because of its durability and because it is one of the best filling materials that can be placed in areas of the mouth that are difficult to keep dry.

We will focus this statement on issues relating to the ADA’s role in promoting the development of alternative dental materials and patients’ choice among appropriate treatment options.

Making Clinical Dentistry Better

For 75 years, the ADA, through the Paffenbarger Research Center of the ADA Foundation in Gaithersburg, Maryland, has been working to develop and improve dental equipment and materials—including improved filling materials. The labs at PRC have a

long history of developing technologies that increase the treatment options available to dentists and their patients. The ADA Foundation's mission is to "make clinical dentistry better," and the Foundation is proud of its success in advancing both the prevention and treatment of dental disease.

PRC researchers invented composite resin filling materials—so called “white fillings”—in the late 1950s, and they are the most commonly used filling material today. In addition to making possible the immediate placement of strong tooth-colored fillings, this discovery led to the dental sealants used to prevent decay on the biting surfaces of teeth.

Research is still ongoing in the PRC labs on ways to make composite resins stronger, more wear resistant, longer lasting and useful for different kinds of fillings. A recent invention has been the incorporation of new technologies into composite resins that help them actually stimulate the natural healing abilities of teeth, rather than just repairing damage done by dental decay. This should result in less need for replacement of worn, broken or decayed fillings, root canals and implant replacements for teeth. Moreover, in the early 1980s PRC researchers invented adhesives that could reliably bond fillings to teeth, making it much easier to place smaller, more conservative fillings. PRC researchers now are working on the next generation of decay-preventing toothpastes and mouth rinses and cavity-fighting candies and chewing gums.

Choosing a Filling Material

The ultimate decision about what filling material to use is best determined by an informed patient in consultation with his or her dentist. Toward that end, the ADA has developed a chart (*Attachment 2*) that compares restorative dental materials. The chart provides comparative information on thirteen distinct factors, including durability, clinical considerations, leakage and recurrent decay, and resistance to wear and fracture. This information sheet has been widely circulated through ADA publications and is on our website. Recently, the ADA Council on Scientific Affairs published a companion piece for dentists on direct and indirect restorative materials, *JADA*, April 2003.

The ADA does not recommend or promote any single restorative material. The Association believes that patients, in consultation with their dentists, should have a full range of treatment options, including filling materials, basing decisions on what is most clinically appropriate to meet each patient's needs. Dental amalgam is but one of many dental filling materials that the ADA evaluates to help dentists and their patients choose safe, appropriate and effective treatments.

Esthetic dentistry is increasingly popular, and the use of dental amalgam is declining, as more patients and dentists choose newer, more natural-looking, tooth-colored restorative materials when such treatment is a viable option. Yet, dentists and patients still value amalgam because of its unique qualities, and the ADA is therefore committed to protecting the patient-doctor decision to select this durable, cost-effective material among the safe options available for restoring decayed teeth.

Dentistry has no vested interest in the continued availability of amalgam beyond its utility as a safe option for restoring decayed teeth. Our concern is for patient choice, because alternative materials generally cost more, involve longer, more complex procedures to place and, in some cases, are less durable.

The ADA publishes brochures (*Attachment 3*), which dentists distribute to their patients - that accurately state the pros and cons of many dental treatments, including fillings. The ADA's web site also contains a wealth of information about dental filling choices including ionomers, composites, gold, porcelain, as well as amalgam (<http://www.ada.org/public/topics/fillings.html#Restoring%20Your%20Smile>).

Principles of Practice: ADA's Code of Professional Conduct

The ADA has gone one step further in its commitment to providing patients with the best possible information about all aspects of oral health and dental care. We have developed fundamental principles in our Code of Professional Conduct, to which all members voluntarily agree to abide as a condition of membership, that stress patient autonomy, nonmaleficence, beneficence, justice and veracity. As stated in the Code's preamble, "The ethical dentist strives to do that which is right and good. The ADA Code is an instrument to help the dentist in this quest."

The following are excerpts from the ADA Code of Professional Conduct that put in context the Association's position about patients' right to complete and accurate information about their dental care:

Section 1 — Principle: Patient Autonomy ("self-governance"). The dentist has a duty to respect the patient's rights to self-determination and confidentiality.

This principle expresses the concept that professionals have a duty to treat the patient according to the patient's desires, within the bounds of accepted treatment, and to protect the patient's confidentiality. Under this principle, the dentist's primary obligations include involving patients in treatment decisions in a meaningful way, with due consideration being given to the patient's needs, desires and abilities, and safeguarding the patient's privacy.

1.A. Patient Involvement

The dentist should inform the patient of the proposed treatment, and any reasonable alternatives, in a manner that allows the patient to become involved in treatment decisions.

Section 3 — Principle: Beneficence

Principle: Beneficence ("do good"). The dentist has a duty to promote the patient's welfare.

3.C. Research And Development.

Dentists have the obligation of making the results and benefits of their investigative efforts available to all when they are useful in safeguarding or promoting the health of the public.

Section 5 — Principle: Veracity

Principle: Veracity ("truthfulness"). The dentist has a duty to communicate truthfully.

5.A Representation of Care. Dentists shall not represent the care being rendered to their patients in a false or misleading manner.

5.B.6. Unnecessary Services. A dentist who recommends and performs unnecessary dental services or procedures is engaged in unethical conduct.

5.D.2 Marketing or Sale of Products or Procedures (excerpt)

Dentists should not induce their patients to purchase products or undergo procedures by misrepresenting the product's value, the necessity of the procedure or the dentist's professional expertise in recommending the product or procedure.

With these excerpts from the ADA Code as context, consider the Code's professional conduct provision and advisory opinion dealing specifically with dental care and dental restorative materials:

5.A. Dentists shall not represent the care being rendered to their patients in a false or misleading manner.

5.A.1. Dental Amalgam and Other Restorative Materials. Based on available scientific data the ADA has determined that the removal of amalgam restorations from the non-allergic patient for the alleged purpose of removing toxic substances from the body, when such treatment is performed solely at the recommendation or suggestion of the dentist, is improper and unethical. The same principle of veracity applies to the dentist's recommendation concerning the removal of any dental restorative material.

In other words, the ADA Code obliges dentists to inform patients of the proposed treatment and any reasonable alternatives in a way that allows the patients to make an informed choice about their dental treatment. In providing this information to patients, the code obliges dentists to be truthful and not misrepresent the therapeutic benefits of the treatment. These ethical principles apply to all dental restorative materials, whether it is gold alloy, resin composites, glass ionomers or dental amalgam.

Myth vs. Fact

Despite the ADA's straightforward policies regarding patient autonomy and dentist veracity to foster that autonomy, myths and misstatements abound about the ADA, its

positions on dental amalgam and the scientific basis for those positions. The following are but a few of the misstatements, with the Association's responses.

Myth: *The ADA and dentists attempt to conceal that mercury is a principal ingredient in amalgam by calling the fillings "silver."*

Response: Dentists and scientists generally refer to this material as "dental amalgam." However, some dentists and many patients refer to these restorations as "silver fillings," because, traditionally, it was a way to distinguish them by appearance from "gold fillings" (gold) and the more recently developed "white fillings" (composite resin). In fact, the word amalgam means an alloy of mercury with another metal.

Myth: *The ADA somehow profits from amalgam, either by holding patents or taking money from amalgam manufacturers.*

Response: Scientists at the ADA Foundation (ADAF) obtained two patents in the early 1970s for changes in the formulation of dental amalgam. These patents were never exploited commercially and have long since expired. Neither the ADA nor its foundation earned a cent from the patents.

In the past, the ADA charged a modest fee to manufacturers to help cover a small part of the cost of evaluating products submitted to the ADA's Seal of Acceptance program. The Seal program evaluates dental products according to stringent, objective criteria of safety and effectiveness and awards the Seal to products that are found in tests to meet

these criteria. Participation is strictly voluntary, and the fee was charged regardless of whether the product was accepted or not. The ADA receives no money from the sale of an accepted product.

The total cost to maintain the Seal program is approximately \$1.5 million annually. Fees paid by amalgam manufacturers to the Seal program totaled about \$5,100 per year, or less than one-half of one percent of the program's total costs. ADA members pay most of the cost of operating the Seal program as a service to the public and the profession. On July 1, 2002, the ADA eliminated fees for evaluating all professional products.

Myth: *The ADA has a “gag rule” that prevents dentists from talking about the “dangers” of amalgam.*

Response: The ADA supports and defends the right of dentists to discuss freely, appropriately and accurately all aspects of dental care with their patients. This includes answering any questions patients might have about the mercury content in dental amalgam. Information that a dentist gives a patient should be consistent with accepted science and the applicable standard of care governing clinical practice. That said, a dentist who recommends removal of a serviceable amalgam from a non-allergic patient claiming that doing so will remove toxic substances or cure some systemic disease is acting unethically, by misleading the patient about the therapeutic value of the proposed treatment.

The ADA has neither the interest nor the desire to “gag” anyone. But dentists are held to the ethical standard that what they advise their patients should be truthful and not deceptive.

***Myth:** Further, during the November 14, 2002, hearing, Rep. Watson claimed that the Iowa Dental Examiners Board “lifted the gag rule” on Iowa dentists regarding amalgam.*

Response: A statement from the dental board tells a much different story. While the Iowa Dental Examiners Board did announce that it would make minor changes to its rule preventing dentists from initiating the removal of serviceable amalgam restorations from the non-allergic patient for the “alleged purpose of removing toxic substances from the body,” the Board stated: “Although the sub rule [on removal of amalgams] is being rescinded at this time to allow the Board to consider whether to redraft another sub rule to specifically address amalgam restorations, the Board’s position concerning the removal of serviceable restorations has not changed. In the absence of this specific sub rule, the Board will continue to pursue disciplinary action in appropriate cases...the Board is authorized to prosecute a dentist for making medical diagnoses outside the scope of the practice of dentistry, incompetent or substandard practice, fraudulent or misleading representations in the practice of dentistry, willful or gross malpractice or **subjecting a patient to needless or harmful treatment regimes** (emphasis added).”

Contrary to how some may portray the action, the Dental Board of Examiners specifically states that, “The Board is rescinding the sub rule in light of concerns that the rule may not be sufficiently detailed to fully guide dentists in adhering to prior decisions of the Board on the removal of restorations.” It is clear that the Dental Board of Examiners in Iowa acted to protect the public from unscrupulous treatments and to ultimately provide licensed dentists with more detailed guidance on appropriate professional conduct.

Worse than the misinformation about the ADA is the seemingly limitless number of claims about dental amalgam that purport to be based on science. Here are a few of the more persistent and pervasive ones.

Myth: *Mercury is toxic; therefore, amalgam is toxic.*

Response: Like virtually every substance to which people are exposed, mercury can be toxic in specific forms and specific doses. It is important to distinguish dental amalgam, a solid intermetallic compound of mercury, silver, tin and copper, from mercury.

Exposure to dental amalgam cannot correctly be compared to exposure to an equivalent amount of mercury, whether in the human body or the environment. Nor is the mercury contained in amalgams present as methylmercury, or readily converted to this organic form, which is of most concern to human health.

Myth: *Amalgam is considered toxic before it is placed in a patient and after it is removed from a patient; therefore it is toxic in a patient’s mouth.*

Response: Dental amalgam is not the same as mercury. The mercury in dental amalgam is chemically bound with other metals, including silver, copper and tin. These components are bound into a hard, stable and safe substance. The only relevant question is whether a substance creates a measurable, negative effect on health, and dental amalgam does not. Like many substances used in health care, dental amalgam requires proper handling during manufacture, shipping, storage use and disposal in accordance with federal, state and local laws and rules. The ADA strongly recommends recycling amalgam waste, but this does not affect whether amalgam is safe when used appropriately to restore decayed teeth.

Myth: *There is growing evidence that amalgam fillings are associated with a number of disorders from neurological problems to heart disease.*

Response: The **FDI World Dental Federation** and the **World Health Organization of the United Nations** state, “No controlled studies have been published demonstrating systemic adverse effects from amalgam restorations.”¹ The **U.S. Food and Drug Administration (FDA)** has said, “FDA and other organizations of the U.S. Public Health Service (USPHS) continue to investigate the safety of amalgams used in dental restorations (fillings). However, no valid scientific evidence has shown that amalgams cause harm to patients with dental restorations, except in the rare case of allergy.”² In July, 2001, the associate director for science of the **CDC** stated, “[W]e believe it’s

¹ FDI World Dental Federation/WHO Consensus Statement on Dental Amalgam, 1997.

² U.S. Food and Drug Administration, Center for Devices and Radiological Health, *Consumer Update: Dental Amalgams (Updated 12/31/2002)*.

inappropriate to stop using or to recommend removing amalgam. There's no current scientific evidence that amalgam poses a risk to human health, except for the exceedingly small number of allergic reactions."³ A 2003 report by the CDC found that most of the mercury in people's blood results from their diets, specifically by consuming fish that contains the organic form of mercury known as methylmercury. The report went on to say that the mercury levels in the U.S. population were "well below occupational thresholds of concern." In addition, the report observes that, "Finding a measurable amount of mercury in blood or urine does not mean that the level of mercury causes an adverse health effect."⁴

In fact, the support and advocacy organizations for many of the conditions proponents of this bill often cite as being caused by dental amalgam have specifically gone on record as finding no link between dental amalgam and specific conditions. The **Alzheimer's Association** states, "According to the best available scientific evidence, there is no relationship between silver dental fillings and Alzheimer's. . ."⁵ The **National Multiple Sclerosis Society** maintains, "There is no scientific evidence to connect the development of MS or other neurological diseases with dental fillings containing mercury."⁶ The **Autism Society of America** has gone on record saying, "There is no known single cause for autism, but it is generally accepted that it is caused by abnormalities in brain structure or function. Brain scans show differences in the shape and structure of the brain in

³ Dr. Bill Kohn, associate director for science, Centers for Disease Control and Prevention (CDC), Division of Oral Health, July 2001.

⁴ Centers for Disease Control, January 2003, Second National Report on Human Exposure to Environmental Chemicals.

⁵ Alzheimer's Association, Q&A: About Dental Fillings and Alzheimer's Disease, October, 2001

⁶ The National Multiple Sclerosis Society, The MS information Sourcebook, Dentistry, 2001.

⁷ Immunization Safety Review: Thimerosal Containing Vaccines and Neurodevelopmental Disorders. Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention 2001.

autistic versus non-autistic children. Researchers are investigating a number of theories, including the link between heredity, genetics and medical problems. In many families, there appears to be a pattern of autism or related disabilities, further supporting a genetic basis to the disorder. While no one gene has been identified as causing autism, researchers are searching for irregular segments of genetic code that autistic children may have inherited. It also appears that some children are born with a susceptibility to autism, but researchers have not yet identified a single 'trigger' that causes autism to develop.” The Institute on Medicine has concluded that there was no evidence linking mercury to any of the pathophysiological changes known to be associated with autism, such as genetic defects.⁷

Myth: *Mercury released from a mother's amalgam fillings is neurotoxic to a developing fetus and nursing infants.*

Response: Several studies have examined the levels of mercury (from fish and amalgam) in the blood of pregnant women and in breast milk. The conclusions were that mercury is found in blood and breast milk^{1,2,3,4}, that the contribution of mercury to the fetus from dental amalgam was insignificant compared to the contribution from maternal fish consumption², and that the low levels of mercury detected (from either source) would not be expected to have any adverse effects on infants^{1,2,3}. In fact, one study³ showed that the mercury level in commercial formula was higher than the mercury level in the breast milk of mothers with amalgam fillings.

There is another issue that requires clarification. Rep. Watson’s bill, H.R. 1680, the “Mercury in Dental Filling Disclosure and Prohibition Act,” states that the “California Dental Association, by court order, is sending health warnings about mercury fillings to California dental offices for posting ... which read, “NOTICE TO PATIENTS: PROPOSITION 65 WARNING: Dental amalgam, used in many dental fillings, causes exposure to mercury, a chemical known to the state of California to cause birth defects or other reproductive harm.”

On the contrary, the notice provides only that amalgam contains mercury and that mercury—not amalgam—has been determined by the State of California to cause adverse health effects. The California Dental Association’s (CDA) action demonstrates dentistry's commitment to comply with the 1986 voter initiative (Proposition 65) mandating certain warnings. CDA does not disavow its faith in amalgam as a safe and effective dental restorative material for dental treatment.

¹ Oskarsson A, Schutz A, Skerfving S, Hallen IP, Ohlin B, Lagerkvist BJ. Total and inorganic mercury in breast milk and blood in relation to fish consumption and amalgam fillings in lactating women. *Arch Environ Health* 1996;51:234-241.

² Drexler H. The mercury concentration in breast milk resulting from amalgam fillings and dietary habits. *Environ Res.* 1998;77:124-91.

³ Drasch G, Aigner S, Roeder G, Staiger F, Lipowsky G. Mercury in human colostrum and early breast milk. Its dependence on dental amalgam and other factors. *J Trace Elem Med Biol.* 1998;12:23-7.

⁴ Ask BK, Vahter M, Petersson-Grawe K, Glynn A, Cnattingius S, Darnerud PO, Atuma S, Aune M, Becker W, Berglund M. Methylmercury and inorganic mercury in Swedish pregnant women and in cord blood: influence of fish consumption. *Environ Health Perspectives* 2003 [ehponline.org \(http://dx.doi.org/\)](http://dx.doi.org/).

Notably, the court was uncomfortable with approving any warning that so manifestly contradicted the Food and Drug Administration's conclusions that amalgam is a safe and effective dental restorative material. Refusing to approve an early proposal as unduly alarming to the consumer, the court added the following wording: "The U.S. Food and Drug Administration has studied the situation and approved for use all dental restorative materials. Consult your dentist to determine which materials are appropriate for your treatment."

Access to Care for the Underserved

And what of the millions of Americans who do not have access to dental care? The ADA believes that it is a national disgrace that so many Americans, particularly children, lack dental care, including all appropriate treatment options. As an association, we took the recent Surgeon General's "Call to Action" to heart. As such, the ADA continues to advocate for improved access to care for underserved populations and encourages coverage of the full range of restoration treatment options, not simply the least costly option, which is usually dental amalgam. To heighten awareness of this problem, while working to expand access to care, the ADA:

- Undertook a massive campaign this past February, the "Give Kids A Smile" program, which emphasized the need to improve access to dental care for children. This program treated an estimated one million children at approximately 5,000 locations in all 50 States.
- Advocated for S. 1626 and H.R. 3659 in the 107th Congress, the "Children's Dental Health Improvement Act, which would provide support to states as they determine how best to improve access to dental care for children in their communities. While most Americans have access to the best oral health care in the world, low-income children suffer disproportionately from oral disease. Even as our nation's health has progressed, dental caries (tooth decay) remains the most

prevalent chronic childhood disease. This year we are working with members of the House and Senate again on the development of similar legislation that will focus on increasing access to oral health care for needy children.

- Promotes legislation, the "Medically Necessary Dental Care Act of 2003," to assist certain medically compromised senior citizens in obtaining necessary dental care in situations where oral infection interferes with the treatment of their underlying medical condition. Oral health care would be extended to people suffering from head or neck cancer, lymphoma, and leukemia and requiring prosthetic heart valve replacement or organ transplantation.
- Agrees that choice in dental filling materials is important and that private and public insurance plans should cover a full range of treatment options, not simply the least costly option, which is usually dental amalgam. To that end, the ADA encourages our state associations to continue to advocate that all state Medicaid programs and private plans reimburse for all dental filling materials.

In conclusion, health care policy must be based on sound science because our patients deserve nothing less. As the leader of a science-based profession, the ADA is open to new scientific information and welcomes the opportunity to debate it according to the standards that prevail in the scientific community. In keeping with numerous U.S. and international organizations responsible for protecting the public's health, the American Dental Association reiterates its position that dental amalgam is a safe restorative material whose continued use has value.

Therefore, we oppose H.R. 1680, the "Mercury in Dental Filling Disclosure and Prohibition Act," which would eliminate this viable option for treating dental disease.