Attachment 1

STATEMENT

BY THE

AMERICAN DENTAL ASSOCIATION

TO THE

GOVERNMENT REFORM COMMITTEE

UNITED STATES

HOUSE OF REPRESENTATIVES

ON

"MERCURY IN DENTAL AMALGAMS:

AN EXAMINATION OF THE SCIENCE "

THURSDAY, NOVEMBER 14, 2002

Mr. Chairman and members of the Committee, thank you on behalf of the American Dental Association (ADA) for inviting us to testify today. The ADA is very pleased to speak to the safety and efficacy of dental amalgam and the Association's position that *every* dental patient should have an opportunity to make an informed choice about his or her dental treatment options.

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. Banning amalgam would deprive patients and dentists of an essential treatment option that is clinically and scientifically substantiated to be safe and effective.

The ultimate decision about what filling materials to use is best determined by the patient in consultation with the dentist. Toward that end, the ADA has developed a chart that compares restorative dental materials. The chart provides easily understood 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.

Rep. Diane Watson (D-Calif.) in April introduced H.R. 4163, the Mercury in Dental Filling Disclosure and Prohibition Act, which would ban the use of dental amalgam by 2007. Congresswoman Watson's attempt to ban dental amalgam because of concern for patient safety flies in the face of accepted scientific information about the safety of dental amalgam.

Dental Amalgam Offers a Safe, Cost-Effective Treatment Option

It should be clearly understood at the outset that dental amalgam and mercury are not the same thing, and their characteristics and properties are not interchangeable. Chlorine is a toxic gas, but when combined with sodium, a toxic metal, table salt is the resulting product. No one compares the proprieties of table salt to either chlorine or sodium. Similarly, when mercury is combined with other metals to make dental amalgam, it is safe for use in accepted dental applications.

Dental amalgam has been used for more than 150 years. After all that time, and considering the billions of amalgams that have been placed, we would expect to see some epidemiological evidence if there were any ill effects on patient health. Instead, we have fewer than 100 cases of documented localized allergic reaction.

Thousands of dentists and their staffs work with dental amalgam every day, with no demonstrated ill effects on their health. Dentists are exposed daily to a number of materials, often at dosage levels and durations much higher and longer than a patient, so it is likely that any adverse outcomes would be manifested first in the dentist. Again, we simply have not seen them in the case of amalgam.

The ADA has funded many studies looking at potential occupational hazards facing dentists, including mercury from amalgam. The American Dental Association Health

Foundation (ADAHF) has compiled the largest repository of data on the occupational health of dentists from data gathered at the annual ADAHF Health Screening Program. Research has been done on the mean urinary mercury levels of dentists from 1975-83 and again from 1984-2001 (Chou H-N, in press; Naleway CA, 1985). The research shows that dentist urinary mercury levels are well below established limits for occupational exposure. Dentist urinary mercury levels have fallen from 1975, until they now approach those of the general population. This is largely due to better mercury hygiene methods prompted by the ADA, such as the use of precapsulated amalgam. ADA investigators have looked at a possible correlation between kidney dysfunction and urinary mercury levels (Naleway CA, 1991). None was found.

ADA scientific investigators have examined whether enteric bacteria might have the ability to convert inhaled or ingested mercury to more toxic organic (methyl) mercurials. They hypothesized that, if bioconversion did occur, then occupationally exposed dentists would show higher levels of organic mercury in blood than non-dentists. Their research showed no significant difference in organic mercury levels. Higher blood organic mercury levels did not correlate with the number of amalgams in an individual's mouth, nor did it correlate with the number of amalgams placed or removed by the dentists. However, organic mercury did correlate well with the frequency of seafood consumed. This study concluded that bioconversion of mercury from amalgam in an occupationally exposed group did not occur at a detectable level (Chang S-B 1992, 1990, 1988, 1987; Siew C, 1987).

Of course, if amalgam presented a health hazard, no cost considerations would warrant its continued use, and the ADA would be the first to advise its members of the risks. However, the major U.S. and international scientific and health bodies, including the National Institutes of Health, the U.S. Public Health Service, the Food and Drug Administration, the Centers for Disease Control and Prevention and the World Health Organization, among others, have all stated that dental amalgam is a safe restorative material. In fact, dental amalgam is the most thoroughly researched and tested restorative material among all those in use.

Indeed, the Alzheimer's Association, the Autism Society of America, the National Multiple Sclerosis Society and the American Academy of Pediatrics all have explicitly stated that there is no scientific evidence linking dental amalgam with any known disease or syndrome that those groups track. These organizations, which devote their entire efforts to understanding the diseases they represent, surely would not make such statements without confidence that they are true.

Not only is dental amalgam safe, it remains a valuable restorative option for dentists and their patients because it is so effective. Banning dental amalgam would have a dramatic effect on oral health care. At present, there is no direct restorative material that works as well as amalgam for certain types of fillings. Amalgam, unlike other direct restorative materials, tolerates moisture during placement. That is important for fillings in places that are difficult to keep dry, like below the gum line. Amalgam is also still the strongest, most durable direct restorative material for large, load-bearing restorations on the posterior teeth. Certain indirect restorative materials, like gold and porcelain, may also

be suitable for these situations. But they are considerably more expensive because of the material and because they require at least two office visits and laboratory services to complete. The U.S. Public Health Service, at its website, addresses the economic impact of banning amalgam: "[A] total conversion from dental amalgam to alternative materials would cause a significant increase in U.S. health care costs."

In fact, many patients choose dental amalgam because while safe, it is less expensive than the alternatives. Dental amalgam is approximately 25 to 30 percent *less* expensive on average than the next least expensive restorative material, composite resin, according to the ADA Survey Center's 1999 *Survey of Dental Fees.* Cost is a major consideration for most individuals seeking dental care because, unlike medical insurance, a good deal of patients' own money is used to pay for dental services. The demand for dental services is significantly responsive to changes in dental fees – it's intuitive, the higher the fees, the lower the demand. As a consequence, fewer people are likely to seek needed dental treatment in a timely fashion as the cost of care rises, or if a safe, less costly material were not allowed for use.

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U.S. Federal Agencies and International Organizations Conclude that Dental Amalgam is Safe

As questions have arisen about the safety of dental amalgam related to its mercury content, they have been investigated by responsible bodies and answered to the satisfaction of the major U.S. and international scientific and health organizations. From 1991 to 1992, the U.S. Public Health Service (PHS) performed a comprehensive risk assessment of dental amalgam. In 1993, the PHS issued a report on its findings and concluded that dental amalgam did not have any adverse health effects other than a few reported cases of allergic reaction due to individual sensitivity rather than the amalgam itself. Specifically, a Risk Assessment Subcommittee of PHS, comprised of 34 senior level experts from the fields of health promotion and disease prevention, dentistry, dental materials, toxicology, and biostatistics, reviewed nearly 120 publications that reported the results of studies on levels of exposure to mercury. The Risk Assessment Subcommittee found that available data showed that there were no health hazards identified in non-occupationally exposed persons.

A companion PHS subcommittee, the Benefits Assessment Subcommittee, reviewed the benefits of dental amalgam products. It concluded that dental amalgam, which had been used successfully to treat millions of individuals, was an effective restorative material. The subcommittee also stated that dental amalgam products had reasonable clinical serviceability, wide potential applications, ease of manipulation, and relatively low cost.

The conclusions reached in the 1993 PHS Report were reaffirmed by the PHS in both 1995 and 1997. The 1997 PHS Report included information from two PHS-sponsored workshops on mercury and amalgam safety. Both workshops concluded that scientific evidence did not link mercury vapor exposure, at typical levels associated with dental

amalgam restorations, with an unacceptable or significant health risk to the general population.

Moreover, in response to several citizen petitions filed in 1993 requesting that FDA take various actions regarding dental amalgam and mercury – including banning dental mercury – the FDA convened a group of experts to assess the extensive scientific publications submitted by the petitioners seeking to demonstrate that amalgam was unsafe. The publications cited by the petitioners were grouped by study type (i.e., general toxicology, neurotoxicology, immunotoxicology, epidemiology, dental/clinical materials) and disseminated to scientific specialists and dental professionals recruited from various PHS agencies. The government reviewers focused on five major areas of concern: (1) adequate controls; (2) methodological flaws; (3) mercury exposure measurements; (4) relevance of the article to dental amalgam safety assessment; and (5) fetal mercury exposure.

Ultimately, none of the experts who reviewed the petitioners' data concluded that dental amalgam restorations caused adverse health effects to patients. The experts involved in this review, like those authoring the 1993, 1995, and 1997 PHS Reports, were familiar with the characteristics of both free mercury and dental amalgam. Free mercury, like other heavy metals, can be toxic, depending on the dose level. Dental amalgam does not share the same toxicity characteristics of mercury. These experts concluded that there is no evidence in the medical or dental literature to suggest that individuals with dental amalgam restorations will experience adverse health effects from these restorations.

In addition, the FDA has evaluated a number of reports from international authorities that both assessed the available body of scientific literature as well as reviewed the opinions of leading researchers and renowned experts in the fields of oral health, toxicology, medicine, and other related disciplines. Expert groups from Sweden, New Zealand, Canada, and the European Commission all concluded that the minimal exposure to mercury from dental amalgams does not have an adverse effect on patients' health, with the exception of isolated cases of allergic reactions noted above.

Likewise, a report generated from a nine-country information exchange concluded that no systemic toxic effects have been shown to be related to dental amalgams. Also, several studies included in a comprehensive report published by the World Health Organization concluded that there is no direct evidence of an adverse effect on patients' general health from dental amalgam.

Issued in late 1997, the FDI World Dental Federation and the World Health Organization consensus statement on dental amalgam stated, "*No controlled studies have been published demonstrating systemic adverse effects from amalgam restorations*." The document also states that, aside from rare instances of local side effects of allergic reactions, "*the small amount of mercury released from amalgam restorations, especially during placement and removal, has not been shown to cause any … adverse health effects*."

In its 1997 Annual Report, the FDA conducted an extensive literature search on dental amalgam. The findings of the Office of Science and Technology are included here:

> *In response to three citizen's petitions, the Working Group on Dental Amalgam, a group under the PHS Environmental Health Policy Committee, was charged with evaluating 175 citations related to the potential adverse effects of dental amalgam mercury. OST scientists organized the review literature in order to determine if the science cited by the petitioners, in whole, or part, shed any new light on the safety of dental amalgam and past risk assessments performed by PHS and others. The citations represented an assortment of literature, including peer-reviewed publications, non-refereed publications, untranslated foreign documents, print media articles, and letters to the editor.*
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> *Therefore, OST scientists first performed a triage of the citations in order to focus its evaluation on these studies that met a set of criteria established by the review group. This process resulted in 57 articles, which were reviewed by scientific experts from FDA, CDC, and NIH representing disciplines of general toxicology, neurotoxicology, immunotoxicology, epidemiology, dental materials, and clinical dentistry. These experts commented on the strengths and weaknesses of each paper, the appropriateness of methodologies, control groups and statistics, and whether the conclusions were supported by the data.*
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> *The conclusions drawn by these experts were overwhelmingly unanimous. None of the reviewers suggested that any study under review would indicate that individuals with dental amalgam restorations would experience adverse health effects. When the citations were considered in the aggregate, the data did not imply to the reviewers that adverse human health effects would occur as a result of exposure to dental amalgam.*

And, finally, critics of dental amalgam have often cited the Agency for Toxic Substances and Disease Registry's (ATSDR) 1999 Report titled "Toxicological Profile for Mercury" as evidence the federal government believes dental amalgam is dangerous. Specifically, opponents of dental amalgam incorrectly claim that this report concludes that mercury vapors released from amalgam pose a major health risk for the developing brains of children.

The 1999 ATSDR Report reviewed a wide spectrum of literature in this area; being included in this review does not mean that the reviewers agreed with the study's conclusions. The broad scope of the 1999 ATSDR Report includes a subsection entitled "More on Health Effects and Dental Amalgam" to specifically address the state of the science with regard to dental amalgam. This section clearly concludes and states that "*[a] number of government sponsored scientific reviews of the literature on the health effects associated with the use of dental amalgam have concluded that the data do not demonstrate a health hazard for the large majority of individuals exposed to mercury vapor at levels commonly encountered from dental amalgam*."

Additional Studies Support the Safety and Efficacy of Dental Amalgam

There have been numerous peer reviewed scientific studies concerning the safety of dental amalgam. These studies disprove any link between dental amalgam and various medical conditions. We have listed some of them below:

- Mackert JR, Berglund A. "Mercury exposure from dental amalgam fillings: absorbed dose and the potential for adverse health effects" Crit Rev Oral Biol Med 1997; 8:410-436.

The researchers conducted a critical review of the scientific literature on mercury exposure from dental amalgam and examined the question whether adverse health effects are attributable to amalgam-derived mercury. Taking into consideration the release rate of such mercury vapor from amalgam and various parameters that influence the absorption of mercury vapor, their analysis of the literature showed that the daily absorbed doses of mercury from amalgam restorations is quite low: from 1 – 2 μg for inhaled mercury and less than 1.5 μg for ingested mercury.
Conclusions: These low levels are unlikely to constitute a health hazard.

- Dahl J. E., Sundby J, Hensten-Pettersen A, Jacobsen N. " Dental workplace exposure and effect on fertility" Scand J. Work Environ Health 1999 Jun; 25(3): 285-90.

The study groups consisted of 558 female dental surgeons (1/3 of whom placed more than 50 fillings a week) and 450 high school teachers (control) that had given birth in Norway to at least 1 living child. The study comprised data from a total of 1408 pregnancies. The effects of practicing dentistry and of the given workplace exposure on fertility were analyzed with the discrete proportional hazard regression method.
Conclusions: Occupational exposures had no clear adverse effects on fertility among the female dental surgeons studied.

- Schuurs A. H. " Reproductive toxicity of occupational mercury. A review of the literature" J. Dent 1999; 27(4): 249-56.

This paper provides insight into the potential reproductive effects on handling dental silver amalgam. Both animals and case reports and epidemiological studies were reviewed.
Conclusions: The studies conclude that there are no adverse effects to reproductive function from exposure to mercury in the dental office. Consequently, given the even lower exposure to mercury from dental amalgam, the patient is at even less risk than dental staff.

- Saxe S.R., Wekstein M.W. et al. " Alzheimer's disease, dental amalgam and mercury", JADA 1999 Feb; 130(2): 191-9

This study consisted of 68 human subjects with diagnosed Alzheimer's disease and 33 control subjects without Alzheimer's to determine mercury levels in multiple brain regions at autopsy and to ascertain the subjects' dental amalgam status and history.
Conclusions: Mercury in dental amalgam restorations is not a neurotoxic factor in the pathogenesis of this disease. The authors found that brain mercury levels are not associated with dental amalgam, either from existing amalgam restorations or according to subjects' dental amalgam restoration history. Furthermore, dental amalgam restorations, regardless of number, occlusal surface area or time, do not relate to brain mercury levels.

- Ahlqwist M., Bengtsson C. et al, " Serum mercury concentration in relation to survival, symptoms, and diseases: results from the prospective population study of women in Gotherburg, Sweden". Acta Odontol Scand 1999 June; 57(3): 168-74

This prospective population study of women in Gothenburg, Sweden was started in 1968-69 and comprised of 1462 women aged 38-60 years at baseline. Follow-up studies were conducted in 1974-75, 1980-81 and 1992-93.
Conclusions: No statistically significant correlation was observed between dental amalgam and the incidence of diabetes, myocardial infarction, stroke, or cancer. No association was established between disease and mercury on a population basis in middle-aged and older women.

- Wahl M.J. "Amalgam – resurrection and redemption. Part 1: The clinical mythology of anti-amalgam". Quintessence International 2001 32(7), 525-535

A literature search revealed that the vast majority of amalgam restorations do not cause fractured cusps or have recurrent caries. Most amalgam restorations have been shown to last longer than resin composite restorations. The use of dental amalgam has not been banned in any country in the European Union. According to the latest scientific information available, dental amalgam is a remarkably durable restorative material.
Conclusions: Although its appearance is unaesthetic, its clinical performance and effectiveness are unsurpassed by those of resin composite.

- Wahl M.J. "Amalgam – Resurrection and redemption. Part 2: the medical mythology of anti-amalgam". Quintessence International 2001 32(3), 696-710

Literature review indicated that amalgam restorations release infinitesimally small quantities of mercury but not enough to cause systemic health problems. Mercury from dental amalgam restorations cannot be linked to kidney damage, Alzheimer's disease, multiple sclerosis, other central nervous system diseases including ' amalgam disease', mental disorders, damage to the immune system, increases in antibiotic resistance, or harmful reproductive effects.
Conclusions: This review of the latest literature concludes that dental amalgam is a safe and effective restorative material.

Research Continues

Research on dental amalgam is ongoing. The National Institute of Dental and Craniofacial Research (NIDCR) is currently supporting two large clinical trials on any effects on the health of dental amalgam and they should provide additional evidence to support scientific answers to many of the questions raised about this material. Studies underway for several years each in Portugal and the northeastern United States involve direct neurophysiological measures, as well as behavioral and cognitive functional assessments. In addition, the trials are monitoring the effects, if any, of amalgam on immune function, antibiotic resistance and renal function.

Results of the studies are expected to be released sometime in 2006, yet H.R. 4163 proposes to eliminate amalgam by January 1, 2007. Results thus far from these studies have not raised any alarms that would cause the studies to be limited or discontinued, as would be required if any adverse response were recognized.

The ADA believes we owe it to our patients to practice dentistry based on good science and not act precipitously based on flawed or incomplete science. This approach has provided Americans with quality oral health care that is second to none in the world. The ADA is committed to making sure that our patients benefit from improvements in dental practice that will come from sound science.

Conclusion

The ADA and its members are committed to placing patients' health first and to following the guidance of sound science in preventing and treating disease. We also are committed to providing patients with scientifically accurate information and fostering open communication between patients and their dentists about all appropriate treatment options – leaving it to the *patient,* in consultation with the dentist, to make the final treatment decision. We are greatly concerned that emotional and scientifically invalid reports claiming that amalgam is responsible for a variety of diseases are confusing and alarming some people to the point where they may not seek care. The real danger to patients is untreated dental disease. Amalgam is one of the excellent tools available in our fight against dental disease. We urge you to consider only valid, scientific information and not take any action that would deprive our patients of a repeatedly proven safe and effective dental restorative material.