

## **Safety & Effectiveness of Dental Amalgam: Testimony by Dr. Rod Mackert**

Madame Chair and members of the Committee, thank you on behalf of the Arizona Dental Association (AzDA) for inviting us to testify today. I am Rod Mackert, a dentist, PhD and a professor at the School of Dentistry of the Medical College of Georgia. I earned my dental degree in 1976 from the Medical College of Georgia (MCG) and my PhD in materials science from the University of Virginia in 1979. After a one-year visiting lectureship in Japan, I joined the MCG School of Dentistry where I have engaged in research and teaching since 1980, with a sabbatical in 1992 at M.I.T.

The AzDA 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.

It is important to note that the AzDA and the ADA do not advocate the use of one dental filling material over another. Instead, we champion a principle -- that dentists should have the ability to select from a range of materials that the weight of scientific evidence shows are safe to use.

### Dental Amalgam Offers a Safe, Cost-Effective Treatment Option

It should be clearly understood that dental amalgam and mercury are not the same thing, and their characteristics and properties are not interchangeable. When mercury is combined with other metals to make dental amalgam, it is safe for use in accepted dental applications.

Some mistake the properties of mercury, in any form, with the properties of dental amalgam. What those properties are and how they interact with the body are distinctly different. Like virtually every substance to which people are exposed, mercury can be toxic in specific forms and specific dose. It is important to distinguish dental amalgam, a solid material composed of mercury, silver, tin and copper, from mercury. In a dental amalgam, mercury reacts with the silver and tin to form hard, stable and safe intermetallic compounds. 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 mercury contained in amalgams present as methylmercury, or readily converted to this organic form, which is of most concern to human health.

Mercury levels from dental amalgam have been extensively studied. Based on the generally accepted estimates of vapor exposure by Olsson and Bergman, a person with an average of 13 amalgam restorations would be exposed to 1-3 micrograms of mercury vapor per day. This amounts to a small portion of the total mercury every person is exposed to each day from food, water and air. In addition, this exposure is to elemental mercury, a form that is far less toxic than the organic mercury we are exposed to through the consumption of seafood and fish. Using Olsson's and Bergman's model and the

World Health Organization's (WHO) level associated with the most subtle adverse effects, nearly 500 amalgam surfaces would be necessary to produce a noticeable effect in even the most susceptible individual. The general population in the United States currently has an average urinary mercury level estimated to be about 3 micrograms/gram urinary creatinine, ten times lower than the WHO level of first concern. Clearly we are in no danger from our exposure to amalgam fillings.

The 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 – it is.

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 Foundation (ADAF) has compiled the largest repository of data on the occupational health of dentists from data gathered at the annual ADAF 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 since 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).

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. In fact, the *New England Journal of Medicine*, one of the most prestigious medical journals in the world, published an article approximately one year ago stating -- and I quote -- "Current concern arises from claims that long-term exposure to low concentrations of mercury vapor from amalgams either causes or exacerbates degenerative diseases such as amyotrophic lateral sclerosis, Alzheimer's disease, multiple sclerosis, and Parkinson's disease. However, several epidemiological investigations failed to provide evidence of a role of amalgam in these degenerative diseases . . . Patients who have questions about the potential relation between mercury and degenerative diseases can be assured that the available evidence shows no connection." (Source: *New England Journal of Medicine* 349; 18, October 30, 2003, pp. 1731-1737). Note those last three words: **shows no connection**.

Indeed, the Alzheimer's Association, 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.

This statements echo the determinations made by organizations across the world that have found dental amalgam to be a safe and effective treatment option for dental decay. In addition to the ADA, those bodies include the World Health Organization, the U.S. Food and Drug Administration, the CDC, the National Institutes of Health and many other health care organizations.

Dental amalgam remains a valuable restorative option for dentists and their patients because it is so effective. Eliminating or restricting 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 restorations, including large fillings in the back teeth, in a very deep filling, or in fillings below the gum line. Alternatives are often less effective in these situations.

Amalgam is also the only material that can be successfully placed in a wet environment. This is especially critical when working with patients such as children or persons with developmental disabilities who might have difficulty sitting still in the dental chair. Without the availability of amalgam, dentists would be required to administer higher risk forms of anesthesia, to treat these patients with other restorative materials or by extraction.

While amalgam is still a valued option for treating dental decay, its use is declining. In 1990 dental amalgams constituted 67.6% of all dental restorations. By 1999, that figure

had dropped to 45.3%. Current estimates for amalgam use in 2003 place that number at approximately 30%. We expect those patterns to continue. Those cavities that previously would have been treated with dental amalgam are now primarily filled with a resin composite. This trend is primarily driven by the on-going improvements to resin-based materials, better education and training of dentists in placing composite restorations, changes in dental disease patterns and the patient's desire for a natural-looking, esthetically pleasing restoration.

Dentistry continues to follow new findings related to dental amalgam as they are published, as well as any information related to the safety and effectiveness of all filling materials. The FDA, in conjunction with NIH, has recently completed an updated review of all the literature pertaining to amalgam published during the past five to six years. This review includes all of the available literature, including that published by scientists claiming that amalgam is toxic. Each study is evaluated based upon its design, methods, and conclusions, and the entire body of evidence from all studies is taken into account in formulating the final recommendations. While the opponents of dental amalgam have currently blocked the publication of this document, if this review changes their recommendations in any way, we will be quick to make sure this is reflected in how we practice.

The National Institute of Dental And Craniofacial Research is also currently conducting two multi-centered clinical trials comparing signs and symptoms between children who have received, and children that have not received amalgam fillings. The studies began in 1999 and are scheduled to be completed in 2006. Although not yet published, the results thus far have been monitored by an independent Data Safety Monitoring Board, and this group has stated that based upon these results, they see no reason to stop or alter the study in any way. Any study involving children would be quickly ended if there were a hint of any adverse response.

Claims have been made that amalgam has been banned in certain countries. This is simply not true. Use of amalgam in the European Union is governed by the Medical Devices Directive 93/42/EEC. In 1998 an Ad Hoc Working Group of experts from the countries of the EU issued a report on dental amalgam that concluded that there was no scientific evidence of systemic health problems or toxic effects from dental amalgam and the Working Group did not recommend any special reservations on its use. A few countries have made conservative recommendations limiting amalgam use in certain populations, but these have often been based upon environmental concerns or the remote possibility of some adverse effect in more susceptible individuals. These same countries, however, admit that the body of scientific evidence does not substantiate or support these limitations. Health Canada's statement on amalgam clearly states that current evidence does not indicate that dental amalgam is causing illness in the general population. It also goes on to state that neither a ban on amalgam or removal of existing sound amalgam fillings are justified.

In conclusion, health care policy must be based on sound science, not a political agenda. 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 discuss 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. Toward that end, it is the duty of both the American Dental Association and the Arizona Dental Association to provide its members and their patients with the best, most up to date guidance possible. That is what the ADA *Principles of Ethics and Code of Professional Conduct* does.

Thank you for the opportunity to discuss this matter today and I look forward to answering your questions.