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Comments of Dr. Ronald R. Zentz, RPh, DDS
to
Joint Meeting of the Dental Products Panel of the Medical Devices Advisory Committee of the Center for Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research

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Members of the panel, thank you on behalf of the American Dental Association (ADA) for allowing us to provide these comments today. I am Dr. Ronald Zentz, a dentist and pharmacist by training, and senior director of the ADA Council on Scientific Affairs.

The Council on Scientific Affairs is a council of the American Dental Association, the leading professional organization for dentists. For almost 150 years the ADA has been committed to the oral health of the public. It is a science-based organization and, as such, relies on its Council on Scientific Affairs to provide guidance on key issues. The Council is composed of seventeen volunteer dentists who are national leaders in their respective fields of oral health science. The Council is advised by a panel of more than 200 consultants, chosen for their scientific credentials and expertise.

The Council assesses the scientific evidence on issues of importance to the oral health of the public and makes recommendations to the ADA on matters of scientific policy. This includes policy on the safety and effectiveness of dental materials used in the practice of dentistry. The Council actively promotes research to ensure that the public and the profession have the most current, scientifically valid information on which to make choices about dental treatment.

I am very pleased to speak today to the safety and efficacy of dental amalgam and the Association's position that dental patients should have an opportunity to make choices about their dental treatment options that are based on the best available scientific evidence.

The ADA does not advocate for the use of one dental restorative material over another. Instead, we champion the principle that dentists and their patients should be able to select from a range of materials that the scientific evidence shows are safe to use.

The ultimate decision about what filling material to use is best made by the patient in consultation with his or her dentist. To aid them in that discussion, 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. The chart has been widely circulated through ADA publications and similar information is available on our website at ADA.org. The ADA has also produced a patient brochure entitled, "Choice for Restoring Your Smile," which includes descriptions and illustrations of each dental restorative material. I have brought copies of the chart and the patient brochure to share with you today.

If substantial scientific evidence showed that dental amalgam posed a threat to the health of dental patients, we would advise dentists to stop using it. But the best and latest available scientific evidence indicates that dental amalgam is safe. The findings of two highly anticipated clinical trials, widely known as the Children's Amalgam Trial, were published in April in the *Journal of the American Medical Association*. The two randomized clinical trials, funded by the National Institutes of Health, were designed to examine the effect of mercury released from amalgam on the central and peripheral nervous systems and kidney function in children. The researchers looked for signs of damage to the brain and kidneys because these organs are thought to be the most sensitive to mercury toxicity.

The investigators found no adverse health effects related to neuropsychological function (IQ), memory, attention, visuomotor function, nerve conduction velocities or renal function arising from the placement of amalgam restorations in children. While the safety of dental amalgam has been the subject of a number of previous publications, expert panel meetings and national and international conferences, the two new clinical trials are the first to compare overall health effects in children treated with amalgam restorations and children treated with resin composite restorative materials.[1, 2]

Dental amalgam is accepted in the scientific community as a safe and effective restorative material based on the weight of scientific evidence. The safety of dental amalgam was confirmed by a 2004 Life Sciences Research Office (LSRO) review commissioned by the NIH, HHS and FDA. LSRO undertook its review in consultation with a panel of scientific experts selected from outside the dental research community to ensure a fresh, comprehensive look at the literature. These included experts in immunotoxicology, immunology and allergy, neurobehavioral toxicology and neurodevelopment, pediatrics, developmental and reproductive toxicology, toxicokinetics and modeling, epidemiology, pathology and general toxicology. The report concluded:

> "[T]here is insufficient evidence to support a correlation between dental amalgam exposure and kidney or cognitive dysfunction; neurodegenerative disease, specifically Alzheimer's disease and Parkinson's disease; or autoimmune disease, including multiple sclerosis."[3]

An article published in 2003 in the *New England Journal of Medicine*, one of the most prestigious medical journals in the world, stated -- 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."[4]

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.

Many other organizations across the world 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 Centers for Disease Control and Prevention, the National Institutes of Health and many other health care organizations.

In 1998 an ad hoc working group of experts from the countries of the European Union 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. These same countries admit that the body of scientific evidence does not substantiate or support these limitations. Health Canada's statement on amalgam clearly says that current evidence does not indicate that dental amalgam is causing illness in the general population. It also goes on to state that removal of existing sound amalgam fillings is not justified.

Dental amalgam remains a valuable restorative option for dentists and their patients. At present, there is no direct restorative material that works as well as amalgam for large fillings in the back teeth, in very deep fillings, 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 critical when working with patients such as children or persons with developmental disabilities who might have difficulty sitting still in the dental chair. Without 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 ongoing 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 an esthetically pleasing restoration that more closely matches his or her natural tooth color.

Like virtually every substance to which people are exposed, mercury can be toxic in specific forms and doses. While dental amalgam does contain mercury, it is important to distinguish dental amalgam, a solid material composed of mercury, silver, tin and copper, from elemental mercury or organic mercury compounds. In dental amalgam, mercury reacts with the other metals to form a hard, stable and safe intermetallic compound. Exposure to dental amalgam cannot correctly be compared to exposure to an equivalent amount of elemental mercury, whether in the human body or the environment. Nor is the mercury contained in dental amalgam present as methylmercury, or readily converted to this organic form. Methylmercury is the form which is of most concern to human health.

While credible scientific studies show that amalgam does release mercury vapor, the amount is so small that it is measured in billionths of an ounce. There is no scientific evidence that such low levels of mercury vapor cause health problems. To put the issue into perspective, one expert estimated that it would take almost 500 amalgam fillings to produce even the mildest symptoms in the most sensitive patient.[5]

Let me explain how that was determined. 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 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.

In conclusion, the American public deserves health care policy—and FDA regulation—based on sound science, not a political agenda. 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. Clearly, the overwhelming weight of scientific evidence supports the safety and efficacy of dental amalgam, and it should continue to be made available as a dental restorative option.

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

[1] Bellinger DC, Trachtenberg F, Barregard L, Tavares M, Cernichiari E, Daniel D, McKinlay S. Neuropsychological and Renal Effects of Dental Amalgam in Children: A Randomized Clinical Trial. JAMA 2006;295:1775-83.

[2] DeRouen TA, Martin MD, Leroux BG, Townes BD, Woods JS, Leitão J, Castro-Caldas A, Luis H, Bernardo M, Rosenbaum G, Martins IP.Neurobehavioral Effects of Dental Amalgam in Children: A Randomized Clinical Trial. JAMA 2006;295:1784-92.

[3] Life Sciences Research Office. Review and Analysis of the Literature on the Potential Adverse Health Effects of Dental Amalgam. Bethesda: LSRO, 2004.

[4] Clarkson TW, Magos L, Myers GJ. The Toxicology of Mercury — Current Exposures and Clinical Manifestations. New Engl J Med 2003;349(18):1731-7.

[5] 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(4):410-36.