



American Academy of Pediatric Dentistry

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Comments of the American Academy of Pediatric Dentistry before the Dental Products Panel of the Medical Devices Advisory Committee Food and Drug Administration U.S. Department of Health and Human Services

[Docket No. FDA-2010-N-0268]

December 2010

The American Academy of Pediatric Dentistry (AAPD)¹ submits these comments in support of the Food and Drug Administration's ("FDA") existing rule on dental amalgam products and in response to the Federal Register notice regarding a hearing of the Dental Products Advisory Panel.

The AAPD Supports the 2009 FDA Ruling on Dental Amalgam

The FDA classifies encapsulated dental amalgam as a Class II device. The FDA's deliberations began more than seven years ago and involved review of hundreds of scientific studies relating to the safety of dental amalgam. In 2009 the FDA concluded that:

- "Dental amalgam has been demonstrated to be an effective restorative material that has benefits in terms of strength, marginal integrity, suitability for large occlusal surfaces, and durability."

¹ Founded in 1947, the **American Academy of Pediatric Dentistry (AAPD)** is a not-for-profit membership association representing the specialty of pediatric dentistry. The AAPD's 7,800 members are primary oral health care providers who offer comprehensive specialty treatment for millions of infants, children, adolescents, and individuals with special health care needs. The AAPD also represents general dentists who treat a significant number of children in their practices. As advocates for children's oral health, the AAPD develops and promotes evidence-based policies and guidelines, fosters research, contributes to scholarly work concerning pediatric oral health, and educates health care providers, policymakers, and the public on ways to improve children's oral health. For further information, please visit the AAPD Web site at www.aapd.org.

- “Clinical studies have not established a causal link between dental amalgam and adverse health effects in adults and children age six and older.”
- “In addition, two clinical trials in children aged six and older did not find neurological or renal injury associated with amalgam use.”
- “FDA has found that scientific studies using the most reliable methods have shown that dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA. Based on these findings and the clinical data, FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects.”
- “FDA estimates that the estimated daily dose of mercury in *children under age six* with dental amalgams is lower than the estimated daily adult dose. The exposures to children [under six] would therefore be lower than the protective levels of exposure identified by ATSDR and EPA.”
- “In addition, the estimated concentration of mercury in breast milk attributable to dental amalgam is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. FDA has concluded that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapors from dental amalgam.”²

There Is No New Science to Warrant a Review of the 2009 FDA Ruling

These conclusions by the FDA resulted from a long and thorough review of the scientific evidence on the safety and efficacy of dental amalgam. The best scientific evidence continues to support the safety of dental amalgam. This evidence does not support a link between dental amalgam and systemic diseases or risks to pregnant women or developing fetuses. Nor does the evidence support the existence of “sensitive populations” at risk from dental amalgam.³ The AAPD urges the FDA advisory panel to reaffirm what the FDA concluded just last year, that dental amalgam is a safe restorative material.

² Food and Drug Administration, HHS. Dental devices: classification of dental amalgam, reclassification of dental mercury, designation of special controls for dental amalgam, mercury, and amalgam alloy. Final rule. 74 Fed Reg. 38685-714, 38693-4.

³ It is acknowledged that a very small segment of the population may experience localized allergic reactions to dental amalgam, but this is also true for many other materials used in medical or dental offices.

One reason mentioned in the FDA's meeting notice for revisiting the issue of dental amalgam was the recent report on risk assessments issued by the National Academy of Sciences (NAS), entitled "Science and Decisions: Advancing Risk Assessment." This document's application to FDA proceedings is not clear. It expressly addresses the EPA's risk assessment process and makes recommendations with respect to that specific process. It does not address how FDA does or should address risk assessment issues. Nor does it address the need to weigh both benefits and risks associated with a given material, drug or device.

The FDA needs to focus not just on risks but also on the benefits inherent in the continued availability of a material, drug or device. This does appear to be FDA's current practice. Nothing in the NAS document calls into question the FDA's 2009 ruling.

Restrictions on Dental Amalgam Absent a Scientific Basis Would Impact Access to Oral Health Care

FDA action must be supported by science. While the scientific evidence regarding the safety of dental amalgam is well established, and has not changed since FDA's 2009 ruling, the FDA should also acknowledge that the use of dental amalgam has enormous health benefits as a restorative material. Were the FDA to require a warning or limit the use of amalgam, the AAPD is concerned that it would hurt efforts to address the oral health needs of Americans of all ages. There would be a significant impact on young children and those with special needs, where it may not be possible to create the dry environment required for placement of alternative restorative materials. There would likely be an increase in dental restorations being placed while the patient is under general anesthesia, further increasing health care costs. Elimination of dental amalgam as an option, even for limited groups, will have a profound effect on the nation's health care system because of the added cost of alternative restorative materials.

The AAPD's clinical guideline on Pediatric Restorative Dentistry is available online at: http://www.aapd.org/media/Policies_Guidelines/G_Restorative.pdf

These recommendations are based on a *Pediatric Restorative Dentistry Consensus Conference* convened by the AAPD in April 2002. Individual research papers prepared for that conference were subsequently published in the peer-reviewed scholarly journal *Pediatric Dentistry*. The Consensus Statement related to amalgam included the following conclusion:

"The dental literature supports the safety and efficacy of dental amalgam in all segments of the population."

The AAPD's clinical guideline recommends dental amalgam for:

1. Class I restorations in primary and permanent teeth;
2. Class II restorations in primary molars where the preparation does not extend beyond the proximal line angles;
3. Class II restorations in permanent molars and premolars;
4. Class V restorations in primary and permanent posterior teeth.

Were this important restorative material (amalgam) not available, there would be a significant impact on cost and access to care. A 2007 peer-reviewed study examined the impact of partial and full bans on the use of dental amalgam, finding that:

- Without amalgam, the average price of restorations would go from \$278 to \$330 (an 18.7 percent increase);
- As the prices increased, they estimated there would be 15,444,021 fewer restorations each year;
- A ban on amalgam would increase the use of crowns and composite resins, both of which are more expensive;
- Even limiting the ban to children would mean an increase of \$1.1 billion the first year and \$13 billion over a 15-year period.⁴

The Science Supporting Amalgam Safety is Strong and Compelling

Those who support an outright ban on dental amalgam ignore or fail to understand the science supporting the conclusion that it remains a safe treatment option. Typically, they rely on non-peer-reviewed articles, studies that do not comply with Good Clinical Practice (GCP), or on studies which focus solely on sub-clinical effects at the cellular level, ignoring the dearth of evidence that amalgam causes humans any harm.

This overwhelming support of dental amalgam safety is further evidenced by the recent literature update conducted by the American Dental Association's (ADA) Council on Scientific Affairs, which is included in their written comments. A few key recent studies or literature reviews merit special attention.

- A 2008 review of the evidence conducted by a Scientific Committee of the European Commission addressed safety concerns for patients, professionals

⁴ Beazoglou T, Eklund S, Heffley D, Meiers J, Brown LJ, Bailit H. Economic impact of regulating the use of amalgam restorations. Public Health Reports 2007; 122 (5):657-63.

and the use of alternative restorative materials.⁵ The committee concluded that dental amalgams are effective and safe, both for patients and dental personnel. The committee's report states:

“SCENIHR concluded that dental amalgams are an effective restorative material and may be considered the material of choice for some restorations. While some local adverse effects are seen, the incidence is low and usually readily managed. The current use of dental amalgams does not pose a risk to health apart from allergic reactions.”

According to SCENIHR, alternative materials are not without clinical limitations and toxicological hazards. Allergies to some of these substances have been reported, both in patients and in dental personnel.

- The findings of two clinical trials, widely known as the Children's Amalgam Trials, were published in April 2006 in the Journal of the American Medical Association.⁶ These two important, randomized clinical trials, funded by the National Institutes of Health, continue to be among the best studies of the safety of dental amalgam ever conducted. They 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. While the safety of dental amalgam has been the subject of a number of previous publications, expert panel meetings and national and international conferences, these two clinical trials were the first to compare overall health effects in children treated with amalgam restorations and children treated with resin composite restorative materials. **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.**
- The safety of dental amalgam was confirmed by a 2004 Life Sciences Research Office (LSRO) review commissioned by the NIH, HHS and FDA.⁷ LSRO

⁵ See http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf

⁶ 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(15):1784-92; and 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(15):1775-83.

⁷ See Brownawell AM, Berent S, Brent RL, Bruckner JV, Doull J, Gershwin EM, Hood RD, Matanoski GM, Rubin R, Weiss B, Karol MH. The potential adverse health effects of dental amalgam. Toxicol Rev. 2005;24:1-10.

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.”

Conclusion

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 an excellent restorative material for placement 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.

The AAPD is a science-based organization and bases its comments solely on the scientific evidence. Based on that evidence, the AAPD strongly urges the FDA advisory panel to support the well-researched and thoughtful conclusions reached by the FDA in 2009, after years of study.

The AAPD appreciates the opportunity to share these comments with the FDA.