



AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

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delivered via e-mail

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Dr. Mr. Adjodha:

The American Academy of Pediatric Dentistry (AAPD) is pleased to submit these comments for the record concerning the September 6-7, 2006 joint meeting of the FDA's Dental Products Panel and Peripheral and Central Nervous System Drugs Advisory Committee to review and discussed peer-reviewed scientific literature on dental amalgam devices.

The AAPD is the membership organization representing the specialty of pediatric dentistry. Our members are the "front line" providers of oral health care to America's children and educators of health professionals about children's oral health.¹ The AAPD represents not only the nation's pediatric dentists, but also general dentists who treat significant numbers of children in their practices.

The AAPD is the recognized authority on pediatric oral health care, and is a leader in several prominent areas, including: the development of pediatric dentistry oral health policies and clinical practice guidelines; the dissemination of information to parents and caregivers about pediatric oral health care; and partnership with the federal government on several key pediatric oral health initiatives targeted at new mothers, pre-school children, and adolescents.

¹ The Academy's 6,600 members serve as primary care providers for millions of children from infancy through adolescence; provide advanced, specialty-level care for infants, children, adolescents, and patients with special health care needs in private offices, clinics, and hospital settings; and are the primary contributors to professional education programs and scholarly works concerning dental care for children. Individuals trained in Pediatric Dentistry (which requires a minimum of two years' additional residency training post-dental school) learn advanced, diagnostic, and surgical procedures; child psychology and clinical management; oral pathology; pharmacology related to the child; radiology; child development; management of oral-facial trauma; caring for patients with special health care needs; conscious sedation; and general anesthesia. Since children's oral health is an important part of overall health, pediatric dentists often work with pediatricians, other physicians, and dental specialists.

On April 15-16, 2002, the AAPD sponsored a *Pediatric Restorative Dentistry Consensus Conference*. The individual research papers prepared for that conference and the consensus statements developed were published in the September/October 2002 issue of the scholarly journal *Pediatric Dentistry* (24:5, 2002). The Consensus Statement related to amalgam reads as follows (emphasis added):

“Amalgam

The dental literature supports the safety and efficacy of dental amalgam in all segments of the population. Furthermore, the dental literature supports the use of dental amalgam in the following situations:

1. Class I restorations in primary and permanent teeth;
2. two-surface 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.”

Attached to this letter are the two research papers related to dental amalgam from this consensus conference: Osborne JW, Summitt JB, Roberts HW. The use of dental amalgam in pediatric dentistry: a review of the literature. *Pediatr Dent*. 2002; 24:439-447 and Fuks AB. The use of amalgam in pediatric dentistry. *Pediatr Dent*. 2002; 24:448-455.

Recent studies published in the Journal of the American Medical Association² further support the conclusions from the AAPD consensus conference related to dental amalgam safety. According to the results, children with amalgam fillings experienced no difference in neurological and kidney functions compared to a control group of children with composite (white) fillings. These studies support the existing scientific understanding that the small amount of mercury released by amalgam fillings during common activities such as eating and drinking does not adversely affect health.

Based on all the research cited in this letter and attached articles, the AAPD supports the continued use of dental amalgam as an important treatment option,

² 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: 1775-1783.

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as indicated in the AAPD's current clinical guideline on pediatric restorative dentistry (available on-line at http://www.aapd.org/media/Policies_Guidelines/G_Restorative.pdf and also attached to this letter.)

As previously indicated, **Dr. Joel H. Berg**, pediatric dentist, and Professor and Chair of the Department of Pediatric Dentistry at the University of Washington, will testify on behalf of the AAPD at the upcoming FDA meeting.

Thank you again for offering the opportunity for our organization to comment on this issue. If you any questions concerning these comments, please contact Dr. Rutkauskas at 312-337-2169 ext. 28 or jrutkauskas@aapd.org.

Sincerely yours,



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President



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