



## American Academy of Pediatric Dentistry

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### FDA ORAL STATEMENT OF AAPD

I am Dr. John Liu, current President of the American Academy of Pediatric Dentistry. Our 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. Let me briefly summarize the key points of our written submission.

We agree with the FDA's 2009 ruling that dental amalgam is a safe and effective restorative material that does not cause adverse health effects in children.

This is consistent with the American Academy of Pediatric Dentistry's clinical guideline on restorative dentistry, which is based on a *Pediatric Restorative Dentistry Consensus Conference* we convened in 2002. **The dental literature supports the safety and efficacy of dental amalgam in all segments of the population.**

Our clinical guideline recommends dental amalgam for:

- ☐ Class I restorations in primary and permanent teeth;

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

A recent study indicated that without amalgam as a restorative option, the cost of restorations for children alone would increase by \$1.1 billion the first year and \$13 billion over a 15-year period. Such an impact on dental costs and access to care would be acceptable ONLY if amalgam posed harm. But it does not.

The results of the Children's Amalgam Trials, two important, randomized clinical trials, funded by the National Institutes of Health and published in the April 2006 Journal of the American Medical Association, **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 also confirmed by a 2004 Life Sciences Research Office review commissioned by the NIH, HHS and FDA. This review 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 that “there 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.”

The American Academy of Pediatric Dentistry strongly urges the FDA advisory panel to support the well-researched and thoughtful conclusions reached by the FDA in 2009. Thank you.