



American Dental Education Association

May 29 2003

THE MISSION OF THE AMERICAN DENTAL EDUCATION ASSOCIATION is to lead individuals and institutions of the dental education community to address contemporary issues influencing education, research, and the delivery of oral health care for the improvement of the health of the public

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Dockets Managements Branch (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: FDA request for interested persons to provide information for a scientific literature review related to the health effects of dental amalgam in humans, 68 Fed. Reg. 25047-25048.

Dear Sir/Madam:

The American Dental Education Association (ADEA), is the premier national organization that speaks for dental education. It is dedicated to serving the needs of all 56 U.S. dental schools, 731 U.S. dental residency programs, 266 dental hygiene programs, 259 dental assisting programs, and 25 dental laboratory technology programs, as well as the 11,332 full- and part-time dental school faculty, more than 5,060 dental residents and the nation's 37,300 dental and allied dental students. It is at dental education institutions that future practitioners and researchers gain their knowledge; the majority of dental research is conducted; and significant dental care is provided to many underserved low-income populations.

ADEA supports comments submitted by the American Dental Association (ADA) to the Food and Drug Administration (FDA) request for interested persons to provide information for a scientific literature review related to the health effects of dental amalgam in humans.

In summary ADEA concurs with the ADA's recommendations urging the FDA to:

- Broaden its literature search to include peer-reviewed articles of published between 1993 and 1997. The published timeframe that FDA has set (January 1, 1996 to June 1, 2003) is too confining a period to include many articles of importance that ought to be considered.
- Publish the methodology it plans to use to conduct the literature review. ADEA, and others in the scientific community, would appreciate an opportunity to evaluate and comment on the methodology. We strongly endorse inclusion of the elements suggested by the ADA: background, objective(s), inclusion criteria, search strategy, quality assessment criteria, data extraction and analysis.

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- Publish information on the qualifications and selection of the reviewers. Care must be taken to ensure that the reviewers are satisfactorily familiar with dental amalgam and its use in clinical dentistry to understand and interpret the research findings. ADEA encourages the FDA to include members of the dental education and dental research communities as reviewers.

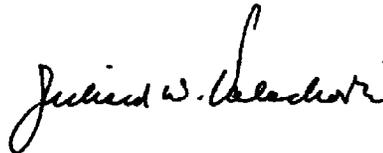
Amalgam has been used in tooth restorations worldwide for more than 100 years. No study has proven a link between amalgam restorations and any medical disorder. Fewer than 100 cases have been reported of allergic reactions to amalgam fillings; with patients exhibiting symptoms similar to a skin allergy. In these instances, mercury may trigger an allergic response. For patients who are allergic to amalgam another restorative material may be used.

The ADEA appreciates the FDA's consideration of our information and suggestions. Should you have any questions, please contact Gina Luke, Director of Legislative Policy Development at (202) 667-9433.

Sincerely,



Paula K. Friedman, D.D.S., M.S.D., M.P.H.
President



Richard W. Valachovic, D.M.D., M.P.H.
Executive Director