

The New Statement of the FDA on the Use of Amalgam in Children; A Controversy

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The US Food and Drug Administration (FDA) has updated its guidelines for the use of amalgam in dental restorations. The agency announced that in any case, the use of dental amalgam should be avoided for certain groups, such as pregnant women, women who are planning to become pregnant, children, and people who already have certain neurological diseases.

The use of dental amalgam continues to be widespread in the United States, despite phasing out or prohibiting programs for certain groups of people in many countries. Before its recent announcement, the FDA considered dental amalgam restorations safe for adults and children over 6 years of age.

The FDA's new position on the use of dental amalgam is that its use may pose a greater risk of adverse health effects in certain groups, so it recommends that its application should be prevented for this group whenever possible and appropriate.

This group includes the following:

- Pregnant women, and their developing fetuses.
- Women who are planning to become pregnant.
- Breastfeeding women, and their infants and children.
- Children, especially children under 6 years old.
- People with preexisting neurological conditions such as multiple sclerosis, Alzheimer's, and Parkinson's.
- People with impaired kidney function.
- People with known allergies to mercury, or other components of dental amalgam.

The international medical and scientific community has argued that there is evidence of a causal relationship between the use of dental amalgam in dental restorations and the development of neurological diseases such as multiple sclerosis (MS). A New Zealand investigation claimed a link between amalgam exposure and multiple sclerosis [1].

On the other hand, in response to the FDA report, the American Academy of Pediatric Dentistry supports the effectiveness and safety of dental amalgam. It has been stated that "There is strong evidence that dental amalgam is efficacious in the restoration of Class I and Class II cavity restorations in primary and permanent teeth.... Concerning the safety of dental amalgam, a comprehensive literature

review of dental studies found insufficient evidence of associations between mercury release from dental amalgam and the various medical complaints. Two independent randomized controlled trials in children have examined the effects of mercury release from amalgam restorations and found no effect on the central and peripheral nervous systems and kidney function” [2].

AAPD Chief Policy Officer, Paul S. Casamassimo Said: “Although the use of amalgam restorations has decreased in the last decade in favor of more esthetic alternatives, it remains an essential treatment option to protect access to care for our most vulnerable patient populations. In particular, this could pose a further barrier to needed care for patients with special health care needs for whom amalgam is the ideal restorative choice” [2].

Finally, it seems that the American Academy of Pediatric Dentistry (AAPD) still emphasizes the safety of amalgam in pediatric dentistry even though the FDA has released a new statement.

Bibliography

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2. <https://www.aapd.org/about/about-aapd/news-room/latest-news/aapd-confirms-safety-and-effectiveness-of-amalgam-in-response-to-fda-report/>

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