

## FDA STATEMENT

# FDA Issues Recommendations for Certain High-Risk Groups Regarding Mercury-Containing Dental Amalgam

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### Statement From:

Director - CDRH Offices: Office of the Center Director

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Part of our role in protecting patients is to regularly evaluate, monitor and update scientific evidence on the risks from medical devices—including issues related to the materials used in devices, such as metals. In the case of implanted and inserted medical devices, where materials may be in contact with the body for extended periods of time, we evaluate safety issues involved with, among other things, the body's long-term exposure to certain materials, taking into account that sometimes uncertainties remain and more research is needed.

Today, the FDA is issuing updated recommendations concerning dental amalgam and potential risks to certain high-risk individuals that may be associated with these mercury-containing fillings used to restore the missing structure and surfaces of a decayed tooth.

The FDA has found that certain groups may be at greater risk for potential harmful health effects of mercury vapor released from the device. As a result, the agency is recommending certain high-risk groups avoid getting dental amalgam whenever possible and appropriate.

These groups that may be at a greater risk for potential harmful health effects include:

- Pregnant women and their developing fetuses;
- Women who are planning to become pregnant;
- Nursing women and their newborns and infants;
- Children, especially those younger than six years of age;
- People with pre-existing neurological disease such as multiple sclerosis, Alzheimer's disease or Parkinson's disease
- People with impaired kidney function; and
- People with known heightened sensitivity (allergy) to mercury or other components of

dental amalgam.

For over 20 years, the FDA has been reviewing scientific literature, monitoring reports and holding public discussions regarding the public health effects of dental amalgam and amalgam-related mercury vapor. Dental amalgam is a mixture of mercury and a powdered alloy made up of silver, tin and copper. The amalgam releases small amounts of mercury vapor over time. While low-levels of inhaled mercury vapor are generally not harmful to most people, these high-risk individuals may be at increased risk of adverse health outcomes. How much vapor is released can also depend on the age of the filling as well as a person's habits such as teeth grinding.

These uncertainties in the most vulnerable patients are why today we are recommending people who may be at high risk for adverse health effects of mercury exposure use non-mercury alternatives to dental amalgam (</medical-devices/dental-amalgam-fillings/treatment-options-dental-caries>), such as composite resins and glass ionomer cement fillings. Dental amalgam-related mercury vapor release may be highest during placement or removal of the filling. The FDA is not recommending anyone remove or replace existing amalgam fillings in good condition unless it is considered medically necessary because removing intact amalgam fillings can cause a temporary increase in exposure to mercury vapor and the potential loss of healthy tooth structure, potentially resulting in more risks than benefits. While the available evidence suggests that dental amalgam use has generally declined over recent years, due to more alternative products being offered and used effectively for dental restorations, high-risk individuals, as noted in our recommendations, should discuss alternative products for restoring teeth with their dentist.

Our reviews and discussions have generally arrived at the same conclusion: while the majority of evidence suggests exposure to mercury vapor from dental amalgam fillings doesn't lead to harmful health effects for most people, there may be some effects in people with certain health issues such as those who are hypersensitive to mercury. Uncertainties remain about: the effects that long-term exposure to dental amalgam may have on the specific high-risk groups we've listed above; the potential for mercury in dental amalgam to convert to other mercury compounds in the body; and whether the accumulation of mercury in some body fluids and tissues results in other unintended health outcomes.

We have made these recommendations after hearing from health care professionals, evaluating published literature and considering the public's comments about dental amalgam and other metal-containing implants. During the November 2019 meeting of the Immunology Devices Panel of the Medical Devices Advisory Committee (</advisory-committees/advisory-committee-calendar/november-13-14-2019-immunology-devices-panel-medical-devices-advisory-committee-meeting-announcement>), which discussed immunological responses to metal-containing implants and dental amalgam, we heard from

several speakers, including those representing underserved communities, who expressed concern about the cumulative effect of mercury vapor exposure from dental amalgam, as well as from other (dietary and environmental) sources.

The FDA continues to believe that the benefits of materials in FDA-approved or cleared implantable and insertable medical devices outweigh their risks for most patients. However, we recognize that it is critical to closely monitor and evaluate new benefit-risk related data as biomedical science is always evolving. We continue to gather input from patients, device manufacturers, researchers and physicians to learn more about their experiences, ideas and feedback related to materials in medical devices, such as dental amalgam. We're committed to advancing new initiatives that are rooted in sound science with a focus on patient safety remaining at the forefront.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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## Related Information

- [Information for Patients About Dental Amalgam Fillings \(/medical-devices/dental-amalgam-fillings/information-patients-about-dental-amalgam-fillings\)](/medical-devices/dental-amalgam-fillings/information-patients-about-dental-amalgam-fillings)
- [Recommendations About the Use of Dental Amalgam in Certain High-Risk](#)