

**FDA Safety communication: Reducing Exposure to Mercury Vapor Released
From Dental Amalgam ("Silver Fillings")**

Date Issued: Jan XX, 2012

Audience:

- Dentists and dental care professionals who place dental amalgams
- All consumers, but especially:
 - Pregnant and nursing women
 - Parents and guardians of infants and children under age 6
 - People with mercury allergy or sensitivity
 - People with neurological disease
 - People with kidney disease

Medical Specialties: Dentistry, Dental Hygiene, Pediatric Dentistry, Pediatrics, Ob/Gyn,
Neurology

Device:

Dental amalgam, also known as "silver fillings," is a kind of dental filling material used to fill cavities caused by tooth decay and to restore the structure and surfaces of a decayed or broken down tooth. Dental amalgam filling material is a solid compound composed of several metals. About half of an amalgam filling is elemental mercury by weight. The other half is an alloy of silver, tin, copper and sometimes zinc. A dental amalgam filling continuously releases low levels of mercury in the form of mercury vapor.

Mercury vapor can cause health problems, particularly to the nervous system but the severity of effects depends on the amount of mercury released and exposure duration.

There is no direct evidence that the levels of mercury released from dental amalgam are

harmful for the general population. However, some subpopulations, such as pregnant and nursing women, children under the age of 6, people with mercury allergy or sensitivity, or people with neurological or renal (kidney) disease may be more susceptible to potential health risks from mercury exposure than the general population.

Purpose:

The purpose of this safety communication is:

- To provide dentists, consumers and medical professionals with definitive guidance and additional recommendations to reduce mercury exposure from dental amalgam fillings for sensitive subpopulations; and
- To communicate to dentists, medical professionals and the public the risks associated with mercury vapor released from dental amalgam fillings.

Summary of Problem and Scope:

Dental amalgam fillings contain mercury, which is released at low levels over time in the form of mercury vapor. Mercury vapor is released continually throughout the life of an amalgam filling. The amount of vapor released decreases as the filling ages, but chewing, tooth grinding or exposing and amalgam filling to hot liquid or food can temporarily increase the amount of vapor released. Mercury vapor levels are highest during and immediately following placement and removal of dental amalgam fillings and can be increased during and shortly after professional cleanings.

The primary route of mercury vapor exposure released from dental amalgam fillings is by inhalation and absorption into the body through the lungs. The body excretes some of this mercury while the remainder is distributed throughout the body and may accumulate in certain tissues, particularly the brain, kidney and liver. Mercury in the blood of a pregnant woman is also distributed throughout her body, but some passes into the blood of the developing fetus.

A number of studies have been conducted to determine if exposure to mercury vapor from dental amalgam is related to adverse health effects. These studies do not provide conclusive evidence linking exposure to mercury vapor from dental amalgam with adverse health effects

In the general population. Based upon the current state of the scientific evidence, the FDA believes the amount of mercury vapor released from dental amalgam poses minimal risks for the adverse health effects in the general population.

Although there is no direct evidence of harm from dental amalgam in the general population, information reviewed by the FDA over the past year presents concern for certain sensitive subpopulations, such as pregnant women and their developing fetuses, children younger than 6 years and other higher risk subgroups who may be more susceptible to potential adverse effects from mercury exposure.

In particular, there is uncertainty about the level of mercury exposure from dental amalgam. In addition, there is limited, if any, clinical data on health effects resulting from exposure to mercury vapor from dental amalgam in these more sensitive subpopulations.

Guidance for Dental Professionals:

To avoid potential and unnecessary health risks to the most sensitive subpopulations and because there are alternative dental restorative materials currently available-such as composite resins-that do not contain mercury, the FDA provides the following guidance regarding the use of dental amalgam fillings:

Dentists should not use dental amalgam fillings in patients with known hypersensitivities or allergies to mercury or other components of dental amalgam. Some individuals have an allergy or sensitivity to mercury or the other components of dental amalgam. Dental amalgam may cause these individuals to develop oral lesions or other contact reactions.

Dentists should not place new dental amalgam fillings in pregnant women.

Placement or removal of dental amalgam during pregnancy results in a temporary increase in mercury exposure, which is associated with increased mercury levels in fetal cord blood and increased exposure to the developing fetus.

Dentists should not place dental amalgam fillings in nursing women, children younger than 6 years and any individual with pre-existing kidney or neurological disease. The developing neurological systems of breast-feeding infants and children may be more sensitive to the neurotoxic effects of mercury exposure. In addition, the use of dental amalgam in those persons with pre-existing kidney or neurological disease may further compromise already impaired renal and neurological systems.

Additional Recommendations:

The FDA recommends against the removal of functional amalgam fillings in any individual, including pregnant women, unless deemed medically necessary by a physician in consultation with the patient's treating dentist. However, the FDA recognizes that patients often present to a dentist requesting removal of dental amalgam fillings under a variety of circumstances, for example, cosmetic appearance, as well as owing to health concerns with or without a concurrent health problem. As part of the dental practice of informed consent, dentists should discuss the benefits and risks of using dental amalgam and restorative alternatives with their patients to allow the patient to make informed choices regarding their treatment options. The ultimate decision about what dental restorative material to use is one that should be made between patients and their dentist.

In some cases, dental amalgam may be the most suitable restoration for certain cavities, and should remain available to dentists for appropriate dental health care. However, alternative materials, such as composite resins that do not contain mercury, can also be used to fill cavities. The FDA believes that these alternative materials would best be offered as the first line of restorative care minimizing the use of dental amalgam.

Information use in FDA's Guidance and Recommendations:

The FDA published a final rule on Aug. 4, 2009, reclassifying dental amalgam from a Class I (low risk) to a Class II (moderate risk) medical device. The FDA also issued a Class II Special Controls guidance document for manufacturers of dental amalgam that outlines the specific performance data and labeling information. The FDA concluded that, based upon valid scientific evidence (including a review of the clinical literature and a 2006 assessment of potential adverse health risks from exposure to mercury vapor released from dental amalgam fillings), the special controls, in conjunction with the general controls, provided a reasonable assurance of the safety and effectiveness of dental amalgam.

After publishing the final rule on dental amalgam, the FDA received several petitions raising questions about the adequacy of the agency's risk assessment approach utilized in the 2009 final rule. In response to questions raised in the petitions, the FDA consulted with experts in toxicology and risk assessment regarding the levels of mercury vapor exposure from dental amalgam and how those levels compare with acceptable reference exposure levels¹ (RELs) established to protect public health.

¹ Reference Exposure Level (REL)-An REL represents an exposure concentration (with uncertainty spanning perhaps an order of magnitude) at or below which no adverse health effects are anticipated in the general human population (including sensitive subpopulations) following exposure to a chemical for a defined period of time. RELs are based on the most sensitive relevant adverse health effects reported in the medical and toxicological literature. An REL derived for mercury vapor that is related to long-term mercury exposure from dental amalgam represents the exposure concentration that is not likely to

These experts, who were asked to consider FDA's risk assessment and the merits of other approaches (attach link M1) questioned whether current standards for assessing the risk from

mercury vapor exposure are protective enough and pointed out that the FDA's risk assessment did not account for body weight differences between children and adults. They presented their analyses at a December 2010 panel meeting (attach link M2) where members also raised questions about the adequacy of previous risk assessments for dental amalgam.

As a means of mitigating the risks of mercury exposure from dental amalgam, the panel offered the following recommendations:

- The risks of mercury vapor exposure from dental amalgam need to be communicated effectively to the public, dentists and medical professionals;
- Restorative options need to be thoroughly discussed with patients and informed consent obtained prior to initiating treatment;
- The FDA should consider warnings against the use of dental amalgam in pregnant women, young children, and those with kidney dysfunction, neurological impairment or allergy to mercury and other components of dental amalgam fillings.

The FDA is providing new guidance and recommendations on the use of dental amalgam because of the general lack of clinical data on exposure to mercury vapor from dental amalgam in sensitive subpopulations.

The FDA believes that certain subpopulations: pregnant women, infants of nursing mothers, patients with known hypersensitivities or allergies to mercury or other components of dental amalgam, children under the age of 6, and patients with neurological or renal (kidney) disease may be at greater risk for adverse health effects as a result of exposure to mercury released from dental amalgam fillings. Accordingly, FDA believes placement of new amalgam fillings should be avoided in these subpopulations.

cause adverse health effects for exposure over a lifetime, including the general population and sensitive subpopulations. The REL is not a threshold of toxicity, that is, adverse health effects would not be expected in patients exposed at the REL. The daily dose of a chemical associated with the REL serves as an indicator of the likelihood that adverse effects will occur when compared to the range of daily doses of the compound that patients are exposed to. Daily exposures above and REL over a lifetime do not necessarily indicate that adverse health effects **will** occur, but doses far above the REL suggest that adverse health effects are more likely to occur.

The FDA continues to believe that exposure to mercury vapor from dental amalgam poses minimal risk for adverse health effects for the general population. This conclusion reflects numerous scientific studies that have failed to show an association between exposure to

mercury vapor and dental amalgam and adverse health effects in the general population and children over six. In particular:

- Studies examining associations between mercury exposure from dental amalgam and neurodegenerative diseases (the progressive loss of brain and/or nerve functions, such as Alzheimer's disease, Parkinson's disease, and Multiple Sclerosis) and diseases of the immune system have been inconclusive.
- Epidemiological studies have shown no association between amalgam mercury exposure and neuropsychological and neurobehavioral deficits (memory, cognition, motor functions, hand steadiness) or renal (kidney) injury in the general population with amalgam fillings.
- Dental professionals exposed to mercury vapor in the occupational setting may be at higher risk for exposure during removal of dental amalgam fillings or if dental amalgams are improperly used, stored, mixed or handled. The FDA believes the use of proper removal and installation techniques in conjunction with attention to mercury hygiene serves to mitigate this risk to both the dentist and patient. However, some studies have provided evidence for neurological deficits in dentists (for example, decreased hand steadiness) at low levels of mercury exposure.
- Controlled clinical trials studying children who had dental amalgam fillings placed as early as age 6 have not shown an association between dental amalgams and adverse health outcomes utilizing the parameters studied. However, the children's health was assessed no more than seven years after placement.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with dental amalgam fillings, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 OR 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices

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