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## FDA Responds to Citizens' Petitions Concerning the Mercury in Dental Fillings

(Washington, DC) --- In response to a lawsuit filed on March 5, 2014, FDA agreed to submit responses to three citizens' petitions filed with FDA in September 2009 challenging FDA's position on the safety of mercury tooth fillings. The citizens' petitions allege that the published scientific literature demonstrates that the absorption of mercury from these fillings presents an unacceptable risk to the health of those in whom this material is placed. The lawsuit alleges that FDA has failed to respond to these petitions within the six-month period provided by regulation. In December 2010, the FDA announced its intention to complete its review by the end of 2011, but it did not actually respond until January 27.

The petitions call for either a formal ban on amalgam use, or classification of these fillings in FDA's Class III. Such classification would require: 1) additional restrictions for vulnerable individuals; 2) more stringent proof of safety; and 3) an Environmental Impact Statement. In August 2009, FDA classified this dental device in Class II, prescribing no controls or other measures intended to protect the public.

Yesterday, FDA filed its responses claiming that only some clarifications to FDA's 2009 Final Rule are warranted, and that amalgam will continue to be classified in Class II. Attorney James M. Love, who filed the lawsuit, stated that, "the FDA continues to allow the American people to be poisoned by their mercury fillings despite the scientifically demonstrated risks. Despite the shift of many countries away from mercury fillings, it appears that the FDA believes that the human mouth is a safe place to store mercury." He further stated that, "the burden of proving safety is on FDA, but FDA ignores this principal and places the burden on us to conclusively prove these fillings are causing diseases. FDA presumes that these fillings are safe-- even for fetuses—while admitting that it has no data demonstrating safety.

"The FDA continues to ignore the fact that the majority of people with mercury amalgam fillings continue to be exposed to daily doses of mercury vapor that exceed safe levels as determined by government agencies around the world. Indeed, despite several independent published risk assessments demonstrating the health risks associated with these fillings, FDA's risk assessment 'justifies' the continued use of mercury fillings as an acceptable dental restorative material."

Top scientists have repeatedly warned the FDA of the risk of harm posed by mercury released from dental fillings:

- **In [2006, the FDA consulted a Joint Panel of physicians and dentists to review the FDA's own White Paper on mercury fillings](#). By a 13 to 7 vote, the Joint Panel concluded that the White Paper did not demonstrate the safety of mercury fillings.**
- In 2009, in their position statement, the Scientific Advisory Board to the International Academy of Oral Medicine & Toxicology stated, "[i]t is incompatible with current, valid scientific evidence



to continue to endorse or otherwise condone the use of a permanently implanted material in teeth that continuously emits a very potent enzyme inhibitor and metabolic toxin.”

- [In 2010, at the urging of its own scientific advisory panel, the FDA agreed to review its amalgam rule based on current science.](#) The panel members consistently voiced concern over the placement of mercury fillings in pregnant women and children.
- A February 2014 study, “[Homme, et al., New science challenges old notion that mercury dental amalgam is safe,](#)” published in the peer-reviewed journal, *Biometals*, reviewed recent scientific literature demonstrating the risks associated with mercury fillings.
- A 2013 study, “[Woods et. al. 2013 – Neurobehavioral Data From CATs Reveals Greater Hg Effects In Boys With Metallothionein Gene Variant,](#)” shows that certain genetic factors make young boys more susceptible to adverse neurobehavioral effects from mercury.
- A 2014 study, [Woods et al., Genetic Polymorphisms of Catechol-OMethyltransferase Modify the Neurobehavioral Effects of Mercury in Children](#) shows further evidence of genetic susceptibility to mercury toxicity in children, and the identification of adverse effects on multiple neurobehavioral functions among boys.
- Another 2014 study, “[Woods, et al., Genetic Polymorphisms Affecting Susceptibility To Mercury Neurotoxicity In Children: Summary Findings From The Casa Pia Children’s Amalgam Clinical Trial,](#)” showed neurological dysfunction in children and especially in boys.
- Mercury is a persistent toxic chemical that can accumulate in the body. It is particularly toxic to the kidneys and the nervous system. Young children are more sensitive to mercury and are exposed to mercury in utero through the placental transfer of mercury and by drinking breast milk.
- More information on the health effects of mercury fillings can be seen in [this video](#).

“We have banned mercury in disinfectants, thermometers, and many other consumer products,” said Stuart Nunnally, DDS, President of the IAOMT. “There is no magic formula that makes mercury safe when it’s put into our mouths. It’s inexcusable to use mercury in dental fillings when there are much safer alternatives.”

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