

FDA re-examining risks of fillings that contain mercury

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The U.S. Food and Drug Administration is taking another look at the risks of mercury in dental fillings, raising hopes among local activists that more stringent regulations will be put in place.

The FDA said Thursday that an advisory panel would hold hearings from 8 a.m. to 6 p.m. Dec. 14-15 at a Holiday Inn in Gaithersburg, Md., focusing specifically "on the potential risk to vulnerable populations, such as pregnant women, fetuses and young children."

"I'm thrilled by this," said Amanda Just of Waterford, one of several Connecticut residents who have written the FDA to urge a ban on amalgam fillings, which contain mercury. "I'm trying not to get my hopes up, though, because ... (dental-industry advocates) always get around it somehow."

The agency previously had put a temporary ban on amalgam fillings for pregnant women and young children, but rescinded the action in July 2009 as it issued labeling requirements slightly more stringent than previously in place.

At least four subsequent petitions to the FDA protested the agency's decision.

One of the petitions, signed by the International Academy of Oral Medicine, among other groups and individuals, called the decision "a denial of consumers' fundamental right to know that a neurotoxin is being placed in their bodies."

It added that "Only inappropriate industry influence can explain a rule that is so inconsistent with not only FDA's mission, but our national policies and values. ... Such callous gambling with the next generation's health inexplicably defies the anti-mercury public record and campaign promises of the President of the United States."

The petition charged that FDA Commissioner Margaret Hamburg, who recused herself from the amalgam ruling, "was believed to have (an) intertwining relationship with dental products colossus Henry Schein Inc." The document, available on the FDA's website, stated that Hamburg served on the company's board of directors, receiving more than \$500,000 from Schein during the two years prior to her appointment as commissioner and continuing to hold stock options up to a day before the final amalgam decision.

"Hamburg's evasiveness about her role in the amalgam rule indicates that the rule is tainted," according to the petition.

The FDA in its 2009 ruling left it up to dentists to decide whether to tell patients about the presence of mercury in amalgam, despite studies showing that most people don't know fillings contain the toxic agent.

"While elemental mercury has been associated with adverse health effects at high exposures, the levels released by dental amalgam fillings are not high enough to cause harm in patients," the FDA ruled at the time.

Just, who had all her fillings removed after suffering from mercury poisoning, continues to wonder how the United States can deem mercury as safe while Norway, Denmark and Sweden ban the substance in fillings.

"It's a known neurotoxin; why not just admit it?" she asked in a telephone interview Thursday.

The FDA now classifies amalgam fillings as devices carrying a moderate risk. The agency warns against their use in patients with mercury poisoning.

But since the 2009 ruling, the FDA said public concerns have been raised about the adequacy of the agency's method of assessing mercury risks, as well as concerns over the exposure of young children to mercury vapor, the accumulative effect of mercury on people with many fillings and the adequacy of studies cited in the decision.

In calling for an advisory-panel meeting on amalgam, the FDA also cited a new National Academy of Sciences study on risk assessments, which, among other things, calls for "greater understanding of the biological processes underlying the production of toxicity or other types of adverse health effects."

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