

FDA concludes mercury in dental fillings not risky

July 28 2009, By LAURAN NEERGAARD, AP Medical Writer

(AP) -- The government declared Tuesday that silver dental fillings contain too little mercury to harm the millions who've had cavities filled with them - including young children - and that only people allergic to mercury need to avoid them.

It was something of an about-face for the <u>Food and Drug Administration</u>, which last year settled a lawsuit with anti-mercury activists by posting on its Web site a precaution saying questions remained about whether the small amount of mercury vapor the fillings can release were enough to harm the developing brains of fetuses or the very young.

On Tuesday, the FDA said its final scientific review ended that concern. Still, the agency did slightly strengthen how it regulates the fillings, urging dentists to provide their patients with a government-written statement detailing the mercury controversy and what science shows.

"The best available scientific evidence supports the conclusion that patients with dental amalgam fillings are not at risk for mercuryassociated adverse health effects," said Dr. Susan Runner, FDA's dental products director.

Anti-mercury activists accused the agency of bowing to the dental industry and said they'd go back to court to try to force a change.

"FDA broke its contract and broke its word that it would put warnings for children and unborn children," said Charles Brown of Consumers for



Dental Choice. "This contemptuous attitude toward children and the unborn will not go unanswered."

Too much mercury can harm the brain. It has made headlines in recent years as scientists have warned that some types of seafood contain enough to harm a fetus or young child.

Used since the 1800s, amalgam fillings are a mix of a different kind of mercury - a kind the body absorbs differently - with silver, copper and tin to harden it.

Tuesday, the FDA took the regulatory step of formally classifying amalgam fillings as a Class II or "moderate risk" medical device to ensure that dentists handle the mercury properly - using adequate ventilation - but to allow the allergy warning. Until now, the FDA had classified the fillings' ingredients separately.

The practical effect of that technical change? The FDA released its review of 200 scientific studies that found no risk to adults or children over 6 from the fillings.

What about pregnant women or younger children? Tuesday's ruling supersedes the precaution from last year's lawsuit settlement, Runner said.

The FDA found that while there have been only a handful of rigorous studies comparing young children given either amalgam fillings or mercury-free tooth-colored resin composite ones, those studies haven't detected any brain problems. Runner cited additional evidence concluding that babies and young children would be exposed to amounts well below safety limits.

But the statement dentists are urged to share with patients does raise the



issue so that people who are concerned about the mercury can discuss an alternative.

Removing the fillings actually releases more mercury vapor, FDA said. People who think they're allergic to a filling ingredient should discuss that with a dentist.

Amalgams now account for about 30 percent of U.S. fillings, their popularity dropping in favor of tooth-colored alternatives. But they remain the cheapest filling and dentists say there are some conditions that demand amalgams, such as spots on back teeth that won't stay dry long enough for composite fillings to bond.

On the Net:

FDA:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/De ntalProducts/DentalAmalgam/default.htm

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