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FDA issues precautionary note on silver fillings

By LAURAN NEERGAARD, AP Medical Writer

Silver dental fillings contain mercury, and the government for the first time is warning that they may pose a safety concern for pregnant women and young children. The Food and Drug Administration posted the precaution on its Web site earlier this month, to settle a lawsuit — making the move a victory for anti-mercury activists.

The warning is not aimed at the general population, only at two groups already urged to limit mercury from another source — seafood — because too much can harm a developing brain.

The fillings, formally known as dental amalgams, "contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses," reads the FDA Web posting.

That doesn't mean it truly harms, and the FDA advises against removing existing fillings.

The agency still is studying whether the small amount of mercury vapor released by chewing and brushing is enough to cause neurologic disorders or other problems in youngsters. There have been only a handful of rigorous studies comparing children given either amalgam fillings or tooth-colored resin composite fillings that are mercury-free — and those studies haven't detected any brain problems.

Nor has that research settled the long-simmering scientific controversy. Two years ago, the FDA's own independent scientific advisers said that while amalgam fillings were safe for most people, more research was needed about potential effects on fetuses and children under 6.

And this spring, the FDA put dentists on notice that it is considering additional controls, including whether to require warnings that would advise consumers of the mercury in amalgams before they have a cavity filled, or perhaps even restrict use in small children and certain other patients. It is accepting public comments until July 28.

"It's an open question what we will do," FDA Deputy Commissioner Randall Lutter told The Associated Press. But, "what this says is there's a clear intent on our part on labeling for sensitive subpopulations."

Expect a final ruling by July 28, 2009, a date set by that legal settlement.

"It's a watershed moment," said Michael Bender of the Mercury Policy Project, who with other advocacy groups had sued the FDA in hopes of forcing restrictions on amalgams.

"This court settlement signals the death knell for mercury fillings," added Charles Brown, an attorney for Consumers for Dental Choice.

Not so fast, say dentists who point to medically crucial reasons to use amalgams — and worry that people who can't afford more expensive alternatives might avoid dental care.

"We don't want these choices taken away based on junk science. We don't want them taken away based on misguided fears," said Dr. Edmond Hewlett, a dental professor at the University of California, Los Angeles, and an American Dental Association adviser.

Amalgam fillings are about 50 percent mercury, joined with silver, copper and tin. The hardened mixture makes the mercury less absorbable by the body than the kind found in fish, said Hewlett, who chose an amalgam filling for his own 7-year-old son.

Used since the 1800s, amalgams' popularity already is dropping. They account for about 30 percent of U.S. fillings, still millions of people a year.

They're cheaper than alternatives — roughly \$100 for an amalgam filling versus \$150 or more for a composite, Hewlett estimates — and they're known as particularly durable. Hewlett said two conditions that demand amalgams: Spots on back teeth that dentists can't keep dry long enough for a composite filling to bond, and in people who forcefully grind their teeth.

Science operates on "a precautionary principle," said Dr. Karl Kieburtz, a University of Rochester neurologist who co-chaired the 2006 FDA advisory committee and praised the new warning.

"For 99 percent-plus of people, there probably isn't harm. But if there is a group of people who might be at risk, they should at least have the knowledge that may be so," he said.

Several other countries limit amalgams, either as a precaution in pregnant women and small children or because of environmental concern. Dental workers make amalgam fillings by mixing liquid mercury with powdered ingredients, requiring special safety steps and filters to limit waste seeping back into the environment.