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Amalgam ban unlikely, new warnings possible

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By: [Laird Harrison, Senior Editor](#)

It was a Rashômon moment. Like the famous movie in which characters remember the same events differently, the ADA and opponents of dental amalgam have offered conflicting versions of what transpired at the FDA last week.

No one disputes that the FDA settled a lawsuit with groups seeking a total ban on amalgam. But the ADA portrays the change as a bureaucratic reshuffling that might not matter at all to dentists. Amalgam opponents describe it as the beginning of the end for the dental treatment they hate. So who's right?

According to the official word from the FDA, the consequences of the settlement will most likely fall in the middle; the agency is unlikely to withdraw dental amalgam from the market in the foreseeable future, but it might warn dentists against using it in certain groups of patients.

Already the FDA has changed information about dental amalgam on its [Web site](#), singling out "developing children and fetuses" as a group worthy of special attention.

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But contrary to the implication in many newspaper headlines, the new statements on the agency's Web site do not directly warn pregnant moms and their babies away from amalgam. Instead, it says, "Pregnant women and persons who may have a health condition that makes them more sensitive to mercury exposure, including individuals with existing high levels of mercury bioburden, should not avoid seeking dental care, but should discuss options with their health practitioner."

In its most literal interpretation, the statement just means dentists should just go on doing what they already do -- talking to their patients about the choice of restoration material.

Until July 28, 2008, the agency is accepting public comment on possible new regulations. And it has promised to take all these comments into consideration and issue new regulations by July 28, 2009.

A ban is unlikely

But whatever comments the agency receives, new regulations aren't likely to prohibit dentists from using the material altogether, said FDA spokesperson Peper Long. "Banning has a very high evidence bar," she said. "We might perhaps be more likely to have more warnings." Warnings can take various forms, the strongest of which is contraindication -- a statement that a drug or device should not be used in certain patients.

Even then, police officers aren't going to storm your office if you place an amalgam filling. Enforcement would happen in court. "We're going to encourage lawsuits," said Charles G. Brown, chief counsel for Consumers for Dental Choice, one of the amalgam opponents. "If a dentist wants to keep his yacht or his second home, he better stop giving this to people."

Brown sees the FDA's new Web site statements as the beginning of a process that will eventually result in no one using dental amalgam -- the goal his group has been fighting to reach. "I think we got them," he said. "I think this is the death knell."

He hopes the final rules will include a warning against amalgam not just for pregnant and lactating women but for all women of childbearing age. Even if the FDA only issues a warning about pregnant women and, say, children younger than 6, Brown reasons that parents will not want the material placed in their older children either. And if they don't want it placed in their children, they won't want it for themselves.

He also focuses on the phrase "persons who may have a health condition that makes them more sensitive to mercury exposure." Dentists will bear the onus of identifying these individuals, he argued. "If dentists can figure those out, then that's beyond me," he said. So for the sake of avoiding malpractice suits, he predicts, dentists will have to stop using the material altogether.

The actual proposal

The ADA, on the other hand, takes a more literal view of the recent settlement. It "simply sets a definite deadline (July 28, 2009) for the FDA to complete what it began in 2002 -- a reclassification process for dental amalgam," according to an ADA press release.

The ADA makes no mention of changes on the FDA Web site (and the ADA declined requests from *DrBicuspid.com* to comment further.) Instead, the ADA focuses on the next step in the bureaucratic process: The FDA is officially taking comments on its current proposal to take dental amalgam out of class I and put it in class II. That change in designation simply allows the agency to regulate the use of the substance.

In the proposal, drafted in 2002, the FDA doesn't envision any warnings at all. (The words "pregnant," "fetus," and "child" don't appear in the 11,000-word document.) Rather it reviews research on the issue and finds no compelling evidence that anyone is at risk.

If this rule becomes law, the only new regulations would be labeling requirements that would spell out in greater detail what each package of encapsulated amalgam contains, instructions for how to handle it safely, and standards for what each package should contain.

That document was written -- as the ADA notes -- in 2002. So what changes since then have prompted the FDA to consider warnings against amalgam? A casual observer might assume that the mention of "developing children and fetuses" on the FDA Web site resulted from some new important research pointing to risk for young folks.

Oddly enough, the most important research on the topic -- in fact, the only large, randomized, clinically controlled trials of dental amalgam -- added to the evidence on the other side of the scale. Two similar studies, one conducted in New England and the other in Portugal, both found that children with amalgam restorations showed no signs of harm.

Even some opponents of dental amalgam acknowledge that there isn't any evidence to show it hurts children more than anyone else. That includes Boyd Haley, Ph.D., a University of Kentucky chemist who filed an affidavit in the recently settled lawsuit. He would like to see dentists stop using dental amalgam, he told *DrBicuspid.com*. And there is evidence that mercury accumulates more rapidly in children than in adults. But "there haven't been any studies showing a neurological result."

Rather, the concern about children and fetuses comes from observations about other substances. For example, according to James S. Woods, Ph.D., M.P.H., a Washington University heavy metals researcher who participated in the Portugal study, pregnant women who consume too many fish containing methyl mercury (a different type and different dosage from the mercury in amalgam) are more likely to have children with birth defects. And studies on many other toxins show that developing brains are more likely to be damaged than already-developed brains.

This theoretical concern -- rather than new evidence -- may underlie the FDA's new statements about children and fetuses. The agency's Web site cites positions taken by the governments of Canada, France, and Sweden that it describes as having taken the "precautionary principle" towards dental amalgam; these countries see the restoration material as guilty until proven innocent. Since other materials -- such as composite resins -- seem to work pretty well, the thinking goes, why take a chance?

For decades now, the FDA has been unable to decide whether to subscribe to that reasoning or to the argument that whatever damage amalgam may be causing is outweighed by its benefits.

Perhaps the most important result of the new settlement is that the dickering and hesitation is over. Over the next 12 months the agency will have to climb off the fence.

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