Did HHS Cancel Proposed FDA Limits on Mercury Fillings?

Robert Lowes | July 29, 2015

In January 2012, the US Food and Drug Administration (FDA) appeared ready to prohibit the use of mercury-based dental fillings, or dental amalgam, in pregnant women, nursing mothers, children aged less than 6 years, and other groups considered sensitive to the metal's neurotoxic vapors.

The agency also was ready to advise dentists that "alternative materials would best be offered as the first line of restorative care minimizing the use of dental amalgam," according to a draft FDA safety communication dated "January XX, 2012."

The proposed FDA guidance, stemming more from cautious uncertainty than clear evidence on dental amalgam's effects on health, would have represented a sea change in the government's regulation of the controversial filling material.

However, as part of the US Department of Health & Human Services (HHS), the FDA needed a green light from higher-ups to issue this guidance. The green light never came.

"We were unable to obtain clearance from HHS," an FDA official told an attorney in February 2012 in a lawsuit seeking to either ban or limit the use of dental amalgam. "We are still working on securing that clearance. When or even if it will happen I cannot say."

What is known is that, in January 2015, the FDA said it was not necessary to either ban dental amalgam or tell dentists to stop putting it in the mouths of pregnant women and very young children. In doing so, the agency reflected the position of the American Dental Association (ADA), which calls the mercury-based fillings safe.

The proposed — but never adopted — FDA guidance on dental amalgam appears as an exhibit in a lawsuit brought against the FDA and HHS by the International Academy of Oral Medicine and Toxicology and others who advocate mercury-free dentistry. The suit, filed in a federal district court in Washington, DC, seeks to put the FDA's draft guidance into effect.

FDA spokesperson Jeff Ventura declined to confirm whether his agency indeed produced the draft safety communication from 2012 or explain why it was never issued.

"FDA's regulation of dental amalgam is the subject of pending litigation," Ventura told *Medscape Medical News* in an email. "The agency does not comment on pending litigation. FDA will continue to evaluate the safety of dental amalgams and will take any further actions that are warranted."

An HHS spokesperson referred questions about the fate of the draft guidance to the FDA.

Canadian Compromise?

The safety of dental amalgam has been debated for more than 150 years. Although mercury is a known neurotoxin, the ADA says that combining it with other metals such as silver, copper, and tin produces an alloy that is "hard, stable, and safe." Opponents of dental amalgam say that the mercury vapor it continually releases causes severe autism, kidney dysfunction, schizophrenia, Parkinson's disease, amyotrophic lateral sclerosis, depression, and a host of other disorders.

Years ago, dentists would purchase liquid mercury and the other alloy components in powdered form and mix them in their office. Now they purchase these ingredients premixed in capsule form.

A 2010 ADA survey found that 54% of dentists in private practice fill cavities with dental amalgam. At the same time, dentists have increasingly turned to alternative filling materials such as composite resins for both safety and aesthetic reasons, so much so that dental amalgam accounted for only about 30% of new fillings in 2010,

according to the ADA.

Because nonmercury fillings cost more, dental amalgam has been the default choice for many low-income patients.

The decline of amalgam coincides with a worldwide movement to reduce mercury exposure in all forms. The World Health Organization in 2009 recommended reducing, but not necessarily banning, the use of dental amalgam. Three years later the United States signed the international Minamata Convention on Mercury, which similarly calls on signatories to "phase down" the use of these fillings. At the time, the ADA said it was "pleased" that the Minamata Convention imposed no restrictions per se on amalgam, and noted that preventing tooth decay can contribute to a phase-down by reducing the need to use restorative materials.

Sweden, Norway, and Denmark, in contrast, have taken a harder line and banned the use of dental amalgam. Softer regulations exist in Canada. While declaring the material to be generally safe, the Canadian equivalent of HHS recommends nonmercury alternatives for children, pregnant women, individuals allergic to mercury, and those with impaired kidney function.

For a time, the FDA seemed to be inching toward the Canadian position. In 2009, the FDA reclassified the mercury ingredient of dental amalgam from a least-risk Class I device to a moderate-risk Class II. Premixed, encapsulated dental amalgam was newly classified as a Class II device. With that classification came guidance for product labeling that spells out the risks and benefits. This guidance forms the basis of what the FDA says about dental amalgam on its website.

"The weight of credible scientific evidence reviewed by the FDA does not establish an association between dental amalgam and adverse events in the general population," the agency says. "Clinical studies in adults and children ages 6 and above have found no link between dental amalgam fillings and health problems."

The FDA says the clinical data is "very limited" at best, however, when it comes to the long-term outcomes for pregnant women, their developing fetuses, and children aged less than 6 years, including those who are breastfed.

"The developing neurological systems in fetuses and young children may be more susceptible to neurotoxic effects of mercury vapor" emanating from dental amalgam, according to the FDA. However, it stops short of declaring the material unsafe for these groups. Instead, it advises pregnant women and parents who have any worries to talk to their dentist.

"I Implore Your Patience"

Opponents of dental amalgam said that the FDA's 2009 classification didn't go far enough and that these fillings at least deserved the highest-risk Class III designation. They asked the FDA to revisit its decision.

In response, the FDA convened an advisory panel to conduct a hearing on the matter in December 2010. The panel upheld the regulatory status quo, but cracked open the door for future changes. It recommended that the FDA study the possible health risks of dental amalgam for pregnant women, their fetuses, and very young children, and consider adding warnings for these groups to product instructions.

In 2011, proponents of mercury-free dentistry anticipated that the FDA would swing their way. In their federal lawsuit, they stated that Jeffrey Shuren, MD, director of the FDA's Center for Devices and Radiological Health, had given both public and private assurances that the agency would issue new amalgam regulations by the end of 2011.

It would be like Dr Shuren to take amalgam opponents seriously, said Diana Zuckerman, PhD, president of the National Center for Health Research, a think-tank focused on women, children, and families, in an interview with *Medscape Medical News*.

"Jeff Shuren was a breath of fresh air for the FDA," said Dr Zuckerman, noting that he had assumed his post shortly after President Barack Obama took office. "He was much more public-health oriented and much more interested in safety issues. He seemed committed to making changes to make devices safer and provide better

warnings to patents, but the longer he's been there, the less that's happened."

2011 passed without any new FDA regulations on dental amalgam. However, there was that draft safety communication dated "Jan XX, 2012," which satisfied some of the demands of amalgam opponents. The document said that the new guidance was needed to "to avoid potential and unnecessary health risks to the most sensitive subpopulations and because there are alternative dental restorative materials currently available — such as composite resins — that do not contain mercury."

Besides pregnant women, nursing mothers, and children aged less than 6 years, other groups that should not receive dental amalgam were patients with known hypersensitivities or allergies to mercury or other filling components, and individuals with preexisting kidney or neurological disease, according to the draft FDA guidance.

Reiterating the agency's previous position, the FDA document said that the amount of mercury vapor released from dental amalgam poses "minimal risks for…adverse health effects in the general population." The guidance on the use of amalgam in "sensitive subpopulations" arose from "the general lack of clinical data" on mercury vapor exposure for these groups.

What happened to this FDA document is hinted at in an email exchange in February 2012 between attorney James Love, who represents dental amalgam opponents in their federal lawsuit, and his contact at the FDA. Love complained to the FDA official that the new policy promised by Dr Shuren hadn't materialized yet. The official replied that the FDA was still trying to get HHS to sign off on it.

"I implore your patience, Jim, as we are not acting alone in this decision," the FDA official wrote Love.

After that, the government "went dark" about its deliberations on dental amalgam, Love said. "At some point, I learned that HHS doesn't want to change the way amalgam is used." And the proposed FDA guidance from 2012? Government lawyers called it "just a pre-decisional draft," he said.

Amalgam opponents previously had filed three separate petitions with the FDA asking it to ban the material or else designate it a Class III device with restrictions. Contending that the FDA was taking too long to respond to their request, they sued the agency in 2014 to get their answer.

The FDA finally issued official responses to the petitions in January 2015, and stuck to its 2009 position on dental amalgam. In response to one particular petition, the FDA wrote that it "does not believe that the scientific information you have provided supports restricting the use of amalgam in specific subpopulations. Your request for restrictions is therefore denied."

No Reason for a New FDA Policy, Says ADA

Love told *Medscape Medical News* that, had they been approved by HHS, the 2012 amalgam restrictions would have been a "step in the right direction."

The ADA disagrees.

"The [ADA] is not aware of any reason whatsoever to support a change in the FDA's position on dental amalgam," the association said a statement emailed to *Medscape Medical News*. "The FDA undertook an exhaustive review of the evidence and concluded no change in their position, strongly reaffirming that amalgam is a safe and effective dental material. The ADA supports the FDA's guidance."

However, a scientist who served as a temporary, nonvoting member of the 2010 FDA advisory panel on dental amalgam believes that that jury is still out on the safety issue.

"There are gaps in the data that need to be filled in," said Michael Bates, PhD, an adjunct professor of epidemiology at the University of California, Berkeley, in an interview with *Medscape Medical News*. "Even though studies haven't shown overwhelmingly that there's a problem, the amount of [research] required for a medical device is insufficient, considering that it does release small levels of mercury in people's bodies."

As a researcher, Dr Bates used to be on the trail of dental amalgam. He was the lead author of a retrospective cohort study published in the *International Journal of Epidemiology* in 2004 that analyzed the medical histories of members of the New Zealand armed services who had amalgam fillings. The study, he wrote, "generally provides reassurances" on safety. The only less-than-assuring note was "the suggestion of an association between amalgam exposure and multiple sclerosis." Dr Bates recommended follow-up studies on this group, especially to track health outcomes as it ages.

Dr Bates said he asked the National Institutes of Health (NIH) for funding to continue this research, but the NIH didn't consider amalgam an important enough subject. "I was knocked back," he said.

When he studied amalgam safety he tried to stay out of the partisan wars on mercury poisoning, which extend to mercury-containing childhood vaccines, and discredited theories that they cause autism. "I don't take a strong line," he said. "I don't want to be affiliated with one side or the other. I take more of a research view."

Asked to appraise the draft FDA safety communication on amalgam from 2012, Dr Bates characterized it as "moderate and reasonable" and "precautionary." He added that he's become out of touch on the amalgam issue, having moved on to other research topics that could garner funding.

Medscape Medical News attempted to speak with five other members of the FDA advisory committee that deliberated on dental amalgam in 2010. They either did not respond to phone and email requests for an interview, or did not make themselves available for one.

Election Year Politics at Play?

So what happened to the proposed FDA regulations on dental amalgam? In a story published July 21, reporter Greg Gordon in the McClatchy Company news bureau in Washington, DC, quoted an unnamed Obama administration official as saying that HHS killed the FDA's amalgam restrictions because low-income Americans might not be able to afford more costly nonmercury fillings. They might let their teeth rot instead.

Attorney James Love finds that reasoning specious. "It's basically saying this product has such a great [cost] benefit that it's okay to poison people," he said.

Love suspects that more lay behind the HHS decision to shelve the proposed amalgam guidance. "HHS is heavily influenced by the ADA, which is bound and determined to keep using this product," he said. Any admission that dental amalgam is harmful could expose dentists to a flood of mercury-poisoning lawsuits.

Dr Zuckerman of the National Center for Health Research points to another possible reason for the apparent regulatory retreat in 2012. It was a presidential election year, she said. The Obama administration might have feared that restrictions on dental amalgam would set off widespread jitters about mercury poisoning. The less controversy, the better.

"Consumers are easily confused," she said. A product ban for certain population groups can be misunderstood as a ban intended for everybody.

Love said that the proposed restrictions could have sown seeds of doubt.

"The sea change would have started to happen," he said. "If it's not safe for this person, why is it safe for me?"

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Cite this article: Did HHS Cancel Proposed FDA Limits on Mercury Fillings? *Medscape*. Jul 29, 2015.