Regulation of Dental Amalgam:
Historical Overview and Current Outlook

Summary

For two hundred years, mercury dental amalgam has been controversial. In recent years, political pressures have stalled the science-based regulation of amalgam. Federal law directs the FDA to obtain proof of safety before approving medical implants, but the FDA has declined to classify amalgam as an implant, leaving the proof-of-safety issue ambiguous. Industry, in an attempt to dodge the burden of proof, claims there is no proof of harm. Public-interest groups are challenging the legality of amalgam but face an uphill battle because courts defer to agencies to interpret the science. However, enough scientific evidence has accumulated indicting amalgam as a neurotoxic health risk both to developing fetuses and children, as well as to genetically susceptible subpopulations, such that plaintiffs may ultimately prevail in court.

1800s Since gold was prohibitively expensive, mercury amalgam became widely used for dental restorations, making alleged dental health possible for the masses, and expanding the demand for dentistry.

The dental association at the time, the American Society of Dental Surgeons, forbade the use of amalgam, given its toxicity. But since this position would have stifled the burgeoning dental profession, the group disbanded while a new pro-amalgam group formed in 1859, called the American Dental Association.

1882 Eugene S. Talbot, MD, DDS, discovered and wrote about leaky amalgams in the Ohio State Journal of Dental Science.

1900s German chemist Alfred Stock began a campaign to publicize mercury's toxicity, but the issue disappeared as World War II began.

1970s The controversy arose again as new dental materials finally allowed patients to have their amalgams replaced, many reporting improved health. In 1973, Brazilian dentist Olympio Pinto prompted Hal Huggins to launch the U.S. anti-amalgam movement.

1976 Congress directed the FDA to evaluate all medical (and dental) devices and to classify them according to the level of control necessary to ensure safety and efficacy. Amalgam is thus known as a "pre-1976-amendment" device.

Under this law, three device classes are recognized:

- Class I -- (GRAS; Generally Regarded As Safe) -- subject to general controls such as manufacturing, labeling, and reporting;
- Class II -- subject to general and special controls such as performance standards and post-market surveillance;
- Class III -- subject to pre-market approval, requiring scientific proof (as opposed to general acceptance) of safety.

Medical implants are categorically regulated as Class III, yet the status of dental implants has been ambiguous.

1978 FDA's Dental Devices Panel requested that amalgam be exempt from classification as an implant. The Commissioner denied the request, ruling that dental amalgam was an implant, yet failed formally to classify and regulate it as such.

1984 NIDR/ADA Workshop on the Biocompatibility of Dental Materials: Hal Huggins presented his clinical fincdings, to a hostile audience. Michael Ziff, a co-founder of the International Academy of Oral Medicine and Toxicology, presented informally.

1987 In a cursory action, the FDA designated dental mercury as Class I, implicitly ruling it to be a non-implant, generally recognized as safe. Yet the FDA also ruled that mercury in over-the-counter antiseptics (e.g., mercurochrome) is not GRAS (generally recognized as safe).

1991 The FDA Dental Products Panel ruled that dental amalgam is safe, despite objections from some panelists. (Note that these science advisory panels change in name and focus from time to time.)

---------- The Current Rulemaking Proceeding

2002 The FDA announced a proposal to reclassify amalgam into Class II, and to require special controls related to dentists.

2006 The FDA issued a White Paper summarizing about 200 journal articles covering 33 studies and concluding that dental amalgam is safe. Opponents claimed the articles and studies were cherry-picked.

At the same time, an FDA science advisory panel (a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee) rejected the FDA's White Paper position that dental amalgam may be considered safe. (The drugs sub-panel had been added because the dental panel lacked toxicology expertise.) The first vote, 13-7 (with the drugs sub-panel voting 9 - 1), addressed whether the FDA had "objectively and clearly present[ed] the current state of knowledge about the exposure and health effects related to [mercury from] dental amalgam." The second vote, also against the agency, with the same tally as the first vote, addressed whether "given the amount and quantity of the information available for the FDA White Paper, its conclusions were reasonable."

2008 The group Consumers for Dental Choice sued the FDA for its failure to classify amalgam. Federal judge Ellen Huvelle told the FDA that "the probability of harm is enormous," and called the agency's 32-year foot-dragging "government at its worst." The FDA settled the lawsuit, agreeing to post a warning about amalgam on its web site and to issue a final rule on amalgam within a year.

The FDA warning read:

> "Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses. When amalgam fillings are placed in teeth or removed from teeth, they release mercury vapor. Mercury vapor is also released during chewing. FDA's rulemaking...will examine evidence concerning whether release of mercury vapor can cause health problems, including neurological disorders, in children and fetuses."
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> "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."

The final rule, due in 2009, was expected to be consistent with the FDA's new public acknowledgement of the risks of amalgam.

Incidentally, the settlement appeared to have left open the question of preemption -- i.e., whether the FDA regulation preempts stricter state and local laws against amalgam -- which the ADA and the FDA had sought to close in their favor.

2009 The FDA issued a final rule (announced July 28, published August 4) reversing its recent acknowledgement of the risks of amalgam, instead reiterating its safety. This rule placed amalgam into Class II as expected, but required only trivial controls related to labeling for dentists. The FDA also published an addendum confirming the conclusions of its 2006 White Paper and allegedly addressing the issues raised by the 2006 joint panel, but did not seek further scientific review.

The FDA removed the lengthy warning from its web site, replacing it with milder language:

> "Dental amalgam contains elemental mercury. It releases low levels of mercury vapor that can be inhaled. High levels of mercury vapor exposure are associated with adverse effects in the brain and the kidneys."

The FDA's reneging on the concepts within the settlement outraged many. FDA Commissioner Margaret Hamburg was accused of a conflict of interest as a shareholder and former director of an amalgam distribution firm. But she claimed she had recused herself informally, leaving the final decision to deputy Joshua Sharfstein.

Consumer and dental professional groups filed several "petitions for reconsideration" with the FDA, as is a prerequisite to filing a lawsuit in court.

2010 In response to four legal petitions for reconsideration of its amalgam rule, the FDA convened a "Medical Devices Advisory Committee, Dental Products Panel" and held a public hearing December 14 and 15, 2010. Reminiscent of the 2006 hearing, a dozen science experts and dentists testified against amalgam, as did several dozen injured consumers. About a dozen dentists and dental industry representatives testified in favor of amalgam, although their testimony was relatively anecdotal compared to that of the opposition. The questions posed by EPA to its advisory panel were surprisingly limited, perhaps to avoid the embarrassment of 2006, in which the panel discredited the FDA's amalgam rule. The 2010 panel, however, did find the science underlying the FDA's amalgam rule to be outdated.

2011 FDA Deputy Commissioner Jeff Shuren (who replaced Sharfstein) announced his intent to issue a decision on the Petitions for Reconsideration by the end of the year, but this did not happen. According to rumor, the FDA's decision was blocked by the Office of Management and Budget, i.e., the White House, perhaps until after the 2012 election.

2012 Over the past decade, several European countries have phased-out amalgam, and in recent years the United Nations Environmental Programme began negotiating an international treaty to ban the commercial use of mercury.

Consumer groups are once again preparing to sue the FDA, this time for its failure to act on the Petitions for Reconsideration.

Commentary

This current regulatory proceeding, which began in 2002, appears to be dysfunctional. Typically, in a regulatory rulemaking process, a team of senior analysts spends months to years reviewing the voluminous technical material and preparing a "criteria document" that analyzes and presents the issues, arguments, and evidence from all sides. This document is then used by agency management, often with assistance from advisory panels, as the basis for any formal rulemaking.

In the case of dental amalgam, the criteria document is the 2006 White Paper and its 2009 Addendum, which were one-sided and out-of-date even when written, and were clearly discredited by the science advisory panel. The FDA appears to have no senior analysts capable of preparing a legitimate criteria document, nor have they subcontracted this project. The agency appears to be in meltdown, such that inaction is its only option.

Ironically, President Obama has voiced his concerns about mercury as a global environmental pollutant. He has also issued an initiative to improve scientific integrity within government. Yet his agency is simultaneously blocking action on this issue.

Regardless of political stalling, the banning of amalgam is inevitable. It may require a court ruling -- probably an injunction against amalgam use pending FDA verification of safety, which will become moot as consumers finally recognize the risks of amalgam -- but this may be a long process.