



Bill Wolfe D.D.S.

U.S. Health Officials Squelched a FDA Proposal that would have Curbed Dentists' Use of Mercury

By Greg Gordon (www.mcclatchydc.com)

Senior U.S. health officials have squelched a *Food and Drug Administration* proposal that for the first time would have curbed dentists' use of mercury—one of the planet's nastiest toxins because it attacks the central nervous system—in treating Americans' decayed teeth. “The FDA proposal” (<http://media.mcclatchydc.com/static/graphics/20150727-Mercury/FDA-SILVERFILLINGS-WARNING.pdf>), approved by top FDA officials in late 2011 and kept secret since, would have told dentists they should not use mercury fillings in cavities in pregnant women, nursing moms, children under 6 and people with mercury allergies, kidney diseases or neurological problems. It also urged dentists to avoid using fillings that contain mercury compounds in any patient, where possible. The FDA has defended the safety of mercury fillings since the agency's inception in 1930 and especially during an ongoing, 23-year legal battle with consumer groups. Consumer lawyers are pressing the government to ban the compounds, as Denmark, Norway and Sweden have done.

The “safety communication” was drafted in response to citizens' petitions and an FDA advisory panel of outside experts, several of whose members expressed concerns in 2010 that the agency had not gone far enough to protect vulnerable groups. The first public hint that the agency might shift its position came during a town hall meeting in September 2011 in San Francisco, where Jeffrey Shuren, director of the *FDA's Center for Devices and Radiological Health*, heard from several dental patients. They described recovering from severe health problems after having their mercury fillings removed. Shuren told them he expected the agency to issue a new policy by year's end. Instead, sometime later, the *Department of Health and Human Services* quietly killed the FDA's communication. The citizen groups sued in federal court last year to compel the agency to respond to their petitions. Jeff Ventura, a spokesman for both the *Health and Human Services Department* and the FDA stated that the “FDA will continue to evaluate the safety of dental amalgams and will take any further actions that are warranted”. Left unexplained are a myriad of questions, including who made the decision, why was it made and whether any special interest group directly influenced the government to curb its warning.

An *American Dental Association* survey in 2009 indicated 54 percent of U.S. dentists were still using mercury fillings, a durable, easy-to-use remedy for over 160 years. Known as “amalgam”, the dental compound consists of about half mercury blended with metal alloys including silver and are usually presented to patients as “silver fillings”. While the mercury is described as encapsulated, the fillings still release low levels of mercury vapor that patients inhale

on a continual basis—the more fillings, the more vapor. Chewing or vigorous brushing can increase the vapor release. However, the number of dentists abandoning those products has risen steadily over the last 20 years as concerns about the toxin's effects have mounted and alternatives have improved. The fillings are still used in taxpayer-funded Medicaid and Medicare programs for the poor and the elderly, in the military, in prisons, on Indian reservations and by doctors serving price-sensitive patients.

Mercury is often described as insidious. Once in people's lungs, it moves to the bloodstream and can accumulate in the kidneys, liver and brain, where it damages the central nervous system. It has been linked to an array of health problems, including memory loss, nerve damage, autoimmune diseases, vision problems, kidney failure, depression, autism and foggy thinking. Recent research suggests it may contribute to Alzheimer's disease. It also can be lethal. In 2013, the United States was the first of 140 nations to sign a treaty, the *Minamata Convention on Mercury*, calling on governments to halt emissions and disposal of products containing the toxin. The treaty is named for a disaster in the 1950s, when mercury-laden wastewater from a chemical plant contaminated fish in Japan's Minamata Bay and then poisoned people who consumed the fish, claiming over 1,700 lives. 140 nations signed the treaty to phase out mercury but the treaty doesn't impose deadlines.

Since the FDA's proposed communication was rejected, the agency has continued to defend the safety of mercury fillings, except in people with mercury allergies. Art Caplan, director of the *Division of Medical Ethics at New York University Medical School* said he finds the secrecy about the proposed warnings troubling. While it's reasonable to conduct cost-benefits analyses, “the government should share what it knows. It should not be hiding, it should not be yielding to lobbying of any sort.” Instead, the 157,000-member *American Dental Association's*, political action committee donated nearly \$2.5 million to candidates for Congress in the two-year cycle ending Dec. 31, 2014.

340 METRIC TONS OF MERCURY ARE IMPLANTED IN TEETH EVERY YEAR WORLDWIDE, ACCORDING TO A 2013 REPORT OF UNITED NATIONS ENVIRONMENT PROGRAM.

James Turner, who is among consumer lawyers battling the agency, said the “core argument is that the public should be told about the risks.” Consumer lawyers and some scientists believe the toll from the pervasive effects of mercury in dentistry already may be impairing millions of

people who have yet to connect serious health problems to their dental work. James Love, an Oklahoma lawyer who in 2009 filed one of three citizen petitions contending the agency should have acted more forcefully in a rule issued that year covering mercury fillings, took a harsher view. "If you inject cost-benefit analysis into the equation," he said, "then we're going to justify legally poisoning people."

THE FDA CONTINUES TO LEAVE THE DECISION ABOUT DENTAL TREATMENT RIGHT WHERE IT NEEDS TO BE—BETWEEN THE DENTIST AND THE PATIENT.

Maxine Feinberg, president,
American Dental Association

Last January 27, the FDA finally responded to the citizen petitions, hours before a federal judge's deadline to do so. The agency denied the petitions and stuck by the 2009 rule that it classified mercury fillings as a Class II medical device, rather than among the riskiest devices, in Class III, as consumer lawyers wanted. A Class III designation would have forced manufacturers to provide scientific evidence of their products' safety before marketing them. In letters to the petitioners, Associate FDA Commissioner Leslie Kux presented a position decidedly different from the ominous warnings drafted in 2011 by the very same agency. The evidence to date indicates, she wrote, that "exposures to mercury vapor from dental amalgam are not associated with adverse health effects."

Dr. Wolfe's comment: In the early 80's, I purchased an industrial mercury vapor detector and began a study to determine how much mercury vapor was coming out of my patient's "silver" amalgam fillings. I tested hundreds of teeth and discovered that there was no correlation with the size and age of the filling and the amount of mercury vapor registered. In 1986, I wrote a letter to OSHA and notified them of the high mercury vapor readings I was obtaining from amalgam fillings and asked the question.

"Is there any difference between the mercury I am detecting in the mouth (intra-oral) and the mercury outside the mouth (extra-oral), which is pronounced as an environmental poison?" Their answer was:

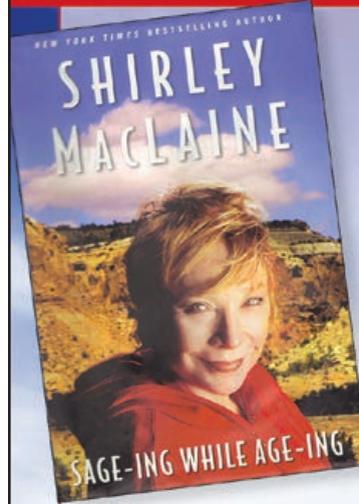
"Although there would be no difference between mercury vapor measured inside the mouth and outside the mouth, the exposure potential of intra-oral mercury would be much greater than that of extra-oral mercury vapor, as mercury is toxic through the routes of absorption and ingestion as well as by inhalation." Gilbert Saulter, Regional Administrator, OSHA. November 26, 1986

Note: This original letter can be viewed on my website at www.drwolfe.com

Never be afraid to raise your voice for honesty and truth and compassion against injustice.... If people all over the world...would do this, it would change the earth.

WILLIAM FAULKNER

SILVER FILLINGS ARE APPROXIMATELY 50% MERCURY!

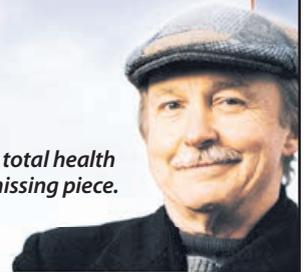


"I was fortunate to meet and be helped by Dr. Bill Wolfe... and I urge you, dear reader, if you are having tooth problems, to go to his website at www.drwolfe.com."

– Shirley MacLaine
Academy Award Winning
Movie Actress

Dentistry is always a piece of the total health puzzle –sometimes a very vital missing piece.

Bill Wolfe, D.D.S.
www.drwolfe.com



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