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Over 2,000 flood FDA with reports of illness from mercury dental fillings, but agency still claims secret pandemic is “rare”

Consumers charge cover-up, press for ban starting with pregnant women and children

WASHINGTON, Nov. 14—Since two expert panels of the U.S. Food and Drug Administration voted Sept. 7 to reject staff conclusions that mercury tooth fillings are safe, the FDA docket has received more than 2,000 filings from members of the public reporting adverse health effects, agency officials confirm.

The reports include many heart-wrenching accounts of dental patients who suffered painful and long-term debilitating illnesses after receiving mercury fillings, many of whom recovered after their fillings were replaced with non-mercury fillings and others who were unable to fully regain their health due to a lifetime of mercury exposure. Most of the reports demand public awareness and government intervention.

And yet, Susan Runner, FDA's Branch Manager of Dental Devices, still maintained in a telephone interview this week with a representative of the non-profit group Consumers for Dental Choice, that health effects from mercury fillings are “rare” and that it's “reasonable” to assume that 5 percent of the U.S. population are affected (15 million people).

However, in another highly publicized case, the FDA two years ago issued a public health advisory for Paxil and Prozac after studies showed that barely 1 percent of patients experience akathisia, the severe agitation that can lead to suicide, which FDA at the time reportedly considered a “frequent” event.

Runner also described the submissions to FDA as “anecdotal,” although many accounts are from dentists themselves, such as Dr. Robert Boe, DDS, who reported to FDA that, “I have seen dramatic improvement in patients diagnosed with multiple sclerosis, Hashimoto's thyroiditis, tachycardia, tinnitus, acne, rheumatoid arthritis, sinusitis, chronic fatigue, systemic candidiasis, and multiple chemical sensitivities, after the amalgam was removed from their teeth and the mercury chelated from their bodies. In my opinion, this could not be a placebo effect because white blood cell counts were also affected.”

One of the strongest statements came from Don Washkewicz, Chairman and CEO of Parker Hannifin Corporation, a Fortune 200 company headquartered in Cleveland, Ohio, who discovered that many of his health ailments were the result of his mercury fillings. After research and regaining his health following the fillings' removal, he wrote FDA, “I felt ethically compelled to help my North American workforce (60,000 employees plus family members).” Finding that most were still getting mercury fillings, he changed the company dental plan to cover 100 percent of the cost of composite (non-mercury) alternatives.

A registered nurse of 23 years charged that, “The ADA, AMA [American Medical Association], and FDA have failed to protect the American people from mercury poisoning...The FDA should require full disclosure of the known dangers of mercury.”

Meanwhile, the agency appears to have ignored 762 similar patient reports of adverse reactions to mercury fillings, which were submitted to its medical devices division in 1993.

This led Consumers for Dental Choice today to charge an ongoing cover-up at least since 1993 – if not for the 160 years that the dental and medical establishments have debated the safety of mercury fillings. “No other pandemic health issue has been intentionally swept under the rug for more than 160 years,” said Freya Koss, a spokeswoman for the group, whose account is one of the more than 2,000 the agency received this fall. “Why does the FDA continue to suppress documentation about the adverse health effects of tooth fillings containing 50 percent mercury, a known neurotoxin? Is it because they find it hard to admit they have been wrong for so long?” (MORE)

In contrast to the thousands of reports now flooding FDA's Dockets Division, the American Dental Association has maintained for years that "there have only been 50-100 reported cases of allergic reactions to amalgam," as it said in a patient brochure entitled "Silver Fillings." Likewise, in the September 2006 public hearings on the topic in Gaithersburg, Md., the FDA's Dr. Richard Canaday perpetuated the agency's longstanding position that there are "exceedingly small numbers of allergic reactions." And Runner said this week that such people are "allergic," although researchers say that term doesn't apply.

Alfred Zamm, M.D., a Kingston, N.Y. practicing allergist and dermatologist who has previously testified before FDA, says the term "allergic reaction" is a misnomer, because "mercury is a biological poison and not an allergen." Zamm says "some individuals are more genetically sensitive and less resistant than others, causing even a small amount of mercury emanating from silver/amalgam fillings to induce a variety of symptoms, some extremely disabling such as fatigue, central nervous and immune system dysfunction, inappropriate coldness, gastrointestinal disturbances, rhinitis, dermatitis, and asthma." This group, he says, "should serve as a marker that warns of the potential dangers of dental mercury to the rest of the population who are also at risk, but may not yet exhibit symptoms."

One or the other of two genetic traits that predispose people to mercury toxicity occurs in as much as 20 percent of the U.S. population, according to Boyd Haley, PhD, a researcher and chemistry professor at the University of Kentucky in Lexington.

David Carpenter, M.D., professor of environmental health and toxicology at the University of Albany's School of Public Health, also disputes the description of these people as "allergic" to mercury. "It is not that one becomes allergic to mercury, but rather that the continuous leaching of mercury from amalgam fillings can alter the immune system and bias it toward hypersensitivity and allergies," he said. "The extreme hypersensitivity reaction is expressed as autoimmune disease, where one becomes allergic to your own body. This is most often expressed as autoimmune kidney disease, but may also be expressed as lupus, multiple sclerosis, rheumatoid arthritis and autoimmune thyroid disease."

Carpenter added, "There has been no scientific evidence that mercury fillings are safe, but there are many studies that indicate that it may be very harmful. Therefore the responsible action of the FDA should be to apply the precautionary principle, which is the principle that in the face of incomplete evidence of danger to human health the appropriate action is to avoid exposure and to stop using mercury amalgams."

The FDA is facing action on several fronts for its failure to address the hazards of mercury fillings:

- Four nonprofit groups and two state officials sued the FDA on April 27, 2006 over its inaction on mercury fillings, in *Moms Against Mercury v. Leavitt*, before the Court of Appeals in Washington, D.C. (see http://www.toxicteeth.org/Petition_FDA_042006.pdf). The case has been accepted on the merits and is proceeding to discovery.
- On June 1, 2006, the plaintiffs filed a motion asking the court itself to ban mercury fillings until FDA complies with the Food Drug and Cosmetic Act and the National Environmental Policy Act (see http://www.toxicteeth.org/FDA_Motion&brief_June2006.pdf).
- Members of Consumers for Dental Choice, the Mercury Policy Project, and the International Academy of Oral Medicine and Toxicology (IAOMT), filed a petition with FDA on Sept. 5, 2006, seeking an immediate ban on the use of mercury tooth fillings in pregnant women to protect the development of their unborn babies. Under the federal Food, Drug & Cosmetic Act, the FDA has six months to respond, or until March 2007.
- Members of two FDA expert scientific panels voted 13 to 7 on Sept. 7, 2006, following two days of public hearings, to reject the agency staff's White Paper, calling it "unreasonable" to consider mercury fillings safe in light of the gap of literature presented, testimony of U.S. and international researchers, and poignant reports of more than 50 people who testified to the panels about illnesses due to their mercury fillings, many of whom recovered following removal of the fillings.
- The IAOMT formally requested after the hearings that the commissioner of FDA reconvene them to hear more testimony, since the staff failed to consider all peer-reviewed studies finding hazards from mercury fillings – including European research, although the FDA since 1990 had promised

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to consider international science on the subject. The IAOMT, which sponsors independent research on the topic, has not received a reply on its request that the panels reconvene.

The so-called "silver" fillings still applied some 70 million times a year in the United States contain about three-quarters of a gram of mercury each, or about as much as an old-fashioned thermometer. A person with 8 fillings has the equivalent of 6 grams of mercury in his or her body, a concentration sufficient to shut down a school chemistry lab or bring a toxic clean-up crew to a lake.

While "white" composite fillings are becoming more prevalent today, largely for aesthetic reasons, there is concern that less-educated, lower-income populations will be subjected to mercury fillings indefinitely unless the government intervenes and traditional dentistry's insistence that mercury is safe is challenged.

"There is clear evidence the mercury vapor is released from amalgam fillings and is ingested, inhaled, and converted to methyl mercury by bacteria in the mouth and gastrointestinal tract," Carpenter said, citing a study in the *Journal of Nutrition and Environmental Medicine* (6:33-36: 1996), "causing chronic low-dose exposure to mercury. The most serious harm is to the developing nervous system, resulting in a reduced IQ, learning disabilities and behavioral problems in children. Adults are also vulnerable."

The World Health Organization and United Nations Global Mercury Assessment Working Group concluded that mercury in fillings is hazardous both to human health and the environment, and that "dental mercury fillings constitute the main mercury exposure risk to humans, exceeding food, air and water sources combined."

Zamm, who was an expert speaker in 1991 at the FDA's previous hearing on the "Potential Toxicity of Dental Amalgam," and was among the 1993 group of commenters, says that today "we have 1826 dental care in the year 2006 because FDA 'grandfathered' dental amalgam without subjecting it to the standard 'double-blind-crossover' testing of safety that all modern medicines have to go through before approval -- the same loophole that allowed tobacco and lead water pipes to come into our daily lives."

Zamm warns: "If you are suffering from an unexplained illness, put mercury fillings on your list of possible causes."

As long ago as 1883, William P. Wesselhoeft, M.D., a prominent Boston physician, presented several case histories of patients who fully recovered after amalgam removal from diseases such as severe gastritis, oral and throat ulcerations, Meniere's disease, tinnitus, hearing loss, vertigo, drooping eyelid (a diagnostic symptom of myasthenia gravis), and skin rash. Every single symptom and disease described by Dr. Wesselhoeft is included in the recent submissions to the FDA, including a dental assistant diagnosed with Meniere's disease who pleaded with the FDA panel to act.

Dr. Alfred Stock, a German chemist, wrote a landmark paper on his ailments from mercury fillings in 1926, saying, "Since the discovery of our misfortune I have found out about a dozen certain cases of insidious mercury poisoning, just in the circle of my acquaintances. They almost always have the same symptoms. Often the correct cause was missed and therefore the correct treatment was missed as well."

Koss herself was misdiagnosed as having lupus, muscular sclerosis and myasthenia gravis, but experienced rapid remission of symptoms when her own mercury fillings were removed, though she still suffers vision problems. She has since tested positive for one of the two genetic traits that predispose people to mercury toxicity.

"In spite of a plethora of credentialed scientific studies proving health and environmental hazards of mercury fillings, and thousands of submissions to the FDA reporting adverse health reactions, the agency continues to claim these commonly used fillings are harmless and related systemic illnesses are rare or non-existent," Koss said. "This latest public response should be a wake-up call to the U.S. government's health agencies and the dental industry, to heed the science and the wishes of the public and stop the use of mercury in teeth, starting with an immediate ban for pregnant women and children."

The FDA docket remains open for now. Public comments may be emailed to fdadockets@oc.fda.gov with the subject, Docket # 2006N-0352 - Mercury fillings.

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