

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MOMS AGAINST MERCURY, CONNECTICUT COALITION)
for ENVIRONMENTAL JUSTICE, OREGONIANS for LIFE,)
CONSUMERS for DENTAL CHOICE, Michael BENDER,)
Karen JOHNSON, Karen PALMER, Corrie CROWE, Anita)
Vazquez TIBAU, R. Andrew LANDERMAN, Linda BROCATO,)
Plaintiffs,)
v.)
Andrew von ESCHENBACH, Commissioner, Food and Drug) Case # 1:07-
Administration; Randall LUTTER, Deputy Commissioner;) cv002332-ESH
Norris ALDERSON, Associate Commissioner; Dan SCHULTZ,)
Director, Center for Devices and Radiological Health)
("The Center"); Chiu LIN, Director, Anesthesiology, General)
Hospital, Infection Control and Dental Devices, The Center;)
Mary Susan RUNNER, Director, Devices Branch, The Center;)
Mike LEAVITT, Secretary, Department of Health and Human)
Services;)
Defendants.

AFFIDAVIT OF BOYD E. HALEY, PhD

FDA AGAIN REFUSES TO ACT TO CLASSIFY AMALGAM

I, Boyd Haley, swear that the following is true and based upon my personal knowledge.

1. I have a Ph.D. from Washington State University and did three years of post-doctoral work at the Yale University Medical School. I am a full professor of Chemistry and Biochemistry at the University of Kentucky and was chairman of the Department of Chemistry for eight years.
2. Throughout my career I have studied the effects of numerous compounds on the changes of the activity of enzymes, proteins and cellular function proteins and the relationship of these changes to disease states. In the past 14 years I have concentrated my research on the effects of mercury toxicity on human health. Specifically, I have researched and evaluated the contributions of dental amalgam, biologics and vaccines on the human body burden of mercury and organic-mercury compounds and the potential effects of these compounds on specific enzymes and cells. I have published approximately 120 papers, and own five patents. Attached, as Exhibit A, are a one-page biography and an abbreviated copy of my Curriculum Vitae. The full CV is approximately twenty five pages and is attached as Exhibit B.
2. My professional research and literature reviews have convinced me that mercury, a virulent neurotoxin, should never be implanted in the mouth or anywhere else in the human body. See my affidavit of April 22, 2008, filed with the Motion for Preliminary Injunction in the above-captioned case, which sets out the scientific basis for this opinion.

3. I am not paid for this statement. I have never charged any mercury-free dentist or any consumer organization for more than travel expenses to serve as an expert witness on the issue of mercury fillings. I have spoken to dozens of scientific, dental, and consumer organizations about mercury fillings, generally for no compensation, although on rare occasions I received an honorarium. I have no financial affiliation with any organization seeking a ban on the use of mercury amalgam.

4. I am an (unpaid) member of the Scientific Advisory Committee of the International Academy of Oral Medicine and Toxicology, www.iaomt.org, a dentist-based organization that shares my views that mercury amalgam should be banned. In that capacity, I have held two meetings in 2007-08 with FDA's top scientist, Associate Commissioner for Science, Norris Alderson.

5. At the first of those meetings, in the summer of 2007, Alderson indicated FDA was ready to move quickly to address toxicity issues regarding mercury amalgam, and would likely order limits on the use of amalgam for vulnerable subpopulations like pregnant women and children. At the second meeting, held March 28, 2008, the entire tone had changed considerably; Alderson repeatedly emphasized that FDA was immobilized on mercury amalgam and unlikely to do anything. That latter meeting was also attended by Professor Vasken Aposhian of the University of Arizona; Professor Louis Chang, formerly a professor at the University of Arkansas and now head of the government of Taiwan's equivalent of the FDA; dentist Richard Fischer of Annandale Virginia; and Dr. Michael Fleming, member of FDA's Dental Products Scientific Advisory Committee --- all requesting Alderson to move forward and classify mercury amalgam in a way to protect the public generally, or at least vulnerable subpopulations (fertile women, pregnant women, children, those with compromised kidney function and those with genetic susceptibilities), from its virulent toxicity.

6. At the March 28, 2008, meeting, the five of us presented Alderson with a substantial body of evidence to support our position that the FDA should place limits on the use of mercury amalgam dental fillings. This included all the items listed on the attached list, marked as Exhibit C (International Academy of Oral Medicine and Toxicology - Submissions to the FDA Panel September 6-7, 2006, Review of the Safety and Effectiveness of Dental Amalgam) and an 11 slide PowerPoint presentation prepared and presented by me, which could not be attached. There was an explanatory cover sheet given to Alderson and the FDA during my oral presentation of the eleven slide PowerPoint(attached as Exhibit D. We explained the scientific evidence supporting our opinion that mercury amalgam dental fillings present an unacceptable health risk to the human body. We also gave Alderson five medical journal articles as further proof of harm from mercury exposure from amalgams. See Exhibits F, G, H, I and J.

7. At that March 28 meeting, when the scientists discussed the toxicity of mercury amalgam, **Alderson replied something to the effect, "You are preaching to the choir."** I understood this comment to mean that Alderson agreed with me and other meeting participants that mercury amalgam dental fillings were an unacceptable source of mercury exposure to the human body and capable of causing health harm.

8. While agreeing with us on the science, Alderson (FDA's top scientist) said the FDA was not going to do anything, repeatedly refusing to say why.

9. Alderson claimed that FDA cannot take actions that might result in the restriction of use of mercury amalgam dental fillings for children, pregnant mothers or women of childbearing age. We were shocked, because it was the opposite of what he had said last year, when he was indicating FDA had intentions to do just that. I asked him why FDA could not restrict amalgam use, and he said he couldn't or wouldn't say why.

10. Alderson said, if the scientists wanted to get FDA to act on mercury fillings, they needed to enlist support from the American Dental Association, or would need to get another law passed. We left the meeting with the firm understanding that the FDA was not going to do anything to change the current status of dental amalgams as an unclassified dental device.

11. Later that day, all of us (but not Alderson) met with several employees of the Dental Devices Branch, the agency in charge of classifying mercury amalgam. I was struck by the youth and inexperience of all but one of the members (the dentist was older) and the total lack of educational background of any of them to evaluate the toxicity of mercury, mercury amalgam, or any other dental material.

13. The evidence against the use of mercury amalgam dental fillings in the human mouth continues to mount every week. I have attached as Exhibit E, a new peer-reviewed article published in the Journal of Exposure Science and Environmental Epidemiology (2008), which analyzed the relationship between maternal dental amalgam fillings and exposure of the developing fetus to mercury. The investigators found a strong positive correlation between maternal and cord blood mercury levels; and, the cord blood mercury levels were significantly associated with the number of maternal amalgam fillings. The investigators concluded that "dental amalgam fillings in girls and women of reproductive age should be used with caution, to avoid increased prenatal mercury exposure."

14. In addition and as stated at the end of paragraph 6 above, we gave the Alderson and the FDA exhibits:

F. Aposhian HV. et al, Urinary mercury after administration of 2,3-dimercaptopropane-1-sulfonic acid: correlation with dental amalgam score, FASEB J., (1992) April;6(7):2472-6.

G. Haley B, Relationship Toxic Effects Mercury to Alzheimer's. Medical Veritas 4 (2007) 1510-1524

H. Hagele TJ, et al, Mercury activates vascular endothelial cell phospholipase D through thiols and oxidative stress, International Journal of Toxicology, (2007) Jan-Feb; 26(1):57-69.

I. Barregard, L, et al, Renal effects of dental amalgam in children: the New England children's amalgam trial, Environmental Health Perspectives (2008) Mar, 116(3):394-9.

J. Rose, et al, The frequency of polymorphisms affecting lead and mercury toxicity among children with autism, Amer J of Biochemistry and Biotechnology, (2008) 4(2): 85-94.

14. I make this Affidavit in support of Plaintiffs' Motion for a Preliminary Injunction in the above-captioned case.

Affiant saith no more.

I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct pursuant to 28 U.S.C. Section 1746. Executed on this May 8, 2008

/S/ _____ (Signature)
Boyd E. Haley, PhD