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SCIENTISTS AND CONSUMER ADVOCATES CHARGE FDA WITH "STACKING THE DECK" IN FAVOR OF KEEPING MERCURY IN TOOTH FILLINGS

FIRST GOVERNMENT HEARINGS IN 13 YEARS ON THIS ISSUE
Sept. 6 and 7

WASHINGTON, D.C. – The federal Food and Drug Administration, under pressure from dental researchers and consumers, will review for the first time in 13 years the health hazards of mercury leaking from amalgam dental fillings. Consumer advocates and scientists, however, say the FDA has manipulated a one-sided hearing, reporting from all appearances that the government has only officially invited and paid for pro-amalgam experts who will defiantly testify that mercury fillings are safe despite recent peer-reviewed studies to the contrary.

Testifying as public witnesses at their own expense, severely limited by the FDA to only 3 to 10 minute presentations, eminent dental researchers who believe that mercury fillings are a health harm will represent the International Academy of Oral Medicine and Toxicology (IAOMT) at the hearings on Thursday and Friday, Sept. 6 and 7 at the Holiday Inn in Gaithersburg, Md. They will be joined by public citizens injured by mercury fillings and members of Consumers for Dental Choice, a non-profit group working to abolish the use of mercury in dentistry. Although equal travel reimbursements for these scientific experts were requested, the FDA has refused to date to offer

customary professional stipends to them. "It appears a stall tactic is underway, since we have had no further word from the FDA Commissioner as to the identities of those invited, and the hearing is now less than a month away," said Freya Koss of Consumers for Dental Choice.

According to Michael E. Adjodha of the FDA's Center for Devices and Radiological Health, all decisions about inviting additional expert witnesses have been made at the level of the Commissioner's office, and according to information given to Consumers for Dental Choice today, Mr. Adjodha is "....not allowed to elaborate on the details", and the draft agenda with list of speakers will not be made public until on or about September 1st, only days before the hearing.

"The knowledgeable public cannot believe that a committee organized by the FDA will ever acknowledge that the FDA has been wrong and neglectful for over 70 years about the dangers of dental mercury," said Dr. Boyd E. Haley, PhD, professor and former chairman of chemistry, University of Kentucky (http://www.chem.uky.edu/research/haley/), one of the experts representing IAOMT.

Charles Brown, general counsel for Consumers for Dental Choice, which has sued the FDA for its inaction, added, "Apparently, it takes a lawsuit to force the government to protect consumers from the hazards of mercury in tooth fillings. The way the FDA is stacking the deck for these hearings demonstrates why. They ought to be ashamed about the secretive and one-sided process they have engineered, on behalf of an industry that is still stuck in the dark ages."

Ethics complaints were filed in April by IAOMT with Harvard University, the University of Maine, the University of Washington, and other sponsors of The Children's Amalgam Trials (CAT), two recent experiments on indigent and orphaned children. The $11 million studies required mercury fillings to be placed in children's teeth to determine if it lowered their IQs, harmed their motor skills and/or damaged their kidneys.

Confirmed by the FDA, it was learned that Timothy DeRuen, a leader of this study will be a key "expert witness" at the hearing. Despite proclamations by DeRuen and other study administrators that mercury fillings pose no risk to human health, Michael Martin, DMD, chair of the Portuguese segment of the trial, alarmingly admitted at the recent Global Mercury Pollution conference in Madison, WI, that a follow-up study is necessary to determine a possible genetic susceptibility to mercury toxicity from amalgam fillings. In addition, Dr. James Woods, PhD, another participating scientist, has said that the study's evaluation of urinary porphyrins, a biomarker for mercury toxicity, was to date inconclusive. Dr. Boyd Haley will also testify as to the inaccuracies of the CAT study. Clearly, the "no risk" conclusion published in the April' 2006**.**Journal of the American Medical Assoc., (JAMA) was scientifically premature.

The full title of the FDA hearings is, "Joint Meeting of the Dental products Panel of the Medical Devices Advisory Committee of the Center or Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research." They will be held starting at 8 a.m. Sept. 6 and 7 in the Walker/Whetstone Room of the Holiday Inn at Two Montgomery Village Ave., Gaithersburg, Md. (a D.C. suburb).

According to the FDA, "This joint committee will discuss peer-reviewed scientific literature on dental amalgam devices. Dental amalgam, also called 'encapsulated amalgam,' consists of dental mercury and amalgam alloys." More information may be seen at http://www.fda.gov/oc/advisory/accalendar/2006/cdrh12518dd09060706.html.

IAOMT critics of the studies said that besides their ethical flaws, the two studies on children to be discussed at the hearings were "designed to fail" because they looked for the wrong health effects in the wrong people for an insufficient length of time. Pregnant women, nursing infants, and adults with a lifetime of exposure are believed to be at greatest risk from the detectable traces of mercury that the fillings steadily emit.

Neither the children studied nor their parents were warned that mercury s suspected in autism, long-term neurological damage, learning is abilities and Alzheimer's disease, or that as much as 25% of people may be predisposed to greater damage because of a genetic inability to excrete mercury from their system. A January 2006 poll by Zogby International found 76% of adults still don't know that the main ingredient in typical dental fillings, often misnamed "silver fillings," is mercury. Each is roughly half mercury and contains as much of the toxic heavy metal as an old-fashioned thermometer. They have been in use since before the Civil War, ranking hem among the most antiquated medical devices from a bygone era.
In the past 30 years, however, U.S. government reports have documented the toxic effects of low-dose chronic exposure to mercury, resulting in he phasing out of this known neurotoxin in every facet of manufacturing, consumer products and medical care – except amalgam dental fillings. According to a 2005 report by the World Health Organization, the predominant source of human exposure to mercury is from these tooth fillings.

Roughly a third of American dentists no longer use mercury fillings at all, and white tooth-colored fillings now predominate. However, the remaining dentists still insert more than 70 million mercury fillings a year, totaling approximately 34 tons of mercury, according to the U. S. Environmental Protection Agency.

Charles Brown of Consumer for Dental Choice said that in all, "1,000 tons of mercury is currently walking around in Americans' mouths – over half of all the mercury still in commerce – and yet most people have no idea it's even there, let alone the health risks. The public deserves better than the FDA's outrageous neglect of its duty."

The International Academy of Oral Medicine and Toxicology is a network of dentists, physicians and medical researchers working together to obtain information concerning the latest interdisciplinary scientific research. The IAOMT regularly funds studies by independent medical and scientific researchers. Its members are adamant that dentistry should be based on peer-reviewed science – not on history and tradition. For more information, please see http://www.iaomt.org/infoDoctors.cfm.

Articles referred to are available upon request to: Freya Koss, Consumers for Dental Choice, e-mail: frekoss@aol.com.

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