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COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

COMMITTEE ON EDUCATION AND LABOR

Opening statement Dennis J. Kucinich, Chairman Domestic Policy Subcommittee Hearing on environmental impacts and response to dental mercury November 14, 2007

Mercury is toxic to the environment. It is a naturally occurring toxin and a man-made pollutant. It bioaccumulates, meaning that ever higher amounts build up in organisms at higher levels of the food chain. Mercury toxicity causes brain and liver damage, even death. The FDA advises women of child-bearing age and children to avoid certain kinds of fish and limit their intake of others, due to levels of methylmercury in those tissues.

Mercury, in the elemental form, is present in the teeth of many Americans. According to the EPA, dentists use 34 tons of mercury per year to create or replace mercury dental fillings in Americans. Dentists are the third largest category of user of mercury in the economy, and existing dental fillings account for more mercury in use at the current time than any other application, including thermometers, batteries, switches, and paints. Over 1000 tons.

Methylmercury, which is the most toxic and mobile form of mercury, is created through the actions of microbes and by combustion of mercury-containing materials. Dental mercury becomes methylmercury when the mercury-containing byproduct of sewage treatment plants, known as "sludge," is incinerated and when it is applied to agricultural land. Methylmercury is created when corpses containing mercury dental-fillings are cremated.

How significant is dental mercury to the emission of mercury into the environment? Assessing that question is one of the purposes of this hearing. According to the U.S. Environmental Protection Agency, it would seem that with all the mercury in use and annually used in dentistry, only a tiny fraction is emitted into the air. But there is reason to believe that EPA's estimates significantly understate the reality.

For instance, EPA estimates airborne mercury attributable to sludge incineration to be 0.6 tons per year annually. However, EPA admits that its mercury emission data for sludge incineration is "poor," a deficiency it attributes to both the small number of facilities tested and the fact that these facilities were not a random sample of the industry. The Northeast States for Coordinated

Air Use Management estimated that mercury emissions in the northeast alone amount to 0.5 ton per year.¹

EPA estimates of total mercury emitted as a byproduct of cremation of human remains to be around 0.3 tons per year. However, EPA's estimate might significantly understate the magnitude of mercury emissions from this source as well. A newly published article, authored by an EPA environmental scientist, estimates mercury emissions from cremation to be ten times more than the EPA estimate, about 3 tons per year, or 10 times EPA's estimate.²

Indeed, today the Mercury Policy Project will testify that total actual mercury emissions could be as much as 5 to 6 times EPA estimates.

Why is this important? It is important because EPA prioritizes its activity based in part on this number. EPA's only dental-specific initiative is its "gray bag" program. This is a voluntary program to encourage dentists to collect mercury amalgam before it enters the wastewater stream. A voluntary, educational outreach program might be justified for a *de minimis* pollution source, but it may not be appropriate for a source as significant as dental mercury.

EPA does not seem to be alone in tolerating the significant understatement of dental mercury's threat to the environment. Mercury dental devices are regulated by the Food and Drug Administration (FDA). FDA, as with all Federal agencies, is legally required to consider the environmental requirements imposed by the National Environmental Policy Act of 1969 (NEPA).³ NEPA requires an Environmental Assessment or Environmental Impact Statement for all governmental actions that have a "significant" effect on the environment.⁴

Dental fillings are subject to regulation under the Medical Device Amendments of 1976 (MDA).⁵ MDA mandated that all devices in use prior to enactment be reviewed and classified pursuant to the Act. FDA did classify the component materials – liquid mercury and amalgam powder -- separately in 1987, and it began the process for classifying dental mercury amalgam by promulgating a proposed rule in 2002. However, FDA did not take steps to finalize the classification rule, and, as of now, the dental mercury amalgam used in dental offices remains an unclassified medical device.

One of the concerns—shared by advocates and FDA—is the appropriateness of FDA's 1987 action classifying liquid mercury as safe for general use. Devices receiving this classification are not subject to much regulation, and other devices so classified include toothbrushes. One of the

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⁴ 42 U.S.C. § 4332. NEPA requires that all agencies of the Federal Government report on the environmental effects of all proposed government actions "significantly affecting the quality of the human environment."

¹ NESCAUM, Inventory of Anthropogenic Emissions of Mercury, (November 2005). (Online at http://www.nescaum.org/documents/inventory-of-anthropogenic-mercury-emissions-in-the-northeast/)

² Alexis Cain et al., "Substance Flow Analysis of Mercury Intentionally Used in Products in the United States,"

³ 42 U.S.C. §§ 4321-4345.

⁵ P.L. 94-295. The Act created a regulatory regime consisting of classifications of devices, where a "I" is considered safe for general use, a "II" is subject to special controls, and a "III" may be subject to evaluation and clinical studies and require approval before they may be introduced in the market.

questions this hearing will consider is whether or not FDA's classification of dental mercury amalgam does in fact require environmental reporting because of possible significant effects on the environment. It has been FDA's position that the classification does not have such an effect and thus no reporting is required. But they may be unique in holding that view, as our witnesses will testify.

Mercury is a danger for the environment, and dentistry seems to be a significant contributor to that environmental threat. Today we will examine the magnitude of the threat and the steps being taken to mitigate the environmental damage.

⁶ In its 2002 draft device classification, FDA proposed that dental mercury amalgam qualified for a Categorical Exclusion (CE), thereby exempting FDA from NEPA's environmental reporting requirements. *See* 21 C.F.R. § 25.34 (outlining CE's for device classifications).