

## United States Senate

WASHINGTON, DC 20510

October 20, 2004

Elias A. Zerhouni, M.D.  
Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Zerhouni:

I am writing because I have serious concerns that the National Institute of Dental and Craniofacial Research (NIDCR) may not be able to perform a disinterested review of mercury amalgam, which is still commonly used in dentistry. A major issue in oral health today is whether mercury-based dental amalgam fillings pose a risk to human health, particularly the unborn and young children.

You are to be congratulated for taking major steps to address conflict of interest problems at the National Institutes of Health (NIH). I ask that you also consider the inherent conflict of interest in NIDCR being the lead institute for investigating the adverse health effects of mercury amalgam fillings. Organized dentistry endorses mercury amalgam. The American Dental Association has given mercury amalgam its Seal of Acceptance. This dynamic does not provide assurance that disinterested scientific analysis will be used to settle serious questions about fetal neurodevelopmental health and the potential risks to young children, in conjunction with dental mercury.

Mercury is a potent neurotoxin that, even at very low doses, can cause brain, lung and kidney damage, especially after exposure *in utero*. In January 2004 the Environmental Protection Agency doubled its estimate of the number of children born annually at risk of neurological problems, to about 630,000, because of unsafe mercury levels in their blood, largely because the mercury concentration in fetal umbilical blood is typically 70% higher than the concentration in the mother's blood. At the same time, several European studies have shown a correlation between the concentration of elemental mercury found in the umbilical cord and the number of mercury fillings the mother has, increasing the level of exposure of the unborn to toxic mercury.

In recent years, the federal government has banned or phased out the use of mercury in paints and certain pesticides, limited its use in cosmetics, established disposal requirements for waste containing mercury, and issued health warnings about mercury in fish. States and local governments are also taking actions to reduce the use of mercury. Most recently, the San Francisco Public Utilities Commission required dentists to obtain wastewater treatment permits for mercury released during patient treatments. Meanwhile, the reported safety of mercury amalgam fillings remains highly controversial.

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Because of the significant potential for widespread, damaging health effects from mercury exposure—including exposure to mercury amalgam—I have serious concerns about the possibility that bias has been shown by the U.S. health institution which has conducted most of this country's research on mercury amalgam. According to the Public Health Service, as of 1997 NIDCR had spent \$33 million on research regarding dental amalgam safety, funding some 500 studies.

Reportedly, many of these studies were neither peer-reviewed nor published. Large grants to study this issue have been awarded to dentists—rather than toxicologists, chemists, or physicians, those trained and qualified to examine the toxicologic health impacts of chronic exposure to very low levels of mercury, especially in the case of those already at risk because of mercury exposure through fish consumption.

Awarding study grants or contracts to dentists, rather than neurologists and toxicologists, appears to have compromised the neutrality that is so paramount in such an investigation. It calls into question the quality and veracity of these studies, and raises the possibility that public funding may have been improperly used.

My concerns are compounded because of a June 2004 House oversight hearing that documented widespread conflicts of interest by scientists at the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). A May 19, 2004, *Washington Post* article on the hearing stated that top legal and ethics officials in the Department of Health and Human Services have repeatedly allowed scientists at NIH and the FDA (which regulates the use of mercury in dental amalgam) to engage in lucrative consulting deals with pharmaceutical and biotechnology companies. In this regard, I was pleased and reassured by your recent announcement of a permanent ban for all senior NIH staff on consulting with pharmaceutical and biotechnology companies, and a one-year moratorium on such activities for all NIH employees.

I am most concerned about the study that NIDCR is currently funding to evaluate the scientific literature on mercury dental amalgam. Serious questions have been raised by several nonprofit consumer groups, regarding aspects of this study, including: whether the contract and subcontract for this study were awarded in compliance with federal contracting regulations; whether the contractor and subcontractor are qualified to perform this study; and whether NIDCR officials acted improperly to limit the scope of the study or otherwise attempt to predetermine its outcome. In addition, because of their close ties to dentistry, valid questions have been raised concerning whether NIDCR officials have an inherent conflict of interest that prevents them from objectively evaluating the health risks of mercury amalgam, in addition to the question of their complete lack of training and expertise in neurology and toxicology.

I therefore request that your office provide answers to the questions about NIDCR and mercury dental amalgam listed in the attachment to this letter.

Question One: Based on your July 30 letter to Consumers for Dental Choice, I understand that NIH is conducting an in-house investigation of NIDCR's contract to perform an independent review of the literature on the adverse health effects of mercury amalgam. Numerous questions have been raised about its prudence,

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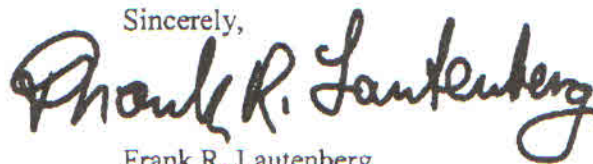
conformity to scientific principles, and even legality. My concern is the actual and perceived independence of NIH employees to investigate the decisions of the top officials at one of your institutes. I am not questioning the integrity of NIH investigators, but believe, with the credibility of NIH at stake (for reasons that pre-date your arrival), only a truly independent investigation can clear the air. Will you ask the Inspector General of HHS to independently investigate the contract on review of the literature on mercury amalgam fillings?

Question Two: NIDCR's contracts generally are given to dentists, who reportedly rarely, if ever, publish their results. This leads to the question of why such grants are given in the first place, and why they are awarded predominantly to dentists. With conflict of interest questions at NIH now paramount, wouldn't it be more appropriate to have the research on mercury amalgam fillings performed outside of a dental-based institute, by qualified scientists with no ties to organized dentistry?

Question Three: Commendably, NIH has developed a campaign to address dental mercury toxicity, entitled "Mad as a Hatter? Join Our Campaign for a Mercury-Free NIH." But NIDCR had taken the opposite position, advising the public not to be concerned about a product which is 50% mercury and which exposes patients to toxic mercury vapor. (See ATSDR's *Toxicologic Profile for Mercury*, March 1999). NIDCR appropriately works on issues of oral health, *not neurological and developmental health*. Toxicologists and those in related scientific disciplines are obviously those best qualified to assess questions about the health risks of mercury amalgam. Please explain, in detail, why NIH has used NIDCR instead of the National Institute of Environmental Health Sciences (NIEHS) to study the health risks of mercury exposure from amalgam dental fillings. Additionally, considering the public's persistent health and safety questions about dental amalgam, please explain why have not already shifted control of this research to NIEHS?

If you have any questions regarding this request, please contact Bob Kenney (224-8581) of my staff or Cindy Bethell (224-3224). I look forward to your prompt response.

Sincerely,



Frank R. Lautenberg  
U.S. Senator

cc: Dr. Alan Price, Director  
DHHS Office of Research Integrity