Consumers for Dental Choice
1725 K St., N.W., Suite 511
Washington, DC 20006
Ph. 202.822-6307; fax 822-6309
www.toxicteeth.org

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Mr. Michael E. Adjodha
Center for Devices and Radiological Health
Food and Drug Administration -- *via e-mail: Michael.Adjodha@fda.hhs.gov*

Re: Requests, Hearings of September 6 and 7

Dear Mr. Adjodha:

In 2002, FDA's Center on Devices promised an independent review of the mercury amalgam literature. Instead, Dr. Mary Susan Runner, conspiring with Lawrence Tabak and Norman Braveman at NIDCR, engineered the handpicked appointment of an unqualified meetings planner (BETAH Associates) as strawperson contractor, and a consultant for Big Tobacco (LSRO) to do a report to mirror a blueprint given them in advance by NIDCR and FDA officials. Drs. Tabak, Braveman, and Runner insisted that no one with research experience be on the panel. Even then, LSRO had to reverse the research question (from evidence of harm to proof of harm) to get the cleansing document this cabal requested. Because this secret procedure so clearly violated the Federal Acquisition Regulation statute, NIH Director Zerhouni appointed a national CPA firm to do an independent investigation – in sharp contrast to FDA, who continues to cite this study as a basis for its pro-amalgam policies while covering up the fact of this investigation.

From the start, we have feared a repeat of the same intrigue to undo the order of April 3. The public record suggests a major institutionalize interest to protect the position you have wrongly staked out: Dr. Dan Schultz, by his abject failure to supervise; Dr. Chu Lin, by his approval of mercury amalgam without proof of safety and without even warnings to children and pregnant women; you, whose e-mail answer to consumer Pam Floener fails to disclose that encapsulated mercury amalgam has never been classified); and Dr. Runner, who disseminates false information denying Health Canada's warnings about pregnant women and children, and gives the ADA and California Dental Association a veto in your sham Consumer Updates on Amalgam. Answering solely to the pro-mercury faction of organized dentistry, the Center's policy is the opposite of the way FDA addresses other mercury products -- hiding the mercury from the American public, and even proposing a rule in 2002 that warns about zinc in order not to warn about the mercury. Rather than being the Gold Standard, FDA's Center on Devices remains, as a Congressional report cited in a Supreme Court opinion notes, "**FDA's Neglected Child**."

I am **now** informed that, for the upcoming public hearings, you granted special status to the creator of the mercury experiment on Portuguese orphans, a move suggesting you are working to bias any scientific inquiry. Timothy DeRouen and his team, who pocketed a multi-million dollar federal contract for an unscientific and unethical experiment on institutionalized Portuguese children, are under federal investigation by

the Office of Human Research Protection. (Have you informed the Panel of this federal investigation of the DeRouen-Martin team?) It is likely that, when the data are sifted through (if DeRouen allows his data to be examined), that this experiment will be as discredited as the LSRO/BETAH deal. But the human cost of DeRouen's personal aggrandizement is much worse: hundreds of Portuguese girls now have unnecessary mercury in their bodies, and some therefore will almost certainly have mercury-damaged babies. DeRouen, knowing that American children can sue after they reach adulthood, cleverly sought out the lowest rung of a semi-developed country – although someone should inform him that these girls/women, too, can go to U.S. courts after turning 18.

DeRouen also has conflicts of interest. (1) His partner in this taxpayer boondoggle is Michael Martin, who sits on the ADA Council of Scientific Affairs. (2) DeRouen went on record at a public hearing, way back in 2002, testifying that mercury fillings are safe, long before analyzing the data, a decision that was criticized even by his handpicked toxicologist, James Wood. Clearly, Martin and DeRouen were sought out by the pro-amalgam dentists inside the federal government because they were already known advocates of mercury fillings. Are you going to ignore this week's FDA pronouncements about conflicts of interest?

Have you assembled the panel we discussed this spring, one focused on mercury-free dentistry? Your proposed 2002 rule, with no evidence, concludes that the benefits of mercury fillings outweigh their risks. The truth is, No benefits exist for mercury fillings. Modern dentists won't use them. They cause mercury toxicity. They cause teeth to crack later – indeed, the fact they cause lifetime employment for dentists is a major reason the ADA endorses their use. So let's put the benefits v. risks of amalgam out for public debate, instead of secretly making unsubstantiated assertions.

You stated in our one conversation that you want staff to make a presentation. We support this, **only if staff will answer questions about its past and current decisions**. Staff needs to answer why they assembled the notorious LSRO/BETAH deal, why they have false information about Sweden and Health Canada in Consumer Updates, why they provide deceptive information about amalgam research to Capitol Hill, why they refuse to give warnings, and why they refuse to classify mercury amalgam as a Class III. If your idea instead is to parade staff at the start to repeat the Center's rhetoric that this mercury being different, then refuse to answer questions about the continuing wrongdoings, it's clear the cover-up is continuing.

Consumers for Dental Choice has six requests.

(1) Remove DeRouen's "guest speaker" status, or give equal status to a rebuttal: With the controversy over this experiment, DeRouen does not merit this privileged status. But if you won't remove it (e.g., if you have already promised this favor to the ADA), then provide equal status (guest speaker) and equal time to Professor Boyd Haley to rebut an experiment in no way justifies the continued use of mercury fillings. If you won't even do that, it's clear where this entire hearing is proceeding. (If you are thinking of bringing in the ADA's favorite scientist, Thomas Clarkson, be forewarned that he is a paid consultant to the #1 manufacturer of mercury fillings, and would violate your rules about undisclosed conflicts.)

(2) Assemble a panel of dentists to discuss the issue of whether mercury fillings have any benefits. Yes, this is quite relevant, because the question for the Panel is weighing advantages vs. risks. Bring in your friends from the ADA as well as mercury-free dentists. In a public forum, no honest dentist will be able to say mercury fillings are needed. The sole advantage these days is dental convenience and dental profits.

(3) Invite qualified independent scientists – those who aren't salivating after NIDCR/FDA million-dollar contracts. Many independent scientists have researched this field. You can invite Professor Vascken Aposhian of the University of Arizona, Professor James Adams of the University of Arizona, Dr. Murray Vimy of the University of Calgary, Professor Fritz Lorscheider (retired, now in South Carolina); or a plethora of scientists from other continents – e.g., Professor Chang of Taiwan or Dr. Maths Berlin of Sweden. These are people that FDA continues to pretend do not exist, doing studies that FDA facilely claims they are not aware of. Previous FOIA requests show that when this information is brought to the attention of Mary Susan Runner, she ignores it. Instead, FDA contracts only with known amalgam advocates, often those with *de minimis* credentials.

(4) Release the memoranda you are giving the panel. Since the Center is deceiving the public, we would be naïve to think you are not likewise trying to deceive the Panel. Show your good faith by releasing, now, the memoranda and correspondence to the two panels. Dr. Lin told me to file a FOIA, knowing that this request can be stonewalled until long after the hearing. For example, FDA's Center of Devices sat on records for three years, until the day before our meeting with Assistant Commissioner Lutter and Assistant Commissioner Brodsky (and even then withheld records, because we have subsequently found responsive documents via other channels).

(5) Allow me to speak. I will need 20 minutes to educate the panel about the misinformation the staff has been providing them and the public for the past two decades, to the fact that FDA is partner to the ADA in withholding from the American public that the fillings are mainly mercury, and that the Center on Devices takes a position on mercury devices at odds with FDA policies that ban even mercury in veterinary products.

(6) Bring Dr. Schultz, Dr. Lin, and Dr. Runner before the panel. Have them explain (a) why they won't classify amalgam, (b) why they won't warn the public about the mercury (instead proposing in 2002 to warn about zinc!), (c) why they won't require proof of safety like FDA does for other mercury products, (d) why they provide fewer protection to children and unborn children from mercury than FDA does for animals, and (e) why they engineered or tolerated the BETAH/LSRO deal instead of an independent literature review.

Sincerely,

Charles G. Brown

cc: Capitol Hill folks, FDA folks (will compile list)