

Consumers for Dental Choice

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Norris Alderson, Ph.D., Associate Commissioner for Science

cc---Meeting attenders of May 10: Mesdames Chernaik, Vinente, Kuntze,
and Warner; and Mr. McConagha

cc---Deputy Commissioner Lutter

Re: Offer meeting with IAOMT's Scientific Advisory Board to correct false
claims disseminated in FDA's name by Schultz, Kahan, and Runner

Dear Associate Commissioner Alderson:

The International Academy of Oral Medicine and Toxicology is a mercury-free dental society and includes scientists and physicians as well as dentists. Unlike the ADA, which focuses on lobbying and lucrative product promotion schemes, IAOMT (www.iaomt.org) focuses on the science.

IAOMT has a Science Advisory Board – scientists (Ph.D.'s not DDS's) who have done actual research showing that mercury amalgam are a genuine health risk. The liaison is local dentist Richard Fischer, in Annandale, VA. Dr. Fischer offers to assemble some of those scientists, in person or via a phone conference, to meet with you and explain the studies. The meeting will be “lawyer-free”; by that I mean our lawyers will not come, although of course Ms. Chernaik and Ms. Vicente are welcome to attend.

The Center for Devices and Radiological Health continues to promote the myth that no studies exist showing the health risks of mercury amalgam. For example, in its latest propaganda, “CDRH Consumer Information: Questions and Answers on Dental Amalgam,” October 31, 2006, CDRH makes the following claim:

Canada and Sweden have environmental policies that favor a reduction of mercury in all products... Both countries, however, state that there is no scientific evidence of a connection between the use of dental amalgam and medical problems. [Emphases added.]

That statement by CDRH is patently false. Furthermore, **Mary Susan Runner and Linda Kahan are provably aware that the statements are false.**

A) Runner knows about the Swedish report which condemns mercury amalgam for health reasons.

An exhaustive 2002 study, under the auspices of Sweden's Ministry of Health and Social Affairs, concluded: “The safety factor thought to exist with respect to mercury exposure from amalgam has been erased”; and “For medical reasons, amalgam should be eliminated in dental care as soon as possible.”, Report of the Dental Material Commission - Care and Consideration, Kv. Spektern, SE-103 33, Stockholm, pp. 41-42 (November 2002) (emphasis added). *Full text, English version:*

www.social.regeringen.se/inenglish/publications/index.htm (Scroll down cover page to “health and medical care,” then open the first item, by Maths Berlin.)

On December 1, 2003, via e-mail, one Michael LeTort, with France’s FDA equivalent, sent Dr. Runner an e-mail stating with “I attach the Swedish report FYI, in case you did not have it.” Runner in turn, on that date three hours later, forwarded it to six persons, including three from FDA (Melvi Stratemeyer, Lireka Joseph, and Lillian Gill) and including one Norman Braveman of NIDCR. Braveman responded via e-mail on that date two hours later:

“Thanks, Susan. Does this have any implication for the FDA consumer fact sheet on amalgam?”

No record exists of Runner replying. What we do know is that Runner never corrected the fact sheet, and, worse, CDRH repeats this false claim in its 2006 fact sheet. Thus,

- For three years, Runner has known about the Swedish report; she received the report, and passed it on.
- Runner is aware that it condemns mercury amalgam for health reasons (unless she ignored her duty by intentionally choosing not to read it).
- An NIH official pointed out to her the incongruity of the Swedish report, suggested she change the fact sheet, and **Runner ignored the request, choosing instead to maintain the false information.**

The evidence is clear: Runner is aware that CDRH is lying to the American people when it claims no studies exist, and she participates in keeping the lie going. This evidence should cause Runner to be removed from her Director position, if not fired outright.

- B) Kahan knows about the Health Canada report which condemns mercury amalgam for health reasons.

On October 9, 2002, two dentists, a lawyer (I), and three consumer advocates met with Director David Feigal (since retired), Deputy Director Linda Kahan, and Dr. Lireka Joseph (since deceased) to discuss the failures of the Center for Devices. A central issue was the false information in the March 2002 Consumer Update. We specifically asked Dr. Feigal to change the Health Canada information, to reflect that country’s position, adopted in 1996, that mercury amalgam should not be used for children under six, pregnant women, and those with kidney problems. See www.mercurypoisoned.com/health_canada.html

Dr. Feigal directed that the changes be made, and the fact sheet was revised on December 31, 2002. Thus

- Kahan witnessed our claim that CDRH was making false claims when it said Heath Canada has no science against mercury amalgam.
- Feigal then (presumably after checking out the facts) pulled the fact sheet and put in a new one, while Kahan was his Deputy.

- When CDRH then issued a new fact sheet in 2006, re-inserting the pre-Feigal false claims that Kahan had learned were false, she either wrote the language, approved the language, or took herself out of the loop to avoid responsibility (the worst of the three options).

This evidence should cause Kahan to be removed from her Deputy Director position, if not fired outright. That the Center would await Feigal's departure, then return to claims it knows are false, speaks volumes too about Schultz's failure to oversee, instead deciding that professional courtesy to dentists supercedes telling the truth to the American people.

Ill-named as a fact sheet, this CDRH work product is replete with false and deceptive claims – the description of the September 6 meeting, per discussion at our meeting; listing mercury last as a component of amalgam in order to mask it; the claim that “there are no scientific studies that show that having dental amalgams is harmful,” etc. The sentence in dispute should read the opposite to how CDRH wrote it, e.g., “both countries state that scientific evidence does exist between the use of dental amalgam and medical problems.”

FDA must pull this consumer update immediately. Furthermore, the Commissioner should pull from Schultz and his cabal the authority to do consumer “fact sheets” on mercury amalgam. Three strikes and you're out; three false consumer updates, 2002-2006, and CDRH is out of the mercury propaganda business.

Keep in mind, please, the fact that mercury amalgam has risks and no benefits means it should be off the market. That a majority of dentists are now mercury-free (see the survey we passed out) shows that mercury fillings are no longer needed in oral health care. It should be embarrassing that, in writing Senator Enzi, the Commissioner's letter could only cite reports from the 1980s [sic] to justify amalgam as a benefit. The improvements in the resin alternative in the past quarter-century make it a substitute for mercury amalgam for any cavity (porcelain and gold are also alternatives) – but you won't learn that from Susan Runner. The Center is falsely claiming that amalgam is still needed; what they are really doing is protecting obsolete dentistry and assembly-line dentistry, a sad commentary in sharp contrast to FDA's real mission to protect children and others from unnecessary exposure to a virulent neuro-toxin.

The Center's reliance on its pre-cooked contracts is misplaced. First, the BETAH/LSRO contract was a corrupt deal, a fact that we believe will be borne out if your lawyers get the 13-page draft report from the independent CPA firm now on the desk of Suzanne Servis, Office of Management Assessment, NIH (we have been blocked from seeing it). Second, the experiment on the Portuguese orphans, a project of two dental school professors at the University of Washington who testified at a public hearing that amalgam is safe before the data were in, was ruled unethical this month by the Office of Human Research Protections; incredibly, they gave neither the adults supervisors nor the children warnings about the health risks before administering the mercury exposures.

We urge you to call Dr. Fischer (phone 703.256-4441), who will promptly arrange for an in-person or telephone meeting with scientists that have actually done the research – scientists who will show you with specifics that the Center is making false claims about the non-existence of studies. It is essential, Associate Commissioner, that you get the truth – research exists showing the real health risks of exposure to mercury from amalgam. Since officials from the Center for Devices and Radiological Health are aware of the truth but choose to lie to the American public, those same officials may well be lying to you as well.

Sincerely,

Charles G. Brown
National Counsel
May 14, 2007

cc---Richard Fischer, DDS, Liaison to Science Advisory Board, International Academy of Oral Medicine and Toxicology