

Consumers for Dental Choice

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January 3, 2006

Office of Inspector General
Department of Health and Human Services
Attn: HOTLINE
330 Independence Ave., SW
Washington, DC 20201

Dear Sir or Madam:

Because you have investigative oversight of FDA and NIH matters, Special Agent Thomas Doyle of FDA's Office of Internal Affairs has suggested we submit this request to you. We think the attached materials warrant a full investigation into FDA and NIH's numerous ethical, civil, and criminal violations in their handling of a scientific review meant to quiet the controversy over dental amalgam.

Included you will find Mr. Doyle's response to our request to investigate, a cover letter, a memorandum containing FDA and NIH's misdoings, and exhibits lettered "A" through "II." If you have any questions or need supplemental information, please contact me immediately.

Sincerely,

Charles G. Brown
National Counsel
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January 17, 2006

Associate Commissioner Randy Lutter, Ph.D., Policy
Acting Associate Commissioner Jason Brodsky, External Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20847 -- *via e-mail and regular mail*

Re: Will Office of Commissioner request I-G to investigate FDA's unseemly role in contract with LSRO/BETAH?

Dear Associate Commissioner Lutter and Associate Commissioner Brodsky,

By now – since we sent both of you the underlying materials via e-mail on November 4^[1] and referenced it in other correspondence -- you should be well-apprised of the unethical and potentially illegal shenanigans by FDA and NIDCR personnel that led to a literature review on mercury amalgam fundamentally at odds with the conclusions of Swedish and German reviews and by independent scientists around the world. You have been apprised, likewise, of the intimate involvement of a cabal from the Center for Devices and Radiological Health (“the Center”) in this contract from start to finish, such as (all in secret) (1) handpicking tobacco consultant LSRO Inc. without regard to FAR rules, (2) quilting contract terms to impede an objective scientific review, and (3) enlisting unqualified BETAH Associates as strawperson contractor. All with no oversight by -- if not outright disinterest from -- the Center's Director and Deputy Director.

In response to the same facts, NIH Director Elias Zerhouni had the integrity to launch an independent investigation, appointing a national CPA firm to conduct it. The response by the leadership of the Center is the opposite: stonewalling any inquiry, even spinning out FDA correspondence to Senators covering up these allegations. **That FDA officials promote the LSRO report as part of the Center's pro-amalgam agenda means the Center is saddling your agency with the stigma of politics triumphing over science and ethics.**

We would be shocked if Acting Commissioner von Eschenbach accepts a lesser ethical standard than what Director Zerhouni demands. But as of this date, such is the case. Thus, even if it would implicate your colleagues occupying key positions at the Center, we feel that the facts already in your possession mandate but one logical next step -- that you expeditiously request the I-G to examine FDA's role in this deal.

^[1] *Viz.*, our letter to FDA Special Agent Doyle accompanied by an 18-page memorandum, both attached, as is our letter to the I-G; supporting documentation available upon request.

Sincerely,

Charles G. Brown, National Counsel

cc--Les Weinstein, Ombudsman, CDRH