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November 2, 2005

Special Agent Thomas Doyle
Office of Internal Affairs
Food and Drug Administration
One Church Street (HF-9), Suite 700
Rockville, MD 20850

Request to investigate FDA's agreement with LSRO Inc. / BETAH Associates, including actions of LSRO, of BETAH, of CDRH's Dental Devices Branch, and of its Director, Dr. Mary Susan Runner

Dear Special Agent Thomas Doyle:

On a scientific study of enormous importance – one requested by CDRH Director Feigal (retired) to determine whether the large quantity of mercury in amalgam dental fillings poses a health risk, to the public in general or only to the most vulnerable populations – FDA officials colluded with the independent dental arm of NIH to

- Handpick LSRO, Inc., a Beltway consultant known for producing results favorable to the grantor;
- Draft, in advance, a blueprint of the desired result that contained scientifically inaccurate claims;
- Contract with a totally unqualified consultant – a meetings planning company, BETAH Associates
- Arrange for BETAH to select handpicked consultant LSRO to do the actual work;
- Undertake the entire process in a surreptitious manner – never posting, never bidding, secretly negotiating, while taking affirmative steps to deny public requests for information -- and that suggests willful violations of FAR;
- Cover up this unscrupulous process to the Congress, the Commissioner of FDA, and the American public,
- Praise the study while NIH Director Zerhouni has been conducting a major independent investigation of it via a national CPA firm.

It is time for FDA to do what NIH realized must be done a year ago: conduct a full investigation to determine if ethical, civil, or criminal violations have occurred.

Dr. David Feigal, then Director of the Center on Devices, promised to a Congressional committee, at a hearing on the public record in 2002, that he would do an independent outside review of the literature. But he then – in good faith, but imprudently – turned decision-making over to Dr. Susan Runner, Director, Dental Devices Branch. Dr. Runner is a leader in the self-proclaimed "Amalgam Vigilance" committee (Exhibit EE), a subterranean pro-amalgam group whose unauthorized actions include (1) blocking release to the public of international studies calling for a ban on amalgam (Exhibit GG), while (2) inserting directly into an FDA Consumer Update – without public input and with no record of advising superiors – the demands of the American and California Dental Association to cover up manufacturer warnings (Exhibit FF).

Although Runner handed to NIDCR the titular lead on this contract, e-mails prove that she and her colleagues at FDA remained fully engaged in the process from start to finish -- from awareness of the secret meetings to handpick LSRO, to drafting the contract with a blueprint of the desired result, to shoehorning in BETAH as strawperson contractor, to facilitating LSRO's retention as subcontractor (Exhibits F, H, J, Q, R, II [eye-eye]).

FDA and NIH have taken completely opposite approaches to this sequence of events -- NIH conducts an independent investigation into alleged FAR violations, while FDA praises the study while concealing the fact that NIH is investigating. That NIH is conducting an investigation is known by the Director of the Center on Devices, Dan Schultz, because he wrote the undersigned in 2004 and promised to cooperate with it.

- Recognizing the potential corruption, in July 2004 NIH Director Elias Zerhouni opened a formal investigation (now designated Case No. 2004-99) of the contract and the actions of the National Institute of Dental and Craniofacial Research (NIDCR), via NIH's Office of Management Assessment. In 2005, amidst growing evidence of wrongdoing and expressions of concern from Capitol Hill, Dr. Zerhouni appointed a preeminent CPA firm to conduct the investigation, to ensure it was at arms' length and had sufficient resources.
- By contrast, FDA's Center on Devices refuses to investigate the contract, even though in 2004 we asked Director Schultz of the Center to do so. Worse, in its communications with Senators Kennedy, Smith, and Murray, and in public presentations, FDA praised the study and withheld the salient fact that it was currently being investigated by NIH -- for procedural violations of the contracting process and deviant methodology -- and also for the behavior of both private contractors and government officials. We believe that (former) Commissioner Crawford and Assistant Commissioner for Legislation Ronan, who signed letters in response to inquiries from members of Congress, were being misled by staff – else they surely would not have withheld the information from the Senators.

Letter to Dr. Crawford: Shortly before his resignation, we wrote Dr. Crawford a letter asking for an investigation; he left before having time to reply. We wish to quote from our letter:

> The ADA and AADR operatives at NIDCR and FDA collaborated to circumvent competitive bidding; presented in advance a blueprint of their desired result – amalgam poses no risks – to a compliant LSRO; blocked participation on the panel of anyone with expertise in researching mercury or amalgam; then shoehorned LSRO in through an existing conference planning contract with BETAH, which promptly "identified" LSRO as subcontractor to do the actual work. The plan included the naming as chief expert Dr. Thomas Clarkson, who was doubling as a consultant to the largest manufacturer of amalgam, and as "External Reviewer" (presumably to advise the panel that he agreed with his own testimony). Clarkson's brazen conflict of interest was not disclosed in the report. Attached is our submission to NIH with sixteen issues to be investigated; the 17th, the Clarkson conflict of interest, was not known (by us) at that time. (LSRO has a history of doing business this way. See attached *Washington Post* article.)
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> Your statement in the letter to Senator Kennedy – that you may rely on the "LSRO report" involving a contract with NIH – raises fundamental questions,

not only about the legal and ethical issues behind the contracting process, but also about FDA's Center for Devices and Radiological Health withholding from you essential information.

First, e-mails and other documentary evidence obtained from NIH show that FDA was involved in the LSRO/BETAH deal from the beginning. CDRH branch director Susan Runner participated in the planning and development of the scheme to contact LSRO secretly, with no competitive bidding or public notice, and to work out false and misleading language in the contract offering. Indeed, since former Center Director David Feigal initiated the call for this review, FDA started out in charge.

Second, the fact that an investigation by NIH is ongoing should certainly have been disclosed to Senator Hatch and Senator Kennedy when you cited the LSRO report, seemingly with approval. The investigation into the legality of the contract was well publicized last year, so we find it difficult to believe that your staff had no knowledge of the conflict of interest implications. Current Center Director Schultz acknowledged the existence of such an investigation in a letter to me, so we are concerned that he may have neglected to keep you properly informed.

Third, you did not disclose (and may not have known) that the contract to conduct scientific research was with BETAH, which has provided logistical support for a number of NIH meetings and conferences. Although qualified to arrange meetings, no doubt, BETAH was **absolutely unqualified to review scientific literature**. Of course, it was not selected to do the work; it was selected because it had an existing NIH contract and could be used as a strawperson to eliminate the inconvenience of competitive bidding. A competitive bidding process could have resulted in a truly independent and scientific study of the literature, which might have reached conclusions similar to the studies conducted by the governments of Sweden, Norway, Germany, and Canada – that there are health risks from exposure to mercury via amalgam.

Unwilling to take that chance, the ADA and AADR operatives at FDA and NIDCR elected to skirt the FAR by concocting contract language that named BETAH as the prime contractor. BETAH then "identified" LSRO as subcontractor to do all the substantive work. The parties obviously knew they were circumventing the law, apparently hoping that using the sham word "conference" in the contract to describe the scientific study would enable them to shoehorn BETAH in as a fig leaf to cover up the scheme.

If you truly wish to supplement your information (in addition to the mandated re-convening of a legally constituted Advisory Panel) on amalgam with an independent report on the scientific literature, you should contract for such a report, via a transparent competitive bidding process – exactly the opposite of what has happened in the NIH/FDA deal with BETAH/LSRO.

(End of excerpts from Crawford letter)

Enclosed is a memorandum prepared specifically for you, the Office of Internal Affairs, with over 30 exhibits appended thereto.

It is time for FDA to stop protecting this contract and promoting its findings without, like NIH, investigating it. The following memorandum provides substantial evidence of wrongdoing.

Sincerely,

Charles G. Brown
National Counsel

Attachments (2)

- 18-page memorandum
- 33 attachments as evidence