

Consumers for Dental Choice

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November 16, 2004

Elias H. Zerhouni, M.D., Director
Suzanne J. Servis, Director, Office of Management Assessment
National Institutes of Health

Case 2004-99: Independence of investigation compromised by NIDCR:
(1) NIDCR tips off status report to target LSRO;
(2) LSRO, in turn, releases summary of report

Dear Director Zerhouni and OMA Director Servis:

The investigation of NIDCR's legally-questionable contract with BETAH and LSRO has been seriously compromised: NIDCR gave target LSRO a status report.

The confidentiality requirements of this investigation were plainly stated by Director Servis, in a letter to me dated October 15, 2004:

All information (including **status of a review** or nature of evidence) is **confidential** and therefore may not be provided to you, the complainant, or **anyone** other than officials with a need to know, subject matter experts, and legal counsel. *[Emphases added.]*

Yet a high-ranking official at NIDCR, Yvonne du Buy, has admitted via an e-mail that the dental institute tipped off LSRO about the status:

From: duBuy, Yvonne (NIH/NIDCR) [mailto:duBuyY@od31.nidr.nih.gov]
Sent: Friday, November 12, 2004 4:42 PM
To: 'FreKoss@aol.com'
Subject: FW: LSRO amalgam review report to be made public

Dear Ms. Koss:

I am out of town so do not have immediate access to all the specific dates. However, as indicated below, we did ask LSRO to delay release of the report to the public until the OMA report was completed. We recently were told by OMA that their report would be completed by November 10. **When queried recently by LSRO as to when the OMA report would be completed, we gave them that date.** You are the one who has brought to our attention that LSRO has posted on their web site their intent to release the report. At this juncture, we have no way to prevent LSRO from releasing the report.

Yvonne du Buy

[Emphases added.]

Thus, **NIDCR violated NIH rules** by releasing confidential information about the investigation of a contract – and not to just anyone. NIDCR, the governmental subject of inquiry, released confidential information to LSRO, the non-governmental subject of the inquiry, a move that almost certainly suggests collusion.

A potentially disastrous consequence immediately resulted from this allegedly illegal act. NIDCR's release of confidential information gave LSRO the green light to break the promise all had agreed to. On November 11 (note: the day after the November 10 date provided by NIDCR), LSRO prematurely published a summary of its report, basically praising mercury fillings and backing up organized dentistry's claims of "safety." Despite the scientific consensus that amalgam exposes the patient to mercury,

the report's summary pretends that even pregnant women have no reason to avoid mercury amalgam and the resultant mercury exposure. NIDCR's close allies, organized dentistry and the amalgam manufacturers, now have a document they can use to promote amalgam. By colluding with LSRO, NIDCR has put its interest in promoting mercury fillings above its duty to protect the integrity of NIH processes.

Director Zerhouni and OMA Director Servis, both NIH and the American public have been victimized by a scissors attack: NIDCR provided classified information to its handpicked subcontractor, then the latter immediately released a report that makes precisely the same claims NIDCR asked for in the blueprint it handed LSRO two years ago. Meanwhile, the emerging science put forward by the governments of Sweden, Norway, and Germany cry out for warnings about the health risks of mercury amalgam – especially for pregnant women and young children.

Case No. 2004-99, we would have to assume, is not closed. Only three weeks ago, we submitted evidence showing 12 violations to be investigated regarding the contract, and four more regarding general wrongdoing at NIDCR. Among the many serious allegations: (1) NIDCR gave a written blueprint of the findings it wanted from LSRO's "independent" study; (2) NIDCR handpicked LSRO rather than doing competitive bidding, then realized it must cover that up in order to secure the company's services; (3) NIDCR found an unqualified strawperson to be the contractor; (4) NIDCR created a façade of legality to qualify the strawperson by falsely terming the study a "conference"; (5) not a single panelist had ever researched amalgam fillings, and at least one picked by LSRO is publicly dismissive of the importance of mercury toxicity in children [!]; and (6) NIDCR Director Tabak provided false or deceptive testimony to Congressman Burton and Congresswoman Watson to cover up this deal. The chief investigator, Maritza Carpenter, acknowledged receipt of the documents in an e-mail only 11 days ago, so one could hardly think she has checked out all these issues.¹

¹ 16 issues for Case No. 2004-99: Issue #1: Did NIDCR officials Lawrence Tabak, Norman Braveman, and Marion Blevins attempt to circumvent the competitive bidding laws? Issue #2: Did Tabak, Braveman, and Blevins generally engage in activities designed to cover up their violations by creating a façade of legality? Issue #3: Did Tabak, Braveman, and FDA's Runner put together an "outcome biased" study? Issue #4: Did Director Tabak provide false or deceptive testimony to Congress about the LSRO/BETAH deal? Issue #5: Did NIDCR take over what was really an FDA project? Issue #6: Did Braveman – along with Runner, "subcontractor" LSRO, and "contractor" BETAH – shut interested citizens and consumer groups out of the process, despite assurances to the contrary? Issue #7: Did BETAH willingly accept its role as the strawperson contractor, in light of its lack of expertise to do scientific studies, or was it pressured into going along with the scheme out of fear of losing other NIH business? Issue #8: Did the participants misrepresent the contract as a "conference" instead of a "study"? Issue #9: Did LSRO secretly negotiate a contract, even though it was neither an existing contractor, nor a sole source supplier, nor the winner of a competitive bid? Issue #10: Did LSRO conduct an "independent" scientific inquiry? Issue #11: Were the violations at the low level or did they involve higher-ups? Issue #12: Were the violations inadvertent or intentional? Issue 13: Is NIDCR engaged in a pattern of paying dentists to conduct sham studies on amalgam that rarely, if ever, get completed or published? How many millions of dollars have been wasted in the process? Issue 14: Is NIDCR contracting with dentists and failing to provide proper disclosure of risks in its mercury experiments in other studies, e.g., on Portuguese orphans and low-income American children? Issue #15: Is having NIDCR contract with dentists to do "independent" studies of amalgam an inherent conflict of interest, as critics such as Senator Lautenberg maintain? Or does it create, at a minimum, the appearance of a conflict of interest? Issue #16: Is having dentists – instead of toxicologists – in charge of NIH studies to determine the toxicological effects of mercury on the neurological system and body organs an imprudent misuse of taxpayer-funded research?

We believe three immediate steps are needed:

1) Request that the Inspector General investigate the NIDCR/LSRO/BETAH deal Senator Lautenberg made precisely this request to Director Zerhouni on October 20:

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, 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? (*Emphases added.*) *Letter attached.*

2) Investigate NIDCR for violating the confidentiality of the investigation by tipping off LSRO. Once again, NIDCR shows that, on the issue of mercury amalgam, it is willing to circumvent government regulations and NIH policy to protect organized dentistry – and stop the real science from emerging. The House Commerce Committee is rightly investigating conflicts of interest at NIH – and, as Senator Lautenberg notes, NIDCR doing the research on amalgam (because of organized dentistry's endorsement of mercury fillings) is an “inherent conflict of interest.” Amalgam research does not belong with dentists, but with toxicologists; it does not belong at NIDCR, but at a different Institute (the Senator recommends NIEHS).

3) Stop the report from being published. If this is not feasible, an alternative approach would be equally effective: Insist that governmental contractor LSRO state, in any release of the report or any summary thereof: (1) this report is not endorsed by NIH, and (2) the contract that led to this report is under investigation by the United States Government. Release of this report could have disastrous consequences for young women and parents who unknowingly expose their fetuses or children to mercury. Bad faith by government officials continues to allow dental economics, not public health, to govern federal policy on mercury fillings. In light of the release of the summary, we must now repeat the warning given to the United States Attorney's Office on August 5:

I further wish to put your clients [NIH and FDA officials] on notice that they should inform LSRO/Betah not to publish this report during the pendent investigation. Should the latter publish a report that misrepresents the overwhelming peer-reviewed literature showing the health risks of mercury amalgam fillings, and should wrongdoing by government officials then be found, it will be an indication of intentional disregard of public health and violation of the public trust. At that point, we will [i.e. would] do all we can to assist parents and pregnant women whose children or fetuses are harmed by mercury exposure to seek a remedy against those government officials and government agencies.

Sincerely,

Charles G. Brown, Counsel