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November 10, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition to FDA

Re: Withdraw Draft Regulation on Mercury Amalgam; To Proceed Is Contrary to Law, Science, and Public Policy – and Would Create a Gross Appearance of Impropriety.

To attention of Associate Commissioner for Policy and Planning

The undersigned submits on behalf of Consumers For Dental Choice, Inc. (Consumers), Charles G. Brown, Esq. General Counsel. This citizen petition calls for FDA to set aside its 2002 draft regulation on mercury amalgam and start over, this time (a) after an honest independent study is made by scientists with experience researching mercury toxicity; (b) after an Advisory Panel that is not packed with dentists, and one that has expertise on scientific developments on mercury toxicity since 1993, meets and makes a recommendation; (c) a transparent process is initiated involving all interested parties, one not dominated by the American Dental Association and its pro-mercury allies, and that includes public hearings; (d) the issue is staffed by the Division of General, Restorative and Neurological Devices -- not by the Dental Devices Branch, who by its dissemination of false and misleading information, its helping to engineer the notorious contract with LSRO and BETAH, its ex parte relationship with the American Dental Association, and its inherent conflict of interest, should be removed.[1]

For the following twelve reasons, the draft regulation absolving mercury-based dental fillings of adverse health risks must be withdrawn:

(1) The draft regulation, whose named author is a dentist, trivializes mercury's virulent toxic effects into a concern about "allergies" – abandoning the science to opt for the rhetoric of the American Dental Association, the nation's only health trade group which endorses placing mercury into children's bodies. Indeed, the proposal makes the pseudo-scientific claim that the "most notable" reason to protect amalgam is its 100-plus years of longevity – not only a disgraceful claim for an agency focused on science, but the very argument used by the cigarette industry to stave off warnings for a half century.

[1] See related petition, filed November 9 by Consumers for Dental Choice: "Transfer Regulatory Responsibility from Dental Devices to General, Restorative, & Neurological Devices; transfer Classification Responsibility from Dental Products to Clinical Toxicology Devices Panel (to attention of CDRH Ombudsman)"

2005P-0465

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(2) The draft regulation pits Dental Devices at odds with the pronounced policies against mercury-containing products by the CDC, CPSC, and EPA, as well as the entire remainder of FDA. Except for these FDA dentists who base their position on the longevity of a product, FDA consistently acts to protect the public from mercury exposure -- bans mercury disinfectants, gives fish warnings, and even protects animals by ordering mercury out of horse medicines.

- Proof that the dentists who proposed this regulation are out of touch with the remainder of FDA and all current science about exposure to mercury is contained is the draft's astounding conclusion: "FDA does not believe there are **any** major risks associated with mercury toxicity when these products are used as directed (emphasis added)."

(3) FDA's announced decision (letter from Commissioner Crawford to Senator Kennedy) to rely on the discredited LSRO/BETAH report in deciding whether to adopt this regulation creates a fundamental appearance of impropriety. The report is under investigation by NIH for contract violations, ethical lapses, and methodology irregularities.

(4) A new Advisory Panel is legally required. Prior to classifying, FDA must seek advice from an Advisory Panel. The Advisory Panel examining this issue met in the early 1990s, so long that it did not have access to the emerging science on mercury toxicity. The science of 1993 is not valid in 2005 – as FDA, CDC, NIH, and EPA have engaged in a plethora of actions since then to protect the public from mercury exposure. Consumers for Dental Choice filed a separate petition stating why the panel must be one with expertise in toxicology – meaning, obviously not the Dental Products Panel.

(5) The draft regulation shows disinterest in the impact of mercury toxicity on fetuses. It is cavalierly dismissive of Americans with an overload of mercury – even though EPA and CDC say that one American woman in six of childbearing age – about ten million women – have so much mercury they are at risk of having a brain-damaged child. The regulation acknowledges that amalgam creates a "spike" of mercury in the body, a potential horror for the fetus. Thus one in six young women – a number so high it should mean all women – must not have any, any, additional mercury. Mercury fillings should be contraindicated for young women.

(6) The draft regulation abandons the FDA role of the US being the gold standard. Many nations – e.g., Sweden, Norway, the U.K., Canada, Germany – are phasing out mercury fillings for health reasons (e.g., Germany, Norway, Sweden), or giving contraindications for pregnant women (U.K., Canada, Australia, New Zealand) and children (Canada) and people with kidney problems (Canada). The draft regulation falsely claims the reason is the environment; though true a decade ago, this is now a false claim. Here is yet another example of the drafters accepting the rhetoric of the ADA instead of doing their own research.

(7) Dentist control of the process is an "inherent conflict of interest" and puts in charge those not qualified to determine if mercury vapor is a risk to the fetus, the brain, and the kidney. Senator Lautenberg is one who has voiced this very concern. But it's common sense: plainly dentists lack the expertise that

toxicologists and physicians have (it is no excuse to say they are in the agency, if dentists are in charge), and equally plainly the ADA product endorsement scheme puts dentists into an inherent conflict of interest.

(8) The biased, exclusionary, and extralegal conduct of Dental Devices Branch disqualifies this section from continuing any role in rule making. Branch personnel participate in a self-described "Amalgam Vigilance committee," a name suggesting unauthorized conduct and borne out by decisions to make policy with other dentist-run sub-agencies (e.g., NIDCR) rather than through the chain of command. Its chief intervened on behalf of with the American and California Dental Associations to delete anti-amalgam information from the FDA Consumer Update, and helped engineer the LSRO deal, currently under investigation by NIH but which the Center on Devices and Radiological Health refuses to investigate.

(9) Misstatements of fact prevalent throughout the rule, such as (a) claiming that failure to classify amalgam was "inadvertent error," a point retracted by Dr Feigal, under oath, before Congress, but which remains in the regulation; (b) adjusting without explanation the daily exposure levels of mercury from amalgam; and (c) claiming that the international consensus supports mercury fillings without limitations.

(10) Acting contrary to FDA policy, which is to advise the public of risks, not to hide them. After stating that the benefits of amalgam outweigh the risks from mercury exposure, the draft rule declines to order that the public be told the risks of mercury vapor. Thus, virtually no one will be warned that amalgam is a major exposure to mercury, a cover-up that benefits the ADA but harms the public.

(11) Dental mercury has a significant effect on the environment – dentists are the third largest purchasers of mercury; dental offices are the largest contributor of mercury to the wastewater; mercury amalgam is the largest source of mercury from households (via feces); mercury amalgam is the largest source of mercury during cremation; etc. More mercury is in our mouths than in all other products combined – so as a matter of law an environmental impact statement is required.

(12) Interest in banning mercury fillings, in Congress and in state legislatures, requires deference, instead of FDA trying to go in the opposite direction. The timing of the proposal regulation was curious – after a barrage of federal and state bills to ban amalgam and/or mandate disclosure of risks, Dental Devices stepped in with a proposal to block warnings and legitimize this mercury product for all dentists. It shows how out of touch FDA is with not only the science but with a growing movement to rid the health care system of all mercury-based products.

A. Action Requested

The undersigned submits this petition under 21 USC § 360c, and 21 CFR §§ 14.40, 14.86, 860.84, and 10.30.

(1) Withdraw the proposed regulation on mercury amalgam for reasons of science, law, public policy, and appearance of impropriety.

(2) Begin action anew -- without the Dental Devices Branch involved -- via a new independent study, reference to the Clinical Toxicology Devices Panel, a transparent procedure, and a focused concern about populations vulnerable to mercury toxicity: fetuses, children, women of childbearing age, and adults with kidney problems.

(3) Pursuant to 21 CFR §10.30(h)(1) & (2), a meeting and public hearing at which time Consumers for Dental Choice may present our general and scientific evidence.

B. Statement of Grounds

1. Trivializing mercury's virulently toxic effects by a focus on "allergies," and justifying mercury fillings because of longevity of use.

While other professions seek innovation, organized dentistry seeks to preserve pre-Civil War system. Mercury was common in medicine too in the nineteenth century, but physicians chose to focus on innovation instead of preserving the status quo. Not so the American Dental Association -- founded as a mercury-using body and to this day maintains a pay-to-play endorsement contracts with manufacturers (the kind of program condemned as unethical by the American Medical Association).

Mercury is a bioaccumulative neurotoxin. FDA agrees. The problem is not whether someone gets a skin rash the next day – the problem is permanent damage to the neurological system of a child or fetus, or other organ damage to a child or adult. For a woman of child-bearing age, the mercury stays in her body, and can thereby injure her baby. That the risk of mercury is its toxicity to the nervous system, the fetus,[2] and body organs, not an immediate allergic reaction, is known to every federal regulatory agency and every part of FDA – except apparently the Dental Devices Branch.

- Whether the draft regulation's focus on "allergy" is engineered as a cover-up to promote the ADA's agenda or is an act of profound ignorance, doesn't matter. **The draft rule fails to protect from mercury exposure the children and the future children of this nation.**

2. Contrary to the pronounced policies against mercury products by the CDC, CPSC, EPA, and FDA itself.

- FDA bans mercury disinfectants; it gives mercury warnings for pregnant women and children regarding fish consumption; it withdrew mercury from childhood vaccines under the Precautionary Principle – and it even protects animals by ordering mercury out of horse medicines. But not the Dental Devices Branch, which places FDA in the morally untenable position of saying horses merit more protection from exposure to mercury than children.

[2] The fetus is significantly more highly concentrated with mercury than the mother's blood – a development of enormous significance discovered after this draft rule was proposed.

- The ban on mercury in horse medicine is instructive. In 2002 FDA instituted a national recall solely because the horse medicine, Miracle Leg Paint, contained mercury. FDA proudly proclaimed, "There are no approved veterinary drug products that contain mercury as an active ingredient." www.fda.gov/oc/po/firmrecalls/equine05_02.html

- FDA banned mercury compounds in human drug products – notice in Federal Register, Vol. 63, No. 77, April 22, 1998. Quoting from an FDA announcement in 2002: "All mercury-containing products were subject to removal from the market place in order to reduce human exposure and safeguard the public health regardless of the source of mercury in pharmaceuticals or medical devices." http://www.fda.gov/cvm/July_August.htm#2241

- The U.S. Centers for Disease Control and Prevention says amalgam is "a major source of mercury exposure to the general population." Centers for Disease Control, *Third National Report on Human Exposure to Environmental Chemicals 2005*, http://www.cdc.gov/exposurereport/, at pp. 45-48. But not the Dental Devices Branch of FDA, which (quoting from the draft rule) "does not believe there are **any** major risks associated with mercury toxicity when these products are used as directed."

- The U.S. Environmental Protection Agency says one woman in six of child-bearing age has so much mercury in her body she should have no further exposure. But not the dentist-run Dental Devices Branch of FDA, which contrary to the evidence claims it is but "a small subpopulation that already have [sic] high body burdens of mercury." Does Dental Devices believe one younger woman in six is "a small subpopulation" that can be shrugged off in order to protect the ongoing marketing of mercury fillings? It's about 10,000,000 people.

- The U.S. National Institutes of Health decides that the contract irregularities in the deal with LSRO and BETAH merit a formal investigation (NIH Case No. 2004-99) by an independent CPA firm. But not the Center for Devices and Radiological Health of FDA, which engineers agency letters praising the study and covering up – from United States Senators Kennedy, Hatch, Smith, and Murray – the very existence of the investigation.

- The U.S. Consumer Product Safety Commission orders toys containing mercury off the market, lest children get exposed to them. But not the dentist-run Dental Devices Branch of FDA, which decides that the most intimate of mercury exposures – an implant inches from the brain – is fully acceptable in low income, minority, and handicapped children of this nation.

3. Reliance on LSRO/BETAH report (a) creates fundamental appearance of impropriety, and (b) fails to meet the threshold valid scientific evidence.

Former Commissioner Crawford wrote Senator Kennedy that FDA intended to rely primarily on the LSRO report in its decision to proceed with this rule. To proceed under Dr. Crawford's plan is legal error, ethical error, and scientific error. This report,

currently under investigation by NIH for contract irregularities and methodology improprieties, involved (a) FDA and NIH's dental arm secretly handpicking LSRO Inc., a consultant with a track record of picking biased panels and returning the result desired by the funder, (b) laying out a blueprint of the desired result, (c) appointing unqualified meetings planner BETAH Associates to be strawperson "contractor," (d) shoehorning in LSRO as "subcontractor," (e) mandating a panel devoid of persons experienced in researching mercury toxicity, and (f) tolerating LSRO's legerdemain of switching the research question so it could change the answer.

It was all a clever, but perhaps unsuccessful, attempt by Dr. Runner, et al., to circumvent FAR rules and regulations. Whether illegal or technically legal (a question currently being addressed by the pending NIH investigation, Case No. 2004-99), it is ethically, scientifically, and morally far below FDA standards. Now, if FDA refuses to renounce the study and start over, it is acting in absence of valid scientific evidence.

See attached: Our letter (4 page) and memorandum (17 pages), accompanied by 33 Exhibits, to FDA's Office of Internal Affairs, seeking an investigation of extensive wrongdoing by Dental Devices Branch and its Director, Mary Susan Runner. Rather than summarize the evidence, we hereby incorporate the attached letter, memorandum and exhibits into this petition by reference.

The anomaly, one that should cause the Commissioner's office to demand why CDRH is withholding information, is that NIH is conducting an investigation of this deal for contract violations, ethical lapses, and methodology irregularities, while FDA not only won't investigate, but has praised the study.

4. A new Advisory Panel is legally required.

The Advisory Panel examining this issue met in a different scientific era -- over a decade ago. Mercurochrome was legal. No fish warnings existed. Mercury thermometers were still used in hospitals. Mercury present in paints, in batteries, and in cars was not being addressed. In short, the movement against mercury in products had not begun in 1993.

Today, in scientific and medical circles, widespread opposition exists to mercury in any product. An entire national organization, Health Care Without Harm, has mercury elimination as its chief goal; this group did not exist in 1993. The science of 1993 is not valid in 2005 – as FDA, CDC, NIH, and EPA have engaged in a plethora of actions since then to protect the public from mercury exposure.

An entire movement has grown up opposing mercury dental fillings – the Advisory Panel did not hear from this movement. Indeed, the panel should, to the "maximum extent practicable," provide a forum for interested parties. [3] Three national dental societies oppose mercury inalterably – the International Academy of Oral Medicine & Toxicology, the International Academy of Biological Dentistry & Medicine, and the Holistic Dental Association; see, e.g., www.iaomt.org. Considering the deepening understanding of mercury toxicity, the panel, and specifically, its consumer

[3] 21 CFR §860.84(c)(5)

representative, would do well by "seek[ing] out relevant information and [the] views" [4] of the above dental societies, as well as consumer organizations. The Food, Drug, and Cosmetic Act states in no uncertain terms that classification panels "shall encourage free and open participation by all interested persons." [5]

It is not scientifically acceptable, and it is not legal either, for FDA to rely on an Advisory Panel that had none of the past decade of regulatory and scientific developments on mercury in front of it.

Separately (see footnote 1), we filed a petition that the panel be one with expertise in toxicology, such as the Clinical Toxicology Devices Panel, and that it may not again be the Dental Products Panel. The latter has a majority ADA dentist members, persons with a conflict of interest, and persons "who are [not] qualified by training and experience" [6] to determine the impact of mercury vapors on the brain and the fetus. The health issue of mercury fillings is not one of whether they fit in the mouth – it is whether their mercury vapors harm the brain or the body. As such, the classification of encapsulated mercury and amalgam alloy should be left to toxicologists, neurologists, and other members with "adequately diversified experience." [7] A panel of dentists, dental educators, social scientists, and corporate attorneys are not well situated to consider the bioaccumulative effects of mercury vapor from dental amalgam.

5. Cavalierly dismissive of impact of mercury toxicity on fetuses.

CDC says mercury amalgam is a major source of mercury, while Health Canada says mercury amalgam is the major source of mercury for most people. The most at risk, says EPA: fetuses. One American woman in six of childbearing age – about ten million women – have so much mercury they are at risk of having a brain-damaged child. The regulation even acknowledges that amalgam creates a "spike" of mercury in the body -- a potential horror for the baby in the womb.

Logically, based on the Precautionary Principle (instead of FDA's self-proclaimed Amalgam Vigilance committee's agenda of protecting organized dentistry), one in six young women – a number so high it should mean all women – must not be exposed to **any** additional mercury. **Mercury fillings should be contraindicated for young women.**

6. Takes FDA off the gold standard.

FDA is the gold standard for the world. But not for mercury amalgam. It lags behind at least a dozen nations by failing even to give warnings of mercury exposure or to protect children and fetuses from this unnecessary use of mercury. Sweden, Norway, and Germany, among others, are phasing out mercury fillings for health reasons. The United Kingdom has contraindication for pregnant women. Canada does too, and extends this warning to children and people with kidney problems.

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[4] 21 CFR §14.86(c)(3)
[5] 21 USCA §360(c)
[6] 21 USCA §360c
[7] *Id.*

The draft regulation falsely claims the sole reason for these phase-outs and warnings is the environment.

Mercury fillings are now absolutely unnecessary. One-third of dentists never use mercury fillings, in any patient. Mercury amalgam is merely a convenience for the dentists -- the domain for the factory-line dentist, the lazy dentist, and the dentist unwilling to learn. Their protector: the American Dental Association, which has two (now expired) patents on mercury amalgam and pay-to-play contracts with amalgam manufacturers.

7. Dentist control: "Inherent conflict of interest"; lets unqualified persons determine if mercury vapor is risk to the fetus, the brain, and the kidney.

Senator Lautenberg is one who has voiced this very concern. But it's common sense: plainly dentists lack the expertise of toxicologists and physicians (it is no excuse to say they are in the section, if dentists are in charge). Equally plainly the ADA product endorsement scheme puts dentists into an inherent conflict of interest.

As evidence, we hereby incorporate into this petition the petition referenced in footnote 1, page 1, above.

8. Biased, exclusionary, and extralegal conduct of Dental Devices Branch.

As evidence, we hereby incorporate into this petition (1) the petition referenced in footnote 1, and (2) the complaint filed with the Office of Internal Affairs, which is attached to the petition referenced in footnote 1.

9. Misstatements of fact pervade proposed rule.

In a bureaucratic face-saving, the draft claims that the failure to classify then the most common filling material, while classifying all other filling materials and even the capsule the amalgam goes into, was "inadvertent error." When questioned by Congressman Burton at a hearing in 2002, CDRH Director Feigal (now retired) retracted the claim. But it remains in the draft.

10. Decision to hide risks rather than alert the public.

FDA has a two-step approach to protecting the public: first, decide if a product may be sold, then decide if it should have limits or warnings. For amalgam, Dental Devices takes the opposite approach to the agency it is charged with representing. First, it never classifies the amalgam, allowing its sale via grandfathering and a sneaky system of equating the amalgam with a non-mercury product for regulatory purposes. Second, it decides that the benefits exceed the risks – then hide the risks.

Dental Devices Branch has proposed a rule whereby the public – even pregnant women – will likely never learn that amalgam contains mercury. Once it puts on controls, it stops referencing mercury. This kowtowing to the ADA is a departure from

FDA's duty and is reason enough to remove Dental Devices and the author of this draft from any further role in the process.

FDA has abandoned its mission. It is proposing a rule where virtually no will would be warned that amalgam is a major exposure to mercury, a cover-up benefiting the ADA and harming the public.

11. Environmental Impact Statement as a legal requirement.

One more legal error – pretending no environmental impact occurs from the torrents of mercury used by the pro-amalgam dentists. The facts are otherwise. See New England Zero Mercury Campaign, *Taking a Bite Out of Dental Mercury Pollution / The 2005 Report Card on Dental Mercury Use and Release Reduction*, by Clean Water Action New England, Clean Water Fund New England, Health Care Without Harm, Mercury Policy Project, Natural Resources Council of Maine, and National Wildlife Federation (2005), www.mercurypolicy.org See also *Dentist The Menace? The Uncontrolled Release Of Mercury*, by the Mercury Policy Project, Health Care Without Harm, Sierra Club, and Toxics Action Center (2002), www.mercurypolicy.org/new/documents/DentistTheMenace.pdf

12. Deference to Congressional and state legislative initiatives is appropriate.

A groundswell of bills began in Congress and in state legislatures (at least in Alabama, Arizona, California, Connecticut, Florida, Georgia, Illinois, Maine, Maryland, New Hampshire, Ohio, and Washington) in 2000-02, along with a resolution of the National Black Caucus of State Legislators. After sitting on the amalgam issue for a dozen years, with no classifying and no warnings and no action of any type, Dental Devices Branch and its director sprung into action. They proposed this rule attempting to keep amalgam legal, to block all warnings about mercury exposure, and to stop efforts for contraindications for pregnant women and children. To suggest this timing was not aimed at cutting off this movement, and supplying political ammunition to the American Dental Association for its counteroffensive in Washington and the state capitals, is naïve. By moving forward now with this ADA-backed draft regulation, FDA would appear to be cutting off debate on H.R. 4011, a bipartisan bill with ten Members of Congress (to date) as sponsors, and trying to block state consumer disclosure and environmental legislation.

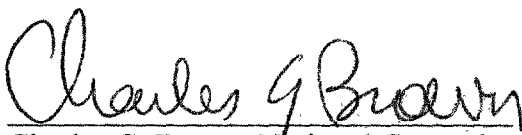
For the world's Gold Standard health regulatory body, this action is untenable.

C. Claim for Categorical Exclusion

A claim for categorical exclusion is asserted pursuant to 21 CFR 25.30(h).

D. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petitioner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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.)
>
> 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

MEMORANDUM TO FDA OFFICE OF INTERNAL AFFAIRS
RE: FDA's LSRO/BETAH CONTRACT
From: Consumers for Dental Choice, November 4, 2005

We ask FDA's office of Internal Affairs to investigate the secretive, no-bid deal – jointly engineered by FDA and National Institute of Dental and Craniofacial Research (NIDCR) officials with Life Sciences Research Office (LSRO), Inc., and BETAH Associates – regarding what FDA had promised would be an "independent" study of the scientific literature on the potential health "risks" related to mercury-based dental amalgam fillings. First, the contractual arrangements, the subcontracting deal, and the surreptitious conduct of government employees took place in violation – the evidence suggests willful violation -- of government competitive bidding rules and scientific ethics. Second, the methodology was fundamentally flawed, starting with a panel of persons devoid of research in mercury toxicity but full of pro-industry conflicts, who to this day ill not identify its bibliography, and who in an act of scientific dishonesty flipped the research question to abandon the focus on "risks."

Over a year ago, the National Institutes of Health (NIH) launched a formal investigation of NIDCR's role in this contract – Case No. 2004-99. This year, the investigation was upgraded to a more serious level -- NIH Director Zerhouni appointed a national CPA firm, Clifton Gunderson, to investigate the charges. (NIH may not investigate FDA, however. FDA must look into its own house, instead of to keep looking the other.)

While NIH investigates the LSRO/BETAH deal, FDA officials take the totally opposite attitude toward allegations of corruption – showing indifference, if not an outright cover-up. In letters to at least three Senators (Kennedy, Smith, and Murray) and in public statements, FDA's leaders laud the contract and fail to disclose to the Senators that NIH has it under investigation (even though the existence of the NIH investigation has appeared in at least three major newspapers). We believe such selectivity is due to the same group at the Center on Device and Radiological Health, who not only did this contract to protect the untrammeled marketing of mercury amalgam, but is charged with enunciating FDA's policies in mercury fillings. (We have filed a petition with FDA to revoke regulatory control over mercury amalgam from the Dental Devices Branch.)

The purpose of FDA and NIDCR's "independent" study is to arrive at pre-determined conclusions that favor pro-amalgam interests. To that end, the competitive bidding process was circumvented and LSRO was handpicked to deliver the desired results. LSRO is currently a consultant for major tobacco companies Phillip Morris and RJR Nabisco. LSRO's capability appears to be more in the realm of complex verbiage than in meaningful findings. For instance, in its recent report on tobacco additives, LSRO offered, as a conclusion in its Executive Summary, the following:

> "Although the addition of ingredients to tobacco is unlikely to change significantly the adverse health effects of cigarettes based on the magnitude of the health effects of cigarettes and the incremental mass of pyrolyzed materials contributed by the added ingredients."

Huh? This isn't simply an ambiguously stated scientific observation. It isn't even a sentence.

One of the reviewers of the LSRO report found it to be little more than an elaborate series of pre-determined conclusions that favor the pro-amalgam position of elements within organized dentistry, their allies at NIDCR and FDA, and by extension, the financial interests of mercury amalgam producers. From the outset, the purpose of this so-called "peer review of the literature" has been to parrot the refrain that mercury-based fillings are safe and to claim, falsely, that there is no scientific evidence to the contrary.

In recent years, scientists around the world have come to recognize that even minute amounts of mercury can cause permanent neurological harm to young children and developing fetuses. Environmental Protection Agency scientists recently announced that 630,000 babies are born each year with too much mercury in their bodies, and that one American woman of childbearing age in six has so much mercury in her system that she is at risk of giving birth to a retarded child. That means millions and millions of American women are so burdened with mercury that they should have no further exposure to mercury whatsoever – but concern over these women falls on deaf ears at the Dental Devices Branch.

It is generally understood that exposure to the neurotoxin mercury comes from many sources, the most common of which are air pollution, certain kinds of fish, and so-called "silver" fillings – which are actually 50 percent mercury. (Amalgam is a combination that is only about 35 percent silver plus other heavy metals, with mercury acting as the glue that holds everything together.) Because of health risks, mercury has been systematically outlawed in virtually all health remedies and consumer products. Lat year, Kellogg was forced to remove from its cereal boxes a Spiderman toy because it is powered by a mercury battery.

Extensive studies conducted by the governments of Norway, Sweden, Canada, Germany, and other advanced nations have resulted in warnings of serious health risks – particularly for pregnant women and young children – associated with exposure to mercury from amalgam fillings. Referring to a 39-page report released by her government in March 2003, Dr. Liljan Smith Aandahl, Norway's Chief Dental Officer at the Directorate for Health and Social Affairs recently stated:

> • "In the last decade, a considerable amount of documentation shows that amalgam releases more mercury, and that more mercury from amalgam is absorbed into the human body, than previously believed."
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> • "[I]n line with the precautionary principle, it is important that the population's exposure to mercury be held at the lowest possible level. It is therefore natural to discontinue the use of amalgam and to use other dental filling materials as much as possible, since good alternatives are available."

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." (pages 41 and 42, Report of the Dental Material Commission - Care and Consideration, November 2002, Kv. Spektern, SE-103 33, Stockholm, Sweden, emphasis added). Eight years ago, Canada adopted

recommendations to stop the placing of amalgam fillings in children, pregnant women, and those with kidney problems. Likewise in Germany, the government requires manufacturers to give warnings that mercury fillings are contraindicated (= DO NOT USE) for children, pregnant women, and people with kidney problems. Similar warnings were briefly given on the American website of Dentsply, a German company that sells amalgam products in the U.S. After pressure from special interests in this country, Dentsply removed the warnings.

Like tobacco, mercury-based amalgam is becoming recognized as a toxic substance that poses significant health risks. Like tobacco, warnings of these risks would help protect the health of the American public. And like tobacco, powerful forces that have profited from amalgam are determined to protect and expand its use, even to the point of using "independent" studies to demonstrate the "safety and effectiveness" of a substance that the weight of scientific evidence has shown to be toxic.

As early as July 11, 2002, NIDCR and FDA drafted a statement to serve as the basis for conducting its "independent" study on amalgam. In the "Background" section, NIDCR completely ignored the evidence behind the warnings of health risks issued in Norway, Sweden, Canada, and Germany, citing instead their own conclusions of a decade ago as the basis for the upcoming study. These old reports claimed that except for "localized allergic reactions" (extremely rare), "there was no evidence" that mercury-based amalgam "posed a serious health risk in human [s]"; and falsely stated that the "World Health Organization, in 1997, reaffirmed this conclusion." In fact – and Susan Runner is well aware of this point – that WHO "statement" was a draft by a consultative group. It is sheer demagoguery by Runner and others at FDA to adopt this ADA rhetoric and call it a WHO report, when they know better. (Dr. Maths Berlin, who formerly chaired the World Health Organization's *Task Group on Environmental Health Criteria for Inorganic Mercury*, was the lead researcher in the 2002 Swedish study, referred to earlier, that recommended "amalgam should be eliminated in dental care as soon as possible.")

Further demonstrating its effort to skirt the mercury question, NIDCR went so far as to provide a misleading label of ingredients, describing amalgam as an "alloy of powdered silver, tin, copper and sometimes smaller amounts of zinc, palladium or indium." Almost as an afterthought, the presence of "elemental liquid mercury" is mentioned, as if it were a trace element. Who would guess from such a description what is its main ingredient – that amalgam is 50% mercury?

NIH must immediately implement two changes:

- Because of their ties to elements within organized dentistry that have for years taken an aggressively pro-amalgam stance, NIDCR's Tabak and his staff, and FDA's Dr. Mary Susan Runner should be disqualified from any future role in evaluating, classifying, or providing warnings about the health risks of mercury amalgam fillings.

- We urge you to ensure that, if ever released, this "independent" study does not draw the imprimatur of the federal government, a step that would deceive parents and pregnant women into taking the risky step of exposing themselves or their

children to a potent neurotoxin: mercury. It's time to void this illegal contract, and have the study done by a truly independent entity – at arms length from the special interests within NIDCR and FDA – one chosen through an honest and open process of competitive bidding, and enlisting a panel of persons with substantial experience in the study of mercury amalgam fillings.

This report is presented to you in four parts, and includes over 30 attachments of mainly internal records, such as e-mails.

I - Conspiracy to Violate Federal Bidding Laws

NIDCR's Director Tabak, his assistant Norman Braveman, and contracting officer Marion Blevins, along with FDA's Runner, conspired to violate the federal bidding laws by handpicking tobacco consultant LSRO to prepare a study, designating the results they wanted, and then – in an attempt to create a façade of legality – shoehorning the deal into an existing contract with a management services company, BETAH.

II - Conflict of Interest

Tabak and Runner have been promoting the "safety and effectiveness" of mercury amalgam fillings while protecting a flagrant conflict of interest via their close ties to pro-amalgam interests within organized dentistry – thus providing an incentive to protect mercury amalgam interests even at the risk of breaking the law.

III - Operating in Secret

As members of the secret committee to name the contractor, Braveman at NIDCR and Runner at FDA conspired to keep the matter secret, blocking legitimate requests for public information.

IV - Attempting a Cover-up

To cover up his violation of law, Tabak provided false and deceptive testimony to Congress, via a letter dated July 23, 2004, to Reps. Dan Burton and Diane Watson.

I - NIDCR Director Tabak, his assistant Braveman, and Blevins, along with FDA official Runner appear to have violated the competitive bidding laws by handpicking tobacco consultant LSRO to mirror their own views.[1]

[1] The evidence presented here is taken from but a fraction of available materials. Despite multiple efforts for public records, Consumers for Dental Choice received only the e-mails from and to Tabak's assistant, Braveman – without attachments and with numerous parts deleted. With discovery, or with compliance with the Freedom of Information Act by FDA and NIDCR, there are likely substantially more documents to review and, potentially, evidence to present to the Court.

In November 2002, David Feigal, M.D., Director, Center on Devices, FDA, decided that there was a need for an independent, outside review of the scientific studies on amalgam.[2]

The assignment created a dilemma of major proportions for Tabak, Braveman, and Runner. On the one hand, as scientifically trained professionals, they were aware of the many peer-reviewed studies raising questions about the safety of mercury amalgam fillings, and the virtual absence of peer-reviewed studies saying that mercury amalgam fillings are safe. On the other hand, if they carried through with their duties as government officials and conducted an independent study, it would necessarily bring to light information damaging to their allies' pro-amalgam interests within organized dentistry.

These government officials systematically planned their version of an "independent" study, repeating the charade they had performed twice previously: announce that they had reviewed the literature and proclaim mercury-based fillings safe. They drafted, or caused to be drafted, a contract dated July 11, 2002, to begin the process. Exhibit G. The evidence of their intent is plainly stated in the "Background" section, where they simply restate the results of their previous reviews and include the false statement that the World Health Organization supports amalgam fillings.

The next step was to hire a consultant willing and able to deliver the intended message while maintaining the appearance of conducting an "independent" study.

Phase One: With no competitive bidding, no request for proposal, and no public notice, NIDCR and FDA officials secretly chose a consultant with ties to the tobacco industry.

At the outset of the process, Tabak's assistant Braveman, Runner, one Dr. Lireka Joseph (now deceased), and one or two other persons formed a committee or task force to name the consultant for the study. Exhibit F. Tabak was kept apprised, e.g., through being cc'd on e-mails. On November 21, 2002, Braveman met with a representative of the tobacco consultant, LSRO. Based in Bethesda, Maryland, LSRO's research activities in defense of tobacco companies made it the perfect candidate. On November 22, Braveman told LSRO to submit a proposal. Exhibit H (bottom e-mail).

After huddling with LSRO, these government officials then wrote, or caused to be written, a second draft contract dated January 14, 2003, that calls for a "Contractor" to do the work instead of the government. The agreement specifies meetings to be held with the "Contractor" at LSRO's headquarters location in Bethesda. Exhibit I.

Astonishingly, this draft plainly states the biased agenda of the parties drafting the contract: Their two previous literature reviews opined that amalgam is safe, and now we have handpicked you, LSRO, as the "independent" contractor to repeat the process and come up with the same results. Reading that contract leaves little doubt about what

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[2] "Feigal: FDA Planning Another Review of Mercury in Dental Amalgams," *FDA Week*, Nov. 22, 2003. Exhibit E.

conclusion these government officials wanted LSRO to reach. LSRO – which had performed so eloquently for the tobacco interests – was *sub silentio* directed to give amalgam a clean bill of health.

This end point, it would appear from the correspondence, LSRO understood well. In an e-mail dated December 3, 2002, and addressed as "Dear Norm (Braveman) and Lireka (Joseph)," LSRO sent, in the words of the writer,[3] a "pre-proposal." Exhibit H. In decidedly unscientific language, LSRO described the project as "right down our alley." In its own words, LSRO made clear they understood what "the trick is" to producing the kind of study these government officials desired.

Braveman apparently then passed this contract on to Tabak, Runner, and others, asking for comments. On January 23, Braveman e-mailed them, saying he had reviewed their comments on the contract, rejecting some and including some. Exhibit J. In this memo, he made clear that the secret decision to hire LSRO had been made:

> "Let's keep in mind that this document is intended to be passed to our contracting people so that we can get a cost associated with what's been outlined. It is definitive only in the sense that it is intended to outline in a broad way the activities that we'd like to have the contractor handle."

These officials violated several sections of the Federal Acquisition Regulation (FAR): no request for proposal, no publication of a desire for a contractor, no competitive bidding, and no open negotiations. Immediately after Director Feigal announced the need for a study in late November 2002, the contracting process focused solely on LSRO, and within a matter of weeks, the terms of the contract were being finalized. By January 2003, Braveman and Runner, along with Tabak, had agreed to contract with LSRO. The entire process was conducted in secret and, as shown below, kept secret from public scrutiny through an orchestrated series of deceptive acts and practices.

In the third draft, Exhibit K (January 23), Tabak, Runner, and associates made a major change in the terms. They decided that they, the government, would determine what literature the "independent" panel would read, precluding the possibility that an inquisitive panel member might venture into uncharted territory (for NIDCR) and that the most up-to-date and thoroughly researched scientific evidence might inadvertently be considered.

> "The government will separately identify and define the initial scope of the literature to be reviewed, and will manage all logistic activities relating to expert panel members. ..."

A question naturally arises about what is meant by "logistic activities" within the context of scientific research. And what criteria did the government intend to use to "define the scope of the literature to be reviewed"? Would the criteria include the warnings resulting from major studies by the governments of Norway, Sweden, Canada,

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[3] LSRO Inc.'s principal is never identified. In an artful decision of dubious legality, his name was redacted every time, but since his direct line telephone number was sometimes not redacted, the person can be identified as Michael Falk, reportedly the CEO.

and Germany? Or would these warnings and other scientific studies suggesting health risks to pregnant women and young children be minimized or ignored? Between January 23 and May 1, despite repeated FOIA requests, Consumers for Dental Choice was denied access to e-mails, or other information that might have shed light on these questions by both NIDCR and FDA. In October 2005, after three years of making requests, FDA finally responded. (While we acknowledge receipt of these records, we believe they remain incomplete. We have received nothing from the files of Dan Schultz, Linda Kahan, the retired David Feigal, or the late Lee Joseph; all have been integrally involved in this issue.)

Phase Two: BETAH Associates was enlisted as straw person contractor.

In the fourth draft (February 23, 2003), LSRO remained the Contractor, but a new name suddenly appeared: BETAH Associates, Inc. Exhibit L. BETAH, also based in Bethesda, Maryland, has an existing three-year contract with NIDCR to do provide management and "logistical" services associated with running conferences. Exhibit M. None of BETAH's services are remotely related to scientific research, and nothing in the NIDCR's contract with BETAH pertains to scientific studies – an area in which BETAH has no qualifications whatsoever. In this draft, BETAH is charged with submanaging "logistic activities" within the Government's responsibilities.

In the fifth contract draft (March 21, 2003), Exhibit M, BETAH's responsibilities became separated from those of the Government. Exhibit N. LSRO was given 10 major delegated responsibilities, Betah just one peripheral responsibility. But in the eyes of Tabak, Runner, and associates, BETAH had the one qualification that LSRO lacked: an existing NIDCR contract.

Enter NIDCR's Marion Blevins. Exhibit O. As the contract officer, she was charged with putting the veneer of legality on the arrangement. At this point (May 1), through a tortuous distortion of Dr. Feigal's original order, the conference-planning support company BETAH became the "Contractor" designated to conduct the "independent" scientific review. On May 13 (Exhibit P), Blevins wrote an "authorization" for BETAH to hire LSRO as a "subcontractor."

Although FDA's Runner handed to NIDCR the lead on this contract, e-mails prove that she and her colleagues at FDA remained 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, and to facilitating LSRO's retention as subcontractor (Exhibits F, H, J, Q, R, II [eye-eye]).

Phase Three: The conspirators erected a façade of legality to try to cover their tracks.

BETAH Associates started as a non-participant, then took on an inconsequential role doing "logistics," and finally was designated as the "contractor." LSRO started as the "contractor," then was shifted to subcontractor, although it was doing all the substantive

work. So LSRO was slipped in through the back door, while BETAH received a handsome payment in return for going along with the deal.

Aware that public comment was supposed to be an important part of this study, and faced with the potential undoing of their scheme, Braveman and Blevins began to pressure BETAH to speed up the process – and get the contract finalized. Exhibit Q, series of e-mails May 21 to June 4.

On May 29, Braveman made clear to his co-conspirators that he would continue stonewalling requests for information until the contract was completed. Exhibit R. In an e-mail titled "Charlie Brown" (presumably referencing the counsel for Consumers for Dental Choice, the undersigned), he referred to an attached letter he had written to Brown (not released under FOIA), but which he would hold . . .

> "until all of the 'i's' are dotted and 't's' crossed in the contract between [sic] LSRO. ... I can't send it until we know for sure that everything is ok with the contract. I'll let you know when that happens."

One more step remained – to shoehorn the work of LSRO into BETAH's existing contract. Through utterly shameless verbal manipulation, the language of the approved contract named the conference-planning company BETAH as the contractor to conduct a study on the critical issue of potential health risks from exposure to mercury in dental amalgam. To complete the fabrication, the contract said that BETAH, not the government, identified LSRO as a subcontractor, and described LSRO's "independent" scientific study as a "conference."

By means of this obviously deceptive mechanism, BETAH was awarded the NIDCR contract. Neither before – nor after – is this work characterized as a "conference." LSRO's activities became a "conference" only momentarily, in the rigged language of a sham contract designed to mislead the public and produce predetermined results in the guise of an "independent" scientific study.

Tabak, his assistant Braveman, Runner, et al., conspired to create the appearance of engaging an existing contractor already doing similar work. In a cynical distortion of government contracting regulations, they identified LSRO as a safe consultant whose track record indicated a willingness to deliver findings consistent with the agenda of the client, drafted a contract of duties, then found an existing contractor – one doing totally unrelated work – on which to piggyback the deal. This Byzantine scenario shows, *prima facie*, that Tabak, Runner, et al., consciously took a carefully scripted set of steps to corrupt the bidding process in order to handpick LSRO as a compliant consultant.

As government officials at agencies that regulate or study the potential benefit or harm of a variety of products, these officials abused their responsibilities by sabotaging the order of FDA Center Director Feigal to conduct an independent study of the literature on health risks associated with mercury in amalgam fillings.

They embarked on a conspiracy to (1) handpick a tobacco industry consultant experienced in using scientific verbiage to create a veneer of authenticity, (2) enlist an existing contractor as straw person to hire that consultant as subcontractor; and (3) erect a

façade of paper legality in an effort to cover their tracks in the first and second steps. Meanwhile, (4) they worked to keep their activities secret from the public and from consumer advocates.

Phase Four: LSRO proceeded, predictably, toward the delivery of a biased, unscientific product

The "study" – or what the BETAH contract with NIDCR defined as a "conference" – proceeded predictably. It turned out to be neither a study nor a conference. LSRO conducted its "independent" study from start to finish in the most unscientific manner imaginable. Not one panelist had expertise or even substantial experience in researching mercury-based dental amalgam products. From the outset, one participant was openly dismissive of risks related to mercury. He went so far as to air his views in a published article and sat for a major newspaper interview.[4]

In June 2004, LSRO sent the draft to "outside reviewers," one of whom had appeared as its chief witness in favor of amalgam fillings. At this point, another reviewer who recognized the need to play the role of whistleblower, alerted Consumers for Dental Choice about a host of irregularities and omissions in LSRO's conduct of its "independent" study: no mention of major international studies on new evidence of health risks associated with amalgam, deceptions and mischaracterizations of the literature, an unscientific report with results plainly predetermined – in short, findings that simply echo the positions advocated by organizations that have a financial stake and/or a vested interest in amalgam.

For example, the report claims that the government of Canada has no problems with mercury amalgam fillings, when the opposite is true. That government advised every dentist in the country in 1996, via a personal letter, not to place mercury-based fillings in children, pregnant women, or people with kidney problems.

But the question remained: how did they reach the opposite conclusion (i.e., explaining away literature on the health risks of mercury amalgam) when all other national literature reviews were the opposite – i.e., Sweden's, Norway's, and Germany's national studies say to ban mercury fillings, while Canada's says to stop its use for children, pregnant women, and adults with kidney disorders. We explained that Braveman gave Falk a blueprint of the desired result, but another step was needed to produce the veneer of a "scientific" report. Via comparing the contract with the final report, we have discovered how it happened.

LSRO accomplished this task by violating the terms of the contract. How? Falk and Brownawell shifted the purpose of the study from what was mandated in the contract to one that would produce the opposite result. Compare the contract between LSRO and BETAH, "Description/Specifications/Statement of Work (SOW)," page 1 (Attachment CC); and the LSRO report, Executive Summary, page 1, Attachment DD.

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[4] Dr. Robert Brent, a member of the panel, told *The New York Times* on July 13, 2004, that parents should stop worrying about environmental toxins like mercury.

The contract: Here is the mission of LSRO, as stated in the contract:

> "Provide and enforce the following charge to the Panel: Is there any evidence in the scientific literature that you have reviewed that would indicate that dental amalgam poses a health risk of humans?" *(Emphases added.)*

The report: Here is what LSRO claimed in the executive summary is its mission:

> "Unlike other recent reviews of the dental amalgam literature (Berlin 2002)**, LSRO was not asked to provide policy recommendations or perform risk assessment or risk-benefit analysis. LSRO was simply asked to review the literature ... to determine if it supported hypotheses relating to adverse health effects." (Emphases added.) [***(Berlin 2002) = The Swedish report condemning mercury amalgam and calling for a ban.*]

LSRO flipped the question, to one that would certainly have to be answered yes, to one that can be answered no.

- The answer to the question of the existence of ANY EVIDENCE that amalgam poses a HEALTH RISK TO HUMANS is patent in the scientific literature! Reports from Sweden, Germany, Canada, and American studies say yes, such evidence exists; no legitimate scientist could deny it. And this is the very question LSRO was required to answer in its contract.
- But LSRO did not answer the question mandated in the contract. It switched the question to an entirely different one. First, it changed the literature to a singular composite, "it," so the question no longer was based on "any" literature, but the weight of the literature. Second, it changed the issue from "risks" to "adverse health effects," which any scientist would know is a wholly different analysis. Third, it inserted the term "HYPOTHESES," then creating a series of them written in a manner so the answer mirrored the initial FDA/NIDCR blueprint (amalgam is "safe.").

Intellectual dishonesty reigns -- a cruel hoax on the American people, an approach that dodges the risk question, collectivizes the literature into a single answer, and poses hypotheses that needed only a 51% likelihood. "Risk," unlike a "hypothesis," does not need a 51% likelihood to be a problem. Employment of this deceptive move of changing the question in the report to get the opposite answer is consistent with the sleaze that marked this deal from start to finish.

The sequence unmasks LSRO as a "Jeopardy game show consultant" – The funding agency provides the answer first, then LSRO figures out the question to match it.

But LSRO could never have done this report had not Tabak, Runner, and associates used a backdoor method to bring in this consultant -- receiving in return a document reflecting their agenda – and those of pro-amalgam interests – while ignoring or mischaracterizing the scientific evidence on health risks related to mercury-based dental fillings. In their efforts to engineer a pre-determined result, these government officials have shown contempt both for the American public, whose health concerns should be foremost in a study of this type, and for the legal process. The motivation is clear: as committed defenders of pro-amalgam interests, they are opposed to any study

that might consider the full extent of peer-reviewed research on health risks related to mercury-based amalgam fillings.

1. NIDCR Director Tabak's assistant Braveman and FDA's Runner violated the FAR by handpicking tobacco consultant LSRO without competitive bidding, RFPs, and publicizing the opportunity to participate.

The Federal Acquisition Regulation ("FAR"), 41 USC §1 et seq., governing virtually all federal agencies' purchasing decisions, mandates an open and competitive system. It has an extensive set of implementing regulations: 48 CFR §5.002 requires contracting officers to publicize contract actions; 48 CFR §5.102 requires solicitations be made available to the public; 48 CFR §6.000 states that the fundamental policy is one of full and open competition; 48 CFR §6.102 states that this system covers basic and applied research, and specifically includes "a peer of scientific review"; 48 CFR §6.303 states that no agency may depart from this basic requirement without a written "justification for other than full and open competition," with mandated criteria. 41 USC §253 (c) and (f).

Contract by negotiation (Braveman uses the term "negotiating" to describe his activities) plainly does not permit a "choose your favorite contractor" potion. Contract by negotiation requires conducting negotiations with a range of qualified applicants, because factors other than fees matter. Contract by negotiation is "a process designed to foster an impartial and comprehensive evaluation of offerors' proposals" (emphases on s' and s added to indicate that "negotiating" means more than one proposal is being evaluated). 48 CFR §15.002. By definition, "negotiating" mandates a "tradeoff process" to reach "the best value." 48 CFR §§15.101-1 and -2. Written information or, in lieu thereof, oral presentations, are required. 48 CFR §15.102. Requests for Proposal (RFPs) communicate government requirements to prospective contractors. 48 CFR §15.203. Like competitive bidding, contract by negotiation is an open process that involves choosing among qualified prospects.

Instead of following these clearly defined steps, NIDCR and FDA officials chose to proceed along a more tortuous path.

2. Their approach of choosing the consultant – then finding a contractor doing unrelated work to write a subcontract and deceptively calling the work a "conference" – also violated the FAR.

Subcontracting, too, must be a transparent, above-board process. The agency must review requests for subcontracting and consider the following factors: Was adequate price competition obtained or its absence properly justified? Were price comparisons made? Was there a sound basis for the contractor to pick the subcontractor? 48 CFR §44.202. Consumers for Dental Choice repeated requests FOIA for documents related to these criteria went unanswered.

Agencies must not consent to contracts when the contracting officer must deal directly with the subcontractor. 48 CFR §44.203. But that is exactly what happened here. NIDCR and FDA officials chose the subcontractor (LSRO) first, then dealt directly with the subcontractor, start to finish. After choosing the consultant, NIDCR/FDA officials brought in an existing contractor (BETAH), but gave the latter only one

peripheral assignment (modified slightly in the final contract). Plainly, BETAH, the so-called contractor, acted as a straw person whose chief advantage was availability. Since contractor BETAH's agreement with NIDCR was to do "conferences," not scientific studies, the contract falsely characterized the " study" as a "conference." By making it appear as if BETAH had simply been given a new responsibility, NIDCR/FDA collectively attempted to circumvent the bidding laws. Allowing this legerdemain to stand would render Federal bidding regulations meaningless.

3. NIDCR and FDA's Center on Devices may have authorized a violation of the Anti-Kickback statute.

The "Anti-Kickback Act of 1986," 41 USC §§51-58, prohibits compensation to prime contractor from subcontractor, as does 48 CFR §3.502-2, the Code of Federal Regulation implementing language. These government officials may have directed a violation of the Anti-Kickback Statute, in that BETAH is getting paid for being an existing contractor through the deal made with LSRO, instead of for actual work consistent with the payment made.

NIDCR's Braveman was involved in every step of this contract, as was a high-ranking official of the Center on Devices, who was cc'd on every key memorandum we have been allowed to see. Braveman wrote the FDA official and others that he was going to "dot all the i's and cross all the t's" of the LSRO/BETAH contract. In his own words, he put pressure on the two parties to sign off on the deal. He was aware, indeed he directed, that LSRO would do the actual work, while BETAH would collect a tidy sum for agreeing to act as a contractual middleman. Such dealmaking, with money changing hands between contractor and subcontractor, is precisely what the anti-kickback statute prohibits.

Here are government officials, sworn to serve and protect the public, engaging in an illegal scheme to hire a private consultant whose job is to conduct a sham study that reflects the views of those officials – and to misrepresent those views as "independent" scientific research.

II - Because of major conflicts of interest, NIH's top dental official, Dr Tabak, and FDA's top regulator of dental amalgam, Dr Runner, should have no involvement in evaluating the health risks related to mercury-based fillings.

Long considered a sacred cow in its ability to conduct research and publish studies without arousing Congressional or media attention to conflicts of interest, NIH is now facing scrutiny for allowing health professionals to make decisions that benefit products and/or organizations with which they are affiliated.

• A *Science* magazine article detailed the disturbing reality that NIH is rife with health professionals who wear two hats: they have close ties to the products or organizations they are supposed to regulate. ("Feeling the Heat, NIH Tightens Conflict of Interest Rules,"July 2, 2004).

• In *The Washington Post*, Jerome P. Kassirer, editor-in-chief emeritus of the *New England Journal of Medicine* and professor at the Tufts University School of Medicine, explained why professionals with such conflicts should not be involved in any way with

conducting studies or issuing guidelines. ("Why Should We Swallow What These Studies Say," August 1, 2004.)

• *The Los Angeles Times* reported in a front-page story (August 6, 2004) that Marilyn Glynn, head of the Office of Government Ethics, described NIH as "beset with a 'permissive culture' and that firm, across-the-board restrictions were needed to restore public confidence." Without tougher standards, she said, "NIH 'could give the appearance that some level of misuse of office is tolerable.' " (Emphases added.)

1) Long-standing ties exist between NIDCR/FDA officials and organizations with pro-amalgam agendas.

Tabak and Runner – the top people on dental issues at their respective agencies – have long-standing ties to organizations that are outspoken in their support for the continued use of mercury-based amalgam fillings: the American Association of Dental Research (AADR) and the American Dental Association (ADA). The AADR, according to its policy statement, claims amalgam "has a well documented history of safety and efficacy," and it "endorses the use of best management practices for the use of amalgam restorations . . .. " (emphasis added). www.dentalresearch.org/about/aadr/policy.html.

Dental research activities at NIDCR have long been influenced, if not controlled, by personnel with strong ties to the ADA, which has been the leading advocate of mercury amalgam products in the United States since its founding more than 150 years ago, and by the AADR. Unlike the American Medical Association, the ADA has long been in the business of promoting commercial products, the most prominent of which is mercury-based amalgam. (By contrast, the American Medical Association's position on promoting commercial products is unequivocal: "The AMA does not have a mechanism or procedure to approve medical or surgical procedures, treatments, or products. The AMA does not sanction, endorse, approve, or disapprove products, procedures, hospitals, or clinics.")

The ADA came into being in the 19th century for the specific purpose of advocating "silver amalgam-mercury use in dentistry." *Consumer Cause v. Smilecare* (2001) 91 Cal.App.4th 454, 458 (emphasis added) *quoting* Miller, *Mercury Amalgam Fillings: Human and Environmental Issues Facing the Dental Profession* (1996) 1 *DePaul J. Health Care L.* 355, 355-359. Amalgam was cheap and profitable, and the public – then as now – naively accepted organized dentistry's claim that they were getting "silver" fillings.

Every amalgam patent that has been awarded for decades has been produced according to ADA specifications – a simple search of the U.S. Patent Office will confirm this fact – and since the 1930s, the ADA has continuously promoted the "safety and effectiveness" of amalgam products through its Seal of Acceptance, paid for by mercury producers and amalgam manufacturers. – an arrangement in which the companies pay ADA for attesting to the "safety and effectiveness" of their products. www.ada.org/seal/index.asp. Currently, more than 50 mercury-based amalgam products are promoted through these ADA "Seal" contracts.

ADA Seal Product Search -- Keywords: AMALGAM:

Becker-Parkin Dental Supply: Amalgam Alloys, Pre-encapsulated: DFL Alloy Capsules. Darby Dental Supply Co.: Amalgam Alloys, Pre-encapsulated: Formula T, Capsules, Non-Zinc; Superdent Dispersed Phase Alloy, Capsules, Non-Zinc; Superdent Dispersed Phase Alloy, Capsules, Zinc; Ternalloy Alloy Capsules. Dentsply L.D. Caulk Division: Amalgam Alloys, Pre-encapsulated; Dispersalloy Self-Activating Capsules, Fast Set; Dispersalloy Self-Activating Capsules, Regular Set; Optaloy II Sure-Caps; Unison Spherical Alloy Self-Activating Capsules. Fen Dental Manufacturing, Inc.: Amalgam Alloys, Pre-encapsulated: Epsilon Capsules. Foremost Dental Mfg. Co.: Amalgam Alloys, Pre-encapsulated: Zenith Premium Dispersed Phase Alloy Capsules, Fast Set; Zenith Premium Dispersed Phase Alloy Capsules, Regular Set; Zenith Royale Dispersed Phase High Copper Alloy, Capsules; Zenith Type-T Spherical Alloy, Capsules. Goldsmith & Revere: Amalgam Alloys, Pre-encapsulated: Aristaloy 21 Dispersed Phase Amalgam Alloy Capsules; Aristaloy CR High Copper Spherical Amalgam Alloy Capsules; Ultra Dispersed Phase Alloy, Capsules, Regular Set; Ultra Dispersed Phase Dental Amalgam Alloy Capsules, Fast Set; Itra Dispersed Phase High Copper Alloy, Capsules; Ultra High Copper Spherical Alloy, Capsules; Veraloy Disperesed Phase High Copper Amalgam Alloy Capsules. Ivoclar-Vivadent, Inc.: Amalgam Alloys, Pre-encapsulated: Valiant, Capsules, Non-Zinc; Valiant® PhD, Capsules, Non-Zinc. Network Sales Co., Inc.: Amalgam Alloys, Pre-encapsulated: Etal Aristalloy 21; Etalloy Cr. Schein, Inc., Henry: Amalgam Alloys, Pre-encapsulated: Henry Schein Ionosphere High Copper Ternary Alloy; Henry Schein Stratosphere, Fast Set, Capsules; Henry Schein Stratosphere, Regular Set, Capsules; Henry Schein Troposphere Spherical Alloy, Capsules. Silmet USA Corp.: Amalgam Alloys, Pre-encapsulated: Nogama-2, Capsules; Spherodon, Capsules; Spherodon-M, Capsules. Southern Dental Industries, Inc.: Amalgam Alloys, Pre-encapsulated: GS-80, Fast Set, Capsules, Non-Zinc; GS-80, Regular Set, Capsules, Non-Zinc; GS-80, Slow Set, Capsules, Non-Zinc; Logic Plus, Fast Set, Capsules, Non-Zinc; Logic Plus, Regular Set, Capsules, Non-Zinc; Logic Plus, Slow Set, Capsules, Non-Zinc; Lojic, Slow Set, Capsules; Patterson Dental Admix Alloy Capsules, Fast Set; Patterson Dental Admix Alloy Capsules, Regular Set; Patterson Dental Spherical Alloy Capsules, Fast Set; Patterson Dental Spherical Alloy Capsules, Regular Set; Permite C, Fast Set, Capsules; Permite C, Regular Set, Capsules; Permite C, Slow Set, Capsules. Wykle Research, Inc.: Amalgam Alloys, Pre-encapsulated: Original D, Extra Fast Set Capsules; Original D, Fast Set Capsules; Original D, Regular Set Capsules; Phasealloy Zinc, Extra Fast Set Capsules; Phasealloy Zinc, Fast Set Capsules; Phasealloy Zinc, Regular Set Capsules.

It is generally acknowledged that the ADA's Seal gives substantial financial advantages to "[c]ompanies competing for their share of the $2 billion market in dental products . . . " (*The Complete Guide to Better Dental Care*, Taintor, Jerry F. and Mary Jane, Facts on File, 1997.)

During World War I, ADA researchers went to work for the Bureau of Standards. Over time, the ADA also developed a close relationship with the dental research arm of the National Institutes of Health (formerly the National Institute of Dental Research, now the National Institute of Dental and Craniofacial Research). By the 1960s, research in restorative materials benefited from "increased Institute support through workshops, grants, and a closer working relationship between the bureau and the ADA" (*Dental Science in a New Age: The History of the National Institute of Dental Research*, Ruth Roy Harris, Blackwell, 1992). The close ties in the dental materials activities involving the ADA, AADR, and government organizations continue to this day.

The professional reputation of the ADA and the AADR (perhaps their very existence) has depended on suppressing any suggestion that there might be health risks associated with implanting mercury in the mouths of patients. To the extent that people with ties to the ADA or other avowedly pro-amalgam organizations, such as the AADR, are involved in any way with amalgam research at NIDCR, this would clearly represent a conflict of interest in overseeing an "independent" scientific study.

Reflecting the *a priori* position of organized dentistry – and against the weight of the latest scientific evidence – Tabak, Runner, and associates could not, and did not, attempt to undertake a truly objective study on amalgam. Their conflicting interests made objectivity on the amalgam issue a virtual impossibility, and as Kassirer pointed out in his *Washington Post* article, they should have recused themselves.

But they did not. Instead, they acted deceptively when directed to commission an outside, "independent" study of the literature on amalgam -- as manifested by their actions to handpick a pliant consultant and Tabak's attempted cover-up in his July 23 letter to Reps. Burton and Watson (see pages 15-17).

These government regulators have marched in lockstep with the pro-amalgam interests of organized dentistry. They have taken public pro-amalgam positions and dismissed the plethora of studies showing the health risks of mercury in dental fillings. They have published, or caused to be published, false information claiming that other nations and/or international organizations have said mercury fillings have no health risks, and have put forth this false information as a basis for conducting their "independent" study.[5]

By coordinating their efforts with their ADA/AADR allies and exercising their power as key officials in the agencies studying (NIDCR) and regulating (FDA) amalgam, Tabak, Runner, and associates have been able to stop disclosures of evidence on the potential risks of mercury-based amalgam that are now given for virtually every other use of mercury in health care. Runner, who oversees the regulation of dental amalgam, has protected its use. Likewise, Tabak has ensured that only supporters of the ADA/AADR position on amalgam are given grants to "study" the health effects of these fillings, and has maintained such minimal oversight that the grantees almost never publish anything.[6] Both Tabak and Runner maintain the fiction that there is no scientific evidence of health risks related to mercury amalgam fillings, and that they are engaged in "independent" research.[7]

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[5] The "Background" section of NIDCR's July 2. 2002, draft includes the false claim that the World Health Organization "reaffirmed" the safety of amalgam fillings, when it was only a dental committee with no authority that made such claim; the WHO says, in fact, that there is no safe level of mercury for human beings. Runner caused to be published an FDA *Consumer Update* claiming the government of Canada found amalgam safe when in fact it has disapproved of amalgam since 1996 for children, pregnant women, and people with kidney problems. The *Consumer Update* was so riddled with erroneous puffery on mercury fillings that her superiors announced on December 12, 2002, that it would be withdrawn. Exhibit D.

[6] In NICDR's most expensive and most controversial study, that of Portuguese orphans who became subjects of toxicity experiments without informed consent, the dentist leading the research announced at a public hearing in Seattle before the review of the data began that mercury fillings are safe. Braveman sees no conflict in continuing to authorize millions of dollars for a pre-determined result.

[7] Runner styles herself as a spokesperson on mercury fillings for FDA, and has speciously claimed in public forums that the benefits outweigh the risks (!). Since mercury fillings are interchangeable with non-mercury fillings, there are no benefits – except to the dentist. For the assembly-line dental practice, the dentist maximizes his/her income by getting the low-income consumer or the child out of the chair faster by implanting mercury and moving on to the next patient, maximizing income per chair per day.

2) Pregnant women and the parents of young children will accept the results of this "independent" scientific study as "truthful," to their potential detriment.

Based on past performance, these government officials and pro-amalgam forces within organized dentistry are poised to trumpet the results of this "independent" study.

How do we know? That is exactly how they and their ADA allies responded after the publication of the now discredited March 2002 FDA *Consumer Update* on amalgam – a report attributed to none other than Mary Susan Runner. That update contained the false statement that the government of Canada supported the use of amalgam fillings and went so far as to encourage the continued use of mercury-based dental materials. Most damaging of all, it gave the impression that FDA had already made up its mind, before the public comment period on its proposed rule began. Dr. Feigal and Dr. Joseph noted the error, stating in the December 2002 letter:

> "We are currently in the process of revising the Update and have redrafted our statement about the proposed rule to remove any perception that we have already made a decision prior to reading the comments."

From March 2002 until the FDA revoked it on December 31, 2002, this *Consumer Update* was the most widely quoted document cited by the ADA at every hearing on amalgam – before state legislatures, federal and state regulatory agencies, and private sector organizations. Its impact was so great that, even two years later, consumer groups and public health organizations have to contend with the aftershock. The fact that an official published document containing misleading information and demonstrating agency bias was used to influence the public debate and affect governmental decision-making is outrageous.

The publication of this "independent" study would have an even more dramatic effect. The ADA would make sure that it goes to every policy maker considering restrictions on the use of mercury-based dental products.

3) Runner and the Dental Devices Branch may use this "independent" study to achieve a federal regulation to conceal the risks of mercury-based amalgam fillings.

Through their professional affiliations, Tabak, as head of NIDCR, and Runner, still in charge of amalgam regulatory decisions at FDA, are committed to protect amalgam via a federal regulation, one proposed in 2002 but put on hold by Dr. Feigal, who has since retired. LSRO 's "independent" study would act as a major step toward securing such a regulation. The appearance of governmental approval of this sham study would allow these government officials to advance their agenda.

The stakes are enormous. While all other uses of mercury are being banned or restricted, these allies of elements within organized dentistry with long-standing ties to amalgam – have conspired to stop public disclosure of the potential health effects of mercury-based fillings.

Relying upon a sham study will deny the right of informed consent to our most vulnerable populations, pregnant women and young children, who will continue to endure the needless risk of mercury exposure when alternative dental materials are readily available.

III - Braveman and Runner defied the Freedom of Information Act and the transparency mandated in FAR to put together a secret contract and an unqualified panel.

When the Director of FDA's Center on Devices, David Feigal, M.D., met with representatives of Consumers for Dental Choice in October 2002, he stated that he was authorizing an outside, independent review of the literature on mercury amalgam fillings. This promise was reaffirmed in a letter dated December 12, 2002, from the late Lireka Joseph, written (the letter states) on Dr. Feigal's behalf (Exhibit D).

At a very early stage, Tabak, Runner, and associates gained control of the process and made it clear that they had no intention of conveying information to consumer organizations or other members of the public. NIDCR's contract with LSRO/BETAH gave all power of appointment of panelists to handpicked consultant LSRO, shutting consumer groups out of a process where they generally have a role.

None of the members of the panel have expertise or even substantial experience in researching mercury-based amalgam products. Although LSRO's Falk promised an independent-minded panel, such was not the case. In June 2004, the *New York Times* disclosed that panelist Robert Brent had written an article saying exposure to environmental toxins should be of minimal concern for parents. In addition, Falk played a central role in testimony to an acknowledged supporter of mercury-based fillings, Thomas Clarkson. Incredibly, Falk then named Clarkson as an "outside" reviewer for the LSRO study.

LSRO's modus operendi was to shut the public out. After a perfunctory half-day hearing, in which panelists were not involved in any discussions whatsoever, LSRO closed its doors to public participation. The promised transparency rang hollow, as LSRO posted after the fact and withheld meaningful information.

For three years (2002-2005), Runner and the Center on Devices stonewalled our FOIA requests, only complying on the workday preceding a meeting we had with two Associate Commissioners. Whether we have all records we cannot determine.

Despite limitations based on the stonewalling of our requests, this letter presents prima facie evidence of a secret conspiracy to:

- circumvent competitive bidding regulations to favor pro-amalgam interests;
- handpick a favored consultant;
- give the consultant a virtual blueprint of what to consider and what conclusions to reach;
- corral an existing contractor to act as straw person; and
- mischaracterize the contract to create a façade of legality.
- produce a work product with biased and ill-prepared panelists
- asking not the question posed in the contract but one inverted so LSRO could respond in a way to conceal the health risks of mercury exposure from amalgam.