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April 19, 2007

Andrew von Eschenbach, Commissioner
Sheldon T. Bradshaw, Chief Counsel
Randall W. Lutter, Ph.D., Deputy Commissioner for Policy
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: (1) Remove mercury amalgam from marketplace now: FDA officials Lin and Runner are illegally approving mercury amalgam applications under the false pretenses of a substantial equivalence order when none exists or none may exist.
(2) Ban mercury amalgam for children and pregnant women now: After admitting five times to Court of Appeals that science is in equipoise, you have no legal or moral choice.
(3) Notice to six high-ranking FDA employees of personal liability exposure for their reckless indifference to the health of children and pregnant women after FDA admits the science is in equipoise yet continues to have no limited or temporary bans and no warnings.
(4) Please respond within 15 days, by May 4.

Dear Commissioner Eschenbach, Chief Counsel Bradshaw, and Deputy Commissioner Lutter:

FDA's policy on mercury amalgam is legally unsustainable, intellectually indefensible, and morally unconscionable. Whereas other Centers oppose mercury products, FDA permits a rogue group at the Center for Devices to carve out an exception for dentists – thus no veterinarian may rub a mercury-containing product on even the skin of a horse or dog, but dentists may implant literally grams of this neurotoxin inches from a child's brain.

Support for mercury amalgam has now dwindled to a shrinking number of dentists and a Center for Devices stuck in the 1980s. The manufacturers of dental filling materials do not oppose a ban for pregnant women and children – indeed, they warn dentists not to place mercury amalgam in children, pregnant women, or those with kidney disease! All such manufacturers have shifted their entire marketing focus to nontoxic filling materials; one went so far as to advise shareholders that an end to amalgam arrives the moment FDA requires it to be proved safe. Dentistry is deeply divided; modern dentists no longer place this primitive 19th century remnant. Supporters of dentistry in mercury fall into just two groups: (1) incompetent, lazy, or greedy factory-line dentists who make more money per chair per day placing mercury in children and low-income adults, and (2) tragically, their FDA enablers, a Center whose dentist-dominated policy has been soundly rejected by two FDA Advisory Committees. The U.S. Centers for Disease Control warns that amalgam constitutes a major exposure to mercury; by contrast, FDA's Center for Devices, in deference to its in-house dentists, conceals this fact from American parents.

The battle has shifted to an internal one at FDA, pitting the in-house dentists, kept in control by physician Dan Schultz's policy of professional courtesy to fellow doctors, vs. real scientists. The staff's pseudo-scientific "white paper" was decisively rejected by FDA's Scientific Advisory Committees, 13 to 7, on Sept. 7, 2006. Lacking even the integrity to be honest about the defeat, the Center for Devices pretended nothing of the sort occurred, **issuing a false and deceptive consumer update on October 31, 2006**, that concealed the vote and claimed the scientists merely wanted more research. Forewarned that the Advisory Committees will shoot down the staff classification, the Center now refuses to convene a meeting -- shelving the classification decision for a 32nd consecutive year. In 2004, realizing the independent literature review FDA promised Congressman Burton would doom a product it favored, the Center helped engineer a sham result – circumventing the Federal Acquisition Regulation by handpicking an unqualified meetings planner as strawperson contractor in order to shoehorn in as real party of interest its choice with whom it had been secretly negotiating, tobacco consultant LSRO. The result was exactly what a NIDCR/FDA cabal has asked for … in writing … in advance. The contract became the subject of a federal investigation wisely ordered by NIH Director Zerhouni. (See footnote 7.)

Last week's decision of *Moms Against Mercury v. FDA* sounds the death knell for the Center's amalgam Potemkin village. Lin and Runner, intentionally left unsupervised by Schultz and Kahan, have repeatedly "approved" encapsulated mercury amalgam applications, using as their written basis the false pretense that the Commissioner has issued a substantial equivalence order. But, the Court states at page 6, the Commissioner never has issued a substantial equivalence order for encapsulated mercury amalgam, and by law lacks the authority to do so. Thus, **FDA's repeated "approvals" of preamendment encapsulated mercury amalgam applications on the grounds of substantial equivalence to another preamendment device are per se illegal.** Your lawyers would agree; in the case, FDA emphasized to the court as the basis of the argument against jurisdiction that the very act which rogue employees Lin and Runner do repeatedly is not allowed. We presume the Center conceals this from the lawyers.

I. Illegal approvals of mercury amalgam by FDA Officials Lin and Runner mandate removal of this device from commerce.

On Friday the 13th of April, in *Moms Against Mercury v. FDA*, at page 6, the United States Court of Appeals ruled:

> "Section 360g(a)(8)[1] brings under the judicial review provision 'an order pursuant to section 360c(i) of this title.' The cross-referenced section describes procedural requirements for the FDA to determine that a post-amendment device is substantially equivalent to a pre-amendment device. In this case, **EAADM[2] has not been – and indeed, as a pre-amendment device, could not be – the subject of any order deeming it substantially equivalent to a pre-amendment device**."

Despite the absence of any FDA substantial equivalence order for encapsulated mercury amalgam (a point also conceded by FDA in its brief), and despite the Court

[1] 21 U.S.C. §360g(a)(8).
[2] "EAADM" = Encapsulated Amalgam Alloy And Dental Mercury (i.e., mercury fillings).

holding that no substantial equivalence order is allowed for encapsulated mercury amalgam, **Division Director Chiu Lin and Branch Director Susan Runner repeatedly "approve" applications for encapsulated mercury amalgam under a sham basis of "substantial equivalence."** For example, Lin, in "approving" Silverfil, an encapsulated dental amalgam on November 15, 2005, wrote: "We … have determined the device is substantially equivalent … to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976." Over and over in his two-page "approval" letter, Lin makes clear that his approval is based specifically on the existence of substantial equivalence authority: "FDA's issuance of a substantial equivalence determination …" and "[t]he FDA finding of substantial equivalence of your device to a legally marketed predicate device." The approval is then signed by Runner.

But Lin and Runner's "approval" is based on no authority at all: the Court stated that no order of substantial equivalence exists for encapsulated mercury amalgam, and none may legally issue. Lin and Runner thus conspired to "approve" a pre-amendment device by calling it substantially equivalent to another pre-amendment device despite the non-existence of any substantial equivalence order. The Silverfil "approval" is made all the more despicable because the applicant advised, right in his application, that his home country of the United Kingdom disallows the device for pregnant women and children. Evincing not an iota of interest in giving American children or unborn children the same protection from mercury exposure ordered in other countries, or at least deciding that protecting dental economics trumps children's health, Lin and Runner "approved" this mercury device for all uses and with no warnings.

Since 2000, Runner has engineered at least ten *ultra vires* "approvals" for the encapsulated mercury amalgam device, all based on a non-existent substantial equivalence order. FDA thus illegally approved ten devices that are 50% mercury so that Runner's fellow pro-mercury dentists can, instead of becoming modern dentists, lazily administer amalgam to make quick and easy profits. In addition to Silveril, the illegally "approved" EAADMs are Securalloy, Bestaloy, Benco Admix, Benco Spherical, High Silver Conventi, Futura Top Non Ga, Ana 2000 Non Gamma 2, Ana 3000 Sm Non Gamm, and Ana Non Gamma 2D.

Lin's and Runner's "approvals" were ratified by the rubber-stamp Center leadership, Dan Schultz and Linda Kahan, who knew (or should have known[3]) that Lin and Runner were relying on a non-existent substantial equivalence order and on an *ultra vires* substantial equivalence power. As recently as 2006, Schultz and Kahan blocked shifting control of the issue by qualified and impartial toxicologists in favor of retaining supremacy of dentists – persons who are not qualified to judge toxicity to the brain and fetus and who have an egregious conflict of interest. By keeping Runner in charge, Kahan certainly knows that her ruling means no warnings to America's parents and no ban on mercury amalgam even for pregnant women. To justify that decision, Kahan made the sham claim that "placement" in the teeth (an issue not in doubt since the 1800s) trumps toxicological harm to children and the unborn.

[3] Perhaps anticipating an investigation at some point, the two top officials of the Center may have constructed an alibi wall by either directing that no documents be sent to them or discarding them as they arrived. We remain puzzled that, in our repeated FOIA requests, neither Schultz nor Kahan produced a single document – an implausible scenario for a controversy that has involved media interviews, Congressional testimony, meetings, petitions, and thousands of public comments.

These "approvals" are void *ab initio* – not only were improper administrative procedures used by the Center for the "approvals," but the Court of Appeals found, as a matter of law, that a pre-amendment device could never be the subject of an order deeming it substantially equivalent to a pre-amendment device, Thus, **mercury amalgam is being sold illegally in interstate commerce**.

Lin and Runner's acts of subterfuge to get a favored product on the market, and Schultz's and Kahan's approval or acquiescence, merit consideration of either firings or at least removals from their present positions of leadership. It is not hard to envision the potential of personal liability exposure because of the children they have harmed by *ultra vires* approvals – in lawsuits filed timely by their parents – or lawsuits filed decades hence when they come of age and can assert their rights on their own. Nor can one rule out an investigation of an alleged criminal conspiracy – which would depend on factors such as knowledge, intent, and outside financial ties. Thus, **any** further involvement by Schultz, Kahan, Lin, or Runner in regulating mercury amalgam raises **severe questions of conflict of interest**. The public interest mandates that those given the power to regulate not have a vested interest to protect themselves, to ratify the *status quo ante* which could in turn protect themselves from disciplinary action, civil actions, or investigations.

Thus, **you must immediately remove Schultz, Kahan, Lin, and Runner from any role in decision-making involving mercury amalgam**. The decision on mercury amalgam must be made in the Commissioner's office, not in the Center. And the Commissioner and Chief Counsel must act forthwith, getting these falsely approved devices off the market now – lest the very integrity of FDA's approval process be called into question.

II. Having admitted the science on mercury amalgam is in equipoise, FDA must immediately halt its use – at least for pregnant women and children

Five times in FDA's brief, you advised the U.S. Court of Appeals that FDA doesn't know if mercury fillings are safe or unsafe:

- Admission: "there is a lack of conclusive evidence regarding the health effects of mercury fillings" (FDA brief, p. 18);
- Admission: "constantly changing scientific evidence" exists on mercury amalgam (*Id.*, p. 39);
- Admission: "complex issues and intense disagreement [exist] about the scientific evidence regarding mercury and its potential health effects" (*Id.*, pp. 40-41);
- Admission: "the complexity of the issue and the lack of conclusive scientific evidence on the health effects of dental amalgams" (*Id*., p. 41);
- Admission: "the lack of … definitive scientific evidence." (*Id*., p. 41).

In the FDCA, no regulatory category exists for "we don't know" or "we can't make up our minds." A drug or a device that is not safe must not be sold. Since you have told the Court that the science is "constantly changing," not "conclusive,"

"complex" and subject to "intense disagreement" by scientists, **you have de facto decided it is not in the "safe" category – hence it must be removed from commerce**.[4]

Having declared itself uncertain, for FDA to leave a mercury implant on the market even for a day, without a ban for children and pregnant women (100% of the world's scientists know that mercury can permanently injure the developing brain of a child or fetus), is reckless, immoral and illegal. Any other course of action but immediately stopping its use for pregnant women and children – if not for everyone -- calls into question FDA's integrity, FDA's compliance with the FDCA, and FDA's very reputation for protecting the public health.

Some at the Center still lobby to adopt its discredited 2002 rule – which claims the "most notable" reason amalgam is safe is its longevity [!]. To adopt such nonsense is against the science (per the Advisory Committees), against common sense,[5] against the law – and a shot across the bow at America's children. It violates the law six ways: (1) the Scientific Advisory Committee rejected its 1993 position by its vote in 2006, and must be called back for a recommendation; (2) the old vote in 1993 is not valid because it never listed reasons to depart from the presumptive Class III, a legal requirement before a II can be considered by the Commissioner; (3) the time since the 1993 vote has shown mercury toxicity is a major problem – especially in the American population of fertile women; (4) no Environmental Assessment was ever performed, nor even a Finding of No Significant Impact of mercury amalgam in the environment, despite the notoriety of amalgam as the leading source of mercury in America's wastewater; (5) the 2002 proposed rule claimed that the science was enough settled to move forward, but the FDA's admissions to the Court of Appeals rescind that position; and, (6) it is impossible for the Commissioner to provide reasonable assurance of safety without committing a fraud on the court, given what you advised the Judges in FDA's February brief to the Court of Appeals. Its adoption, then, would be a singular sign of bad faith.

Commissioner, you are getting horrid advice. For example, to justify a claim that mercury amalgam is still needed, your letter to Senator Enzi last year cited two studies from the 1980s [!] – evidence the Center for Devices is stuck in the previous generation of dentistry.[6] Tens of thousands of American dentists could tell you something the Center conceals: (1) the dental profession has changed dramatically in the past two decades, and (2) new patents on resin make its use interchangeable with mercury. You are also badly served by the Center's rhetoric endorsing the results of the notorious BETAH/LSRO contract. Director Feigal tried to get the Center to contract for an

[4]Since your statements, so plainly at odds with the Center's amalgam rhetoric, are undoubtedly made in good faith and not as a litigation tactic, certainly you won't allow the amalgam advocates to regain ascendancy and, on behalf of FDA, renounce, "qualify," or "explain" what you told the Court. Such could well constitute a **Fraud on the Court**.

[5] Dr. Runner's clever method to hide the mercury from America's parents and pregnant women is, in the draft Special Controls, to mandate disclosing only zinc (of course, a nutrient). Even Dr. Alderson, who led the presentation for the repudiated "white paper," told me he disagreed.

[6] Perhaps such living in the past is due to dentists at the Center building their careers so closely around "winning" the amalgam battle. In a Kafkaesque move, Dr. Runner even wrote a memo proposing that the Center assemble an "Amalgam Vigilance" committee to rally support for continued use of mercury in dentistry.

independent study on the amalgam literature, but that project was sabotaged from within.[7]

III. Notice of Potential Liability Exposure to Norris Alderson, Linda Kahan, Chiu Lin, Randall Lutter, Mary Susan Runner and Dan Schultz

It appears that the Center's leadership may view this all as a litigation game, that as long as their lawyers can win victories on procedural grounds, they have *carte blanche* to continue their reckless ways: approve mercury amalgam applications on sham pretenses and without legal foundation, handpick favored consultants in disregard of the Federal Acquisition Regulation, obtain and promote pre-cooked literature reviews, defy their duties under the National Environmental Policy Act, issue false consumer updates, hide the mercury from American parents, adopt a professional courtesy posture allowing dentists to be in charge over real scientists, ignore the rejection by two Scientific Advisory Committees of its laissez-faire attitude on mercury amalgam in children and pregnant women, promote the pseudo-science that the top risk for children from mercury exposure is an "allergy" (instead of brain damage), and adopt a mercury exposure position absolutely at odds with the rest of FDA.

The question is no longer whether the Center for Devices will reform from within – it won't. The question is whether you, Commissioner Eschenbach, will rein in this rogue bureaucracy. Perhaps up until now you could have claimed to Congress, the White House, or the courts that you did not know what was going on at that Center; as of today, April 19, 2007, such is no longer the case.

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[7] In a particularly insidious venture, FDA announced in 2002 that it would contract for an independent review of the literature regarding health risks of mercury amalgam – then the Center proceeded to insure there was no independent review at all. Officials from FDA's Dental Devices Branch joined with the dentist-run arm of NIH, the National Institute of Dental and Craniofacial Research ("NIDCR"), and conspired to circumvent the Federal Acquisition Regulation statute in order to get a result reinforcing their position. As the contractor to do an in-depth scientific review, they selected a patently unqualified "meetings planner," doing so because that consultant had an existing government contract. To get this unqualified meetings planner BETAH the contract, they called the study a "conference," because that is what BETAH had contracted to do for NIH. BETAH, as the mere strawperson, was instructed to hand the work (and most of the money) to FDA/NIDCR's handpicked choice, tobacco consultant LSRO. Federal officials had secret meetings with LSRO to see if LSRO would cooperate in the NIDCR/FDA agenda; in one, they gave LSRO a blueprint of the result they desired. To block scientists with real expertise, NIDCR-FDA ordered that no panelist be appointed who had done research on mercury amalgam, the very opposite of what government panels are supposed to be. Greatly concerned, Chairman Burton (R-Ind.) and Ranking Member Watson (D-Calif.) of a House Government Reform Subcommittee wrote the NIDCR Director Tabak – who provided misleading, and at one point false, testimony about how the contract was procured. The two House members then wrote NIH Director Zerhouni, who to his credit appointed a national CPA firm to conduct an independent investigation. Even then, the subcontractor, LSRO Inc., in order to get the result its FDA patrons wanted, used legerdemain by inverting the research question – from evidence of risk to proof of harm – and thus violated the contract terms as well as engaged in intellectual dishonesty. When presented with evidence of wrongdoing, the contrast between NIH and FDA is instructive -- NIH conducts an independent investigation, while FDA refuses to investigate (this was when FDA had a different Commissioner and a different Chief Counsel). The CPA firm prepared a 13-page report of its investigation … NIH is holding it until finalized, but admits that it names names of federal officials. Since those names may include officials at the Center for Devices, it is essential that FDA's Chief Counsel obtain that CPA report and see if any FDA officials were engaged in wrongdoing.

The final straw, patently, is **the outrageous FDA position of admitting to the Court that the science is in equipoise while continuing its policy of untrammeled use of mercury fillings, without warnings, for pregnant women and children**. Such a policy is a reckless disregard of the health of America's children, born and unborn. It is **discriminatory against children, the poor, and racial minorities** as well, because white middle-class adults rarely get mercury fillings any longer, while these categories generally still do.

Protection for federal employees from liability is generally merited at FDA, because overwhelmingly FDA employees are conscientious civil servants who should merit public praise. But limits exist.[8] The following persons are hereby put <u>on notice of potential liability exposure</u>: Norris Alderson, Linda Kahan, Chiu Lin, Randall Lutter, Mary Susan Runner and Dan Schultz. Each is aware of this outrageous anomaly between FDA's position in Court and FDA policy toward children and young women, aware of (or participants in) the ongoing malfeasance at the Center for Devices, and in a position to take corrective action – yet each, with reckless indifference to their duties and to the health of children and the unborn, allows this dichotomous situation to continue.[9]

For Lin and Kahan, because of their lawless "approvals," and for Schultz and Kahan, because of the blinders they put on, liability exposure could exist not just for failing to address the current situation but past multiple acts of malfeasance. It could develop, however, that <u>civil</u> liability could be their lesser concern.

The solution, at least for Lutter and Alderson (I want to make clear here that neither man is part of any pre-2007 malfeasance), should be obvious: bring FDA policy in line with its admissions to the Court about the science. First, ban it immediately for pregnant women and children; second, phase it out altogether. If the Commissioner disqualifies Schultz, Kahan, Lin, and Runner from participating in the decision, as he should, then such a solution is <u>likely</u>, because it is consistent with the rest of FDA policy.

<u>Summary</u>: The Commissioner needs to choose between (1) compliance with the law vs. covering for errant colleagues, (2) children's health vs. dentist economics, and (3) the integrity of an agency committed to ending mercury vs. special privileges accorded a mercury-using special interest group by the Center for Devices.

Except for the remaining pro-mercury dentists, the Center for Devices stands alone on mercury amalgam – (1) against EPA and the CDC, who warn against mercury exposure; (2) against the other Centers at FDA, who opposes mercury-based products; (3)

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[8] The Supreme Court has held repeatedly that officials who act maliciously, in bad faith, or in wanton or reckless manner may be sued personally. *See, e.g., Buckley v. Fitzsimmons*, 509 U.S. 259, 113 S.Ct. 2606 (1993); *Burns v. Reed*, 500 U.S. 478, 111 S.Ct. 1934(1991); *Kalina v. Fletcher*, 522 U.S. 118, 118 S.Ct. 502(1997). Generally, public employees may be liable for, and public official immunity is not a defense with regard to, the commission of intentional torts; in this regard, statutes granting immunity from tort liability to certain public officials sometimes specifically provide that they do not apply to intentional torts committed by such officials.

[9] Immunity may not exist for discretionary acts of public officers or employees which are performed willfully, with malice, or with corrupt motives.

against other modern health systems, who ban its use for children and pregnant women; (4) against its own Scientific Advisory Committees, who repudiated its position; (5) against manufacturers of filling materials, who have positioned themselves for the anticipated ban; (6) against modern dentistry, who use non-toxic materials.

But for the continued injuries they risk daily to unborn babies, children, and hypersensitive adults for their wanton recklessness, their circle-the-wagon responses would be viewed as downright comical: recycling news releases from the American Dental Association, hiring tobacco consultants to ratify their position, forming Amalgam Vigilance committees to man the barricades, defending amalgam as safe because it's been used for 100 years, etc.

The Supreme Court, in *Medtronics v. Loehr*, called the Center for Devices "FDA Neglected Child." Correct. Years of the Center remaining unsupervised by past Commissioners has resulted in this amalgam debacle.

Commissioner, we believe you believe that children and unborn children are more important than covering for dentists unwilling to practice 21st century dentistry; that those who falsely claim you issued a substantial equivalence order should be disciplined, with the fruits of their sham "approvals" being voided; and that FDA must be consistent in its regulating of mercury exposure. Certainly children deserve at least as much protection from mercury exposure as horses or dogs.

The Center for Devices has made its choice. **Now it's time for you to make yours**. Take amalgam off the market. Or ban its use for pregnant women and children. Now. Please reply within 15 days – by May 4.

Sincerely,

Charles G. Brown
National Counsel

cc: Rep. Henry Waxman, Chairman, House Government Reform Committee
Rep. Dennis Kucinich, Chairman, Domestic Policy Subcommittee of Government Reform Committee
Rep. Diane E. Watson, Member, House Government Reform Committee
Rep. Dan Burton, Member, House Government Reform Committee
Rep. Jim Moran, Member, House Appropriations Committee