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

Citizen Petition to FDA

Re: 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

Unique among federal agencies which address mercury, alone among the various parts of FDA which address mercury-added products, and alone among world health agencies who claim to have done completed comprehensive review of mercury amalgam, the Dental Devices Branch of the Center for Devices and Radiological Health continues to trivializing mercury exposure, provide inaccurate and incomplete information about what other bodies are doing about amalgam, and prevent the American people from learning that amalgam is 50% mercury, a virulent neurotoxin. [1] Consider:

- FDA has banned mercury-based disinfectants, issued warnings about mercury in fish for children and pregnant women – and even revoked a horse medicine solely because it contains mercury. While not acknowledging actual health risks for mercury in vaccines, FDA ordered thimerosol withdrawn on the time-tested Precautionary Principle. Amalgam has more mercury than any of these products. [2]
- The Centers for Disease Control in 2005 warned that mercury from amalgam is a major source of mercury exposure, [3] while Dental Devices maintains an old Consumer Update with the opposite position. EPA warns that one woman of childbearing age in six has so much mercury she is at risk of having a retarded child [4] – meaning these millions of American women should have no further mercury exposure whatsoever -- while Dental Devices Branch callously withholds from these women the fact that amalgam, when administered, is a significant mercury exposure.
- Governmental studies of amalgam by Canada, by Sweden, by Germany, and by Norway either call for the elimination of amalgam for health reasons, or for a ban on its use to vulnerable populations – children, pregnant women, adults with

[1] *See* exhibit 1.
[2] *See* exhibit 2.
[3] *See* exhibit 3, *available at* http://www.cdc.gov/exposurereport/3rd/pdf/thirdreport.pdf.
[4] *See* exhibit 4, *available at* http://www.epa.gov/waterscience/fish/forum/2004/presentations/monday/mahaffey.pdf.

2005P-0462 CP1

kidney problems. Dental Devices false characterizes these studies as stating otherwise, or for making the recommendation for environmental reasons.

- Rather than advise the public about mercury exposure from amalgam, Dental Devices has proposed a regulation to cover it up, instead absurdly claiming that the health risk from mercury amalgam exposure depends on whether one is "allergic to mercury," [5] a cruel hoax that buries the fact that the harm of mercury is neurological based on its bioaccumulative toxic effect (a point universally recognized by all but dentists aligned with the American Dental Association) -- not whether one has a skin reaction that week.

The chief of the Dental Devices Branch cites in her draft 2002 regulation that the "most notable" [6] reason to block warnings about mercury exposure is the scientifically preposterous rationale that they have been used for a long time (such argument kept cigarettes warning free for decades). Also in 2002, she revised the Consumer Update, withdrawing valuable health information, based on secret ex parte contacts with the American Dental Association and California Dental Association, at a time when the Federal Register stated comments were to be submitted to a public record. [7] Yet she would not change the update when asked to after the Swedish study, [8] instead withholding that information. In its zeal to protect the fillings used by its profession from public scrutiny or even public knowledge, Dental Devices spearheads an "Amalgam Vigilance" committee,[9] a group which shamelessly advocates the pro-mercury position, and even the unscientific pro-amalgam rhetoric, of the American Dental Association. The ADA is a trade group focused on product promotion as much as on representing dentists; the ADA acquired patents on amalgam and has unethical pay-to-play endorsement contracts with amalgam manufacturers where the ADA claims it has tested amalgam and found it "safe and effective," even though in fact the ADA conducts no such tests. [10]

Dental Devices has succeeded in its decades of cover-ups. A Zogby poll shows that only 40% of Connecticut voters know that amalgam contains mercury; almost none know that that amalgam is actually half mercury. [11]

Members of Congress, giving up on waiting for FDA to do its traditional role of banning products loaded with toxins, have introduced a bill to ban the material directly [12] – that Congress is considering banning a product because FDA won't protect the public should shame the agency.

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[5] Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy, 67 Fed. Reg. 7620 (proposed Feb. 20, 2002) (to be codified at 21 CFR pt. 872).

[6] *Id.*

[7] *see* Exhibit 5.

[8] *see* Exhibit 6.

[9] *see* Exhibit 7; The dictionary defines "vigilance committee" (and remember this is the term used by the chief of the Dental Devices Branch, not our term) as "a volunteer group of citizens that without authority takes on itself powers."

[10] *see* Exhibit 8.

[11] *see* Exhibit 9.

[12] *see* Exhibit 10.

In its latest action, Dental Devices circumvented the Federal Acquisition Regulation by spearheading the highly inappropriate BETAH/LSRO deal – handpicking a consultant, handing it a blueprint of the desired result, shoehorning in an unqualified meetings planning company as strawperson contractor, then allowing LSRO to approach the study Jeopardy style: get the answer from the Vigilance committee's blueprint, then seek a question to match it. While NIH is conducting an independent, formal investigation of this contract for irregularities, [13] Dental Devices praises the study and withholds from Senators the fact that NIH is conducting this investigation.

In addition to such an abysmal track record, the simple fact is that dentists simply should not be assigned to regulate mercury fillings – they have an "inherent conflict of interest" (Senator Lautenberg's characterization) [14] and are neither trained nor qualified to determine if mercury harms the brain of a child, the developing fetus, or the kidneys of an adult.

Thus, the undersigned submits on behalf of Consumers For Dental Choice, Inc. (Consumers), Charles G. Brown, Esq. General Counsel, seeking (1) change jurisdiction over regulating mercury amalgam <u>from the CDRH Dental Devices</u> to the much more qualified, and disinterested, <u>Division of General, Restorative and Neurological Devices</u>; (2) shift jurisdiction over this same product from the Dental Devices Panel – composed of 80% dentists, likewise far less qualified, likewise having an inherent conflict of interest, and who acted in lockstep with the American Dental Association when it last examined the issue over a decade ago – to the much more qualified, and disinterested, Clinical Toxicology Devices Panel; and (3) public hearings and public comments denied under because Dental Devices has an open door solely to the ADA but one shut to bona fide scientists with experience researching amalgam toxicity, and consumer groups seeking public accountability.

The undersigned submits this petition under 21 USC § 393, and 21 CFR §§ 3.1, 3.4, 14.40, 19.6, and 10.30 to request the Commissioner of Food and Drugs, along with the Ombudsman of the Center for Devices and Radiological Health, to initiate a transfer of regulatory and classification responsibilities over amalgam

<u>A. Action Requested</u>

(1) Transfer Regulatory Responsibility **from** Dental Devices Branch, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
to *Division of General, Restorative and Neurological Devices*

(2) Transfer Classification Responsibility **from** Dental Products Panel **to** *Clinical Toxicology Devices Panel*

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[13] *see* Exhibit 11.
[14] *see* Exhibit 12.

(3) Pursuant to 21 CFR §10.30(h)(1) & (2), a meeting and public hearing at which time we can present our general and scientific evidence

B. Statement of Grounds

First Request: Transfer Regulatory Responsibility for Mercury Amalgam to General, Restorative and Neurological Devices

The regulation of mercury in dental products is a generation behind the rest of FDA, which recognizes and addresses mercury toxicity. This situation will not change as long as dentists are allowed to set the policy on whether mercury vapors can damage the fetus, the child's brain or the adult's kidney. Whether because of the "inherent conflict of interest" stated by Senator Lautenberg, or the inadequate training compared to toxicologists or physicians, or the intertwined role of the American Dental Association in setting policy (a point we have documented in our complaint to the Office of Internal Affairs), Dental Devices Branch must be stopped from regulating amalgam.

First, Dental Devices fails to inform the public that amalgams are approximately 50% mercury[15] Instead, it proposes that amalgam products be accompanied with labeling that lists all ingredients. This, the Agency offers, would make the clinician "aware of all materials he/she is placing in a patient's mouth." [16] However, dentists are already aware of what they are placing—they have known since dental school that the primary ingredient in amalgam is mercury. The problem is that consumers are unwittingly led to believe that their fillings are indeed "silver," and are not told that each amalgam contains a half-gram of mercury. [17] Historically, dentists have not told their patients that amalgam contains mercury; thus, it is expected that mandatory ingredient labeling would be merely superfluous. In order that FDA's mission of "protecting the public health," [18] be met, it is imperative that consumers know what they are getting at the dentist's office. Dental Devices has abdicated its responsibility in this regard.

Second, Dental Devices has misled the American people about the health risks of mercury amalgam. It claims that a major concern of using amalgam is "allergies," [19] which represent an immediate and shallow reaction. While Consumers recognizes that allergic reactions like oral lichen planus [20] is no small matter, they are often indicative of a larger, systemic malaise. The Branch fails to consider the bioaccumulative and permanent health effects of mercury exposure from amalgam. [21] As such, patients do not have a real appreciation of the health risks associated with using amalgam. The Division of General, Restorative and Neurological Devices is the better choice for assessing the safety of a restorative device containing mercury.

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[15] *see* infra, note 1.
[16] *see* infra, note 5.
[17] *see* infra, note 2.
[18] *see* Exhibit 13.
[19] *see* infra, note 5.
[20] *see* Exhibit 14.
[21] *see* Exhibit 15, page 25.

Third, Dental Devices, and M. Susan Runner in particular, have shown a remarkable lack of independence in carrying out their statutory duties. On February 20, 2002, FDA issued a proposed rule that would, *inter alia*, classify mercury amalgam as a class II device. There were "plenty" [22] of comments on the rule, probably numbering in the thousands. Most of these comments were submitted by "anti-amalgam advocates." [23] At this point, the deliberations on amalgam were public. What was not public, however, were phone calls made from the ADA and California Dental Association to Dr. Runner requesting that she "correct" FDA's Consumer Update on Dental Amalgams. Both groups were concerned that the old version would "be taken the wrong way." At their bidding, and as a result of this *ex parte* communication, Dr. Runner made the requested deletions. [24] It is unlikely that "anti-amalgam advocates" could ever enjoy similar access. Indeed, the present Consumer Update is rife with "inaccuracies;" [25] yet, an anti-amalgam professional association, like the International Academy of Oral Medicine and Toxicology, would be hard-pressed to garner the same agency response. Dental Devices cannot be trusted to regulate amalgam, not when the American Dental Association appears to hold veto power over Agency work-product.

Furthermore, Dental Devices has repeatedly disseminated false and misleading information about international and domestic studies. The Branch maintains that the World Health Organization (WHO) considers amalgam "safe and cost-effective." [26] However, Dental Devices took this from a WHO draft committee report and it thus cannot be relied upon as WHOs official view. In fact, WHO supports an eventual ban on mercury amalgam, and promotes mercury-free alternatives. [27] If amalgam were safe for people and the environment, as Dental Devices maintains, WHO would not look to replace it. Dr. Runner also wrote in the Consumer Update that Health Canada agrees that amalgam is safe and effective. [28] This is misleading. Health Canada's official statement is as follows:

> The statement states that current evidence does not indicate that dental amalgam is causing illness in the general population. It also says that a ban is not justified, and neither is the removal of existing sound amalgam fillings. The Department recommends that dental amalgam not be used in people allergic to mercury, those with impaired kidney function, or in contact with existing metal devices, such as braces. The Department also recommends, that whenever possible, amalgam fillings should not be placed in or removed from the teeth of pregnant women and that alternatives should be considered for use in the primary teeth of children. It also makes a number of recommendations to dentists about technique and handling of dental amalgam. The statement emphasizes that dentists should be providing their patients with sufficient information to make an informed choice regarding the material used to fill their teeth. [29]

Health Canada does not say that amalgam is safe and effective. They decline to say anything regarding the safety of amalgam. Dental Devices also asserts that the Quebec

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[22] *see* infra, note 7.
[23] *Id.*
[24] *Id.*.
[25] *see* Exhibit 16; note 7.
[26] Consumer Update: Dental Amalgams, *available at* http://www.fda.gov/cdrh/consumer/amalgams.html.
[27] *see* Exhibit 17.
[28] *see* infra, note 26.
[29] *see* Exhibit 18.

Report on Amalgam, the product of a directive from the legislature, exonerates amalgam.[30] The truth, however ambiguous, is below:

> [T]he mainstream scientific view holds that mercury exposure, even the very low levels attributable to dental amalgam, might be affecting people adversely, but the evidence currently available is inadequate to determine if this is the case." "To date, no large studies of people whose main exposure is from dental amalgam have been carried out... Therefore, the existing evidence is weak, but the information base is inadequate to conclude that dental amalgam has no effects that might be of concern.

Fifth, Dental Devices failed to warn pregnant women and children about mercury exposure from mercury amalgam. While FDA has done well in some cases by going at it alone, [31] it appears the Agency has failed to take a look at the informed consent developments in the international regulation of amalgam. An increasing number of countries, including Canada, provide contraindications that may contain warnings for pregnant women, children, or people with kidney problems. Dental Devices might have done well by beginning to look at the informed consent issue. The best they could do was to have ingredient lists placed on amalgam labels; the new labels, however, were never meant to make it to the patient.

Dr. Runner also participated in the LSRO/BETAH amalgam literature review. It appears she helped pick an unqualified meetings coordinator to conduct a scientific literature review to determine whether there were any health risks associated with amalgam. It also appears that the results of the review were preordained, with her input. Dr. Runner, along with the Dental Devices Branch, helped hire a contractor they knew would do a sham review of the literature. [32] This contract is now being investigated by the National Institutes of Health. Less surprising, a similar German literature review was being done at roughly the same time, with vastly different conclusions. [33]

Sixth, Dental oversight of amalgam, according to Senator Lautenburg, is "an inherent conflict of interest." [34] The American Medical Association does not endorse products for ethical reasons. [35] However, the ADA appears to consider product endorsement a cornerstone of its operations. [36] The ADA signs endorsement contracts with amalgam manufacturers, and then represents that the device is safe based on ADA testing. Despite having lavish laboratories, ADA has never conducted a known safety study on amalgam. Considering ADA's access to Dental Devices, FDA must remove ADA-affiliated dentists from oversight roles in amalgam issues.

Seventh, to hand control to the Division of General, Restorative and Neurological Devices makes sense. It has responsibility for any kind of device, hence its name, and it has expertise in neurological devices. The health risks of mercury fillings, first and foremost, are neurological. Vapors from the mercury amalgam start only inches from the

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[30] *see* infra, note 5.
[31] For example, FDA requires that devices be effective for their intended uses. Europe only requires that devices be safe and well-made.
[32] *see* infra, note 9.
[33] *see* Exhibit 19.
[34] *see* infra, note 14.
[35] *see* Exhibit 20.
[36] *see* Exhibit 21.

brain and emanate there. So this Division can address amalgam both as a general device and as one with significant neurological dimensions. Furthermore, it has much greater expertise, and lacks the inherent conflict of interest of the dentist-run branch.

FDA can transfer product oversight responsibilities from agency component to another. The Agency did it with therapeutic biologics, [37] and they can do it with combination products, certainly where a device should be assigned "to the agency component with the most expertise related to the most significant safety and effectiveness questions presented by the combination product." [38] Aside from the failures of Dental Devices, and the questionable performance of Dr. Runner in her role as chief, the fact that amalgam contains not insignificant amounts of mercury warrants a major shift in oversight responsibilities. Dentists are not toxicologists, or neurologists. They can tell you that amalgam is effective and durable. But they cannot reasonably tell the American public that the probable benefit of using amalgam outweighs its risk. A Dental Devices Branch run by organized dentistry cannot tell the American public that there is a reasonable assurance that the device is safe and effective. They cannot, because amalgam is half-mercury. Instead, an agency component with experience in mercury toxicity should regulate the product. To that end, we request that the *Division of General, Restorative and Neurological Devices* be responsible for regulating mercury amalgam, unless there is an agency component even better situated to address the toxicological concerns associated with mercury.

Second Request: Transfer Classification Recommendation Responsibility to Clinical Toxicology Devices Panel

The Dental Products Panel is the wrong panel to classify encapsulated mercury and amalgam alloy. Instead, a panel with demonstrated expertise in mercury toxicity needs to review its safety before a proper classification can be made. Toxicologists are better able to assess whether mercury from amalgam causes neurological harm, injures an unborn fetus, or interferes with the proper function of the kidneys.

Five of the panel members are dentists, and thus have a natural aversion to considering potential health risks associated with amalgam placement. Another member is an oral surgeon, while another is a professor of dentistry. Seven of nine panel members are in organized dentistry, a profession that has never produced a known scientific paper proving that amalgam is safe. Another member is general counsel to a manufacturer. And the non-voting consumer representative was a social scientist. It is impossible for this group to, pursuant to 21 CFR §860.1, determine the safety of encapsulated mercury and amalgam alloy.

Furthermore, 21 CFR §14.40(f)(2) requires that the panel be "balanced in terms of the points of view represented..." The regulations also require that the panel include a representative of the "public interest." [39] A panel comprised of dental professionals with no known expertise in mercury toxicity, which are presumably affiliated with the ADA, cannot be considered balanced.

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[37] FR notice, 6.26.03
[38] 21 CFR §3.4
[39] 21 CFR §14.40(f)(5)

have been shown in some studies to decrease kidney and immune function, and to increase the number of antibiotic resistant bacteria in the GI tract. While the full health impacts of long-term low doses of mercury are unclear, preclinical symptoms of mercury poisoning have been observed in some study populations. While many questions remain unanswered, the emerging scientific evidence of the risks posed by exposure to mercury from amalgam fillings warrants a proper scientific assessment, as millions of people may be affected.

Third Request: Have a meeting to learn the emerging science, and have a public hearing so experienced scientists and consumers may at long last participate in the amalgam decision-making process.

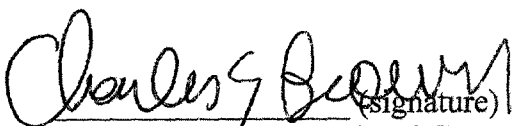
Consistently, FDA has turned first and foremost to the ADA and its allies in organized dentistry for input on its mercury amalgam polices. Excluded are (1) scientists such as Boyd Haley (University of Kentucky), Vascken Aposhian (University of Arizona), Ann Summers (University of Georgia), and James Adams (Arizona State University), who have researched the toxicity of mercury; (2) dental societies which advocate mercury-free dentistry, such as the International Academy of Oral Medicine & Toxicology and the International Academy of Biological Dentistry & Medicine; (3) victims of mercury toxicity from amalgam; (4) consumer groups. The LSRO study was the culmination of this exclusionary policy – replete with meetings behind closed doors but which allowed the consultant for the largest amalgam manufacturer to appear and testify secretly.

C. Claim for Categorical Exclusion

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

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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