

Consumers for Dental Choice

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following twelve reasons, the draft regulation absolving mercury-based dental fillings of adverse health risks must be withdrawn: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

- (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 in 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.

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

_____ (signature)

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