

Consumers for Dental Choice

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To: FDA Public Record


Re: Meeting on Neuro-toxicity of Dental Mercury, September 2006

Mercury Amalgam – Unneeded, No Benefits, Not Legally Approved – and Absolutely Unjustified in the 21st Century

The failure to classify, require proof of safety, warn about, and otherwise to regulate mercury amalgam hangs like an albatross around FDA's neck. As long as FDA's agenda focuses on **protecting the pro-mercury dentists** instead of **properly regulating mercury amalgam**:

- FDA cannot claim it makes decisions by the most qualified scientists as long as dentists – unqualified and lacking in ability to determine toxicological harm to the nervous system – are in charge of mercury amalgam policy.
- FDA cannot claim it is concerned about mercury exposure to children when the single largest exposure goes untouched.
- FDA cannot claim it acts free of special interest dominance when its staff gives a veto to organized dentistry over its Consumer Updates and pretends that “allergies” are the only side effect of exposure to the single most virulent neurotoxic element.
- FDA cannot claim it needs a larger budget when its Dental Devices Branch simply refuses to do its duty to order an Environmental Impact Statement.
- Most serious of all, FDA is losing its mantle of the world's Gold Standard by being last in protecting children and unborn children from mercury implants that cause mercury to go to the child's developing brain and to the fetus.

Encapsulated mercury amalgam occupies a unique, privileged – and illegal – regulatory status at FDA. Known deceptively as “silver” fillings, it is primarily (43-54%) mercury, an acute neurotoxin. Each filling contains as much mercury as a thermometer; dumping just one in a 10-acre lake would make it off-limits to fishermen. Mercury's well-known health and occupational risks – plus the fact that non-toxic filling options are readily available to fill any cavity – divides dentistry into vociferous pro-and-con camps. Under pressure to choose, FDA ducked¹ – defying its statutory duty to classify “all devices” “in a timely manner.” After classifying all other fillings in the 1980s, FDA used a back-door scheme to keep amalgam on the market “temporarily,” then in four cycles of false promises and stall tactics – with a potential fifth beginning April 3, 2006 – acted to protect this illegal status quo.

Encapsulated dental amalgam arrives at a dentist's office with  affixed next to the words “POISON, CONTAINS METALLIC MERCURY.” Mercury, the warning

¹ Hearing before the Committee on Government Reform, Nov. 14, 2002, “Mercury in Dental Amalgams,” Serial No. 107-159, www.house.gov/reform; at p. 125

“Mr. Burton [Chairman, Committee on Government Reform]: Is that a correct statement, the FDA classified all dental filling materials except encapsulated mercury amalgams?”

“Dr. Feigal [Director, Center on Devices and Radiological Health, FDA]: That is correct.”

states, is a “potentially hazardous substance” with “**neurotoxic/nephrotoxic effects**”²; “a chemical **known to the state of California to cause birth defects** or other reproductive harm.” The major amalgam manufacturers -- Kerr, Dentsply, and Vivadent -- tell dentists in writing, **Do not place amalgam in pregnant women, nursing mothers, children under six, and anyone with kidney disease.**^{3 4 5}

The Center on Devices and Radiological Health not only adopts bad science and bad policy, but on the issue of mercury amalgam. It refuses to classify encapsulated mercury amalgam, even though it classified all other dental materials 20 years ago. It refuses to require proof of safety, instead bypassing the PMA test altogether. Without any factual basis, it uses the PMN via the nonsensical argument that encapsulated amalgam is substantially equivalent to the non-mercury powdery alloy. And the approach is plainly illegal too, because no Commissioner ever issued the condition precedent to such a methodology – an order of Substantial Equivalence. The Center refuses to do an Environmental Impact Statement, avoiding that duty by the circuitous approach of not classifying amalgam and having no pre-market approval!

Examples abound of indifference to mercury exposure to children, contempt for the emerging science, handpicking unqualified consultants to mirror staff viewpoints, providing false information to Senators about Health Canada’s program to keep mercury fillings from children and pregnant women, covering up the mercury exposure, giving a

² Neurotoxic: poison to the brain and nervous system; nephrotoxic: poison to the kidneys.

³ Kerr, the largest mercury amalgam manufacturer in the American market: “The health authorities of the various countries, including Canada, Germany, France, the United Kingdom, Norway and Austria have recommended against the placement or removal of an amalgam in certain individuals such as pregnant and nursing women and persons with impaired kidney function.” (Emphases added.)

⁴ Dentsply/Caulk, the second largest mercury amalgam manufacturer:

“Contraindication [N.B.: “Contraindication” is a directive to forbid, not just a “warning.”]

- In proximal or occlusal contact to dissimilar metal restorations.
- In patients with severe renal [*i.e., kidney*] deficiency.
- In patients with known allergies to amalgam.
- For retrograde or endodontic filling.
- As a filling material for cast crown.
- In children 6 and under.
- In expectant mothers.

“Side Effects/Warning: Inhalation, Chronic: ... In severe cases, hallucinations, loss of memory, and mental deterioration may occur. Concentrations as low and (sic "as") 0.03 mg/m³ have induced psychiatric symptoms in humans. Renal involvement may be indicated by proteinuria, albuminuria, enzymuria, and anuria. ... Intrauterine exposure may result in tremors and involuntary movements in the infants. Mercury is excreted in breast milk. ... The fact that Dentsply/Caulk has placed this information on the Internet, available to the public and professionals alike, has a vital impact on various aspects of the current controversy over the safety of mercury/silver amalgam dental fillings.” (Emphases added.)

⁵ Vivadent, the third largest mercury amalgam manufacturer:

“Contraindication:

- If proximal or occlusal contacts with other metal restorations are present.
- If the patient suffers from impaired renal function.
- If the patient is known to be allergic to amalgam.
- For retrograde or endodontic restorations
- As a material for core build-ups under crowns or inlays.
- For children under six years of age.
- For pregnant or nursing women.” (Emphases added.)

veto to organized dentistry over Consumer Update language, claiming safety based on longevity of use instead of science, and creating the mythology that the risk of this mercury exposure is some kind of “allergic reaction.” On amalgam, the Center on Devices and the American Dental Association are, effectively, one and the same.

Never classified: Although classifying all other dental materials two decades ago as required by law, FDA has never classified encapsulated mercury amalgam – nor has he required that amalgam manufacturers prove the product is safe before introducing it into commerce -- despite mounting evidence of harm to human health and the environment. Marketed under the deceptive term “silver” fillings by the trade association whose policies unduly influence FDA’s Dental Devices Branch, the major component in dental amalgam is mercury (about 50%), a fact that is systematically concealed from dental patients and the public. Because FDA has refused to warn pregnant women and parents of this mercury exposure, its regulatory scheme has kept Americans ignorant that “silver” fillings aren’t really silver and has denied them the right of informed consent. A 2006 poll by Zogby International conducted for the Mercury Policy Project / Tides Center reveals that only 24% of Americans can identify mercury as the major component of amalgam; however, 92% believe dentists should be required to inform them of the mercury in amalgam, and 77% would pay more to get a non-mercury alternative.

An unnecessary device: Mercury amalgam’s continued use is highly controversial for reasons of risk to patient health, occupational exposure, and disastrous environmental impact. In the 21st century, dentists no longer need to implant mercury-based fillings – a remnant of 19th century medicine; any cavity may be filled by alternative, non-toxic materials. The sole advantage of mercury amalgam is its profitability. For the dentist, it is cheap, easy to place, and because of its silvery coloring (for which mercury is commonly referred to as “quicksilver”), it is an easy sell to patients who are deceived into believing that they are getting a “silver” filling. Because FDA joins organized dentistry in being silent about the mercury instead of ordering disclosure, these patients have no way of knowing that the dentist is putting approximately half a gram of mercury in their mouths with each filling.

Thirty years of refusing to classify: In 1976, Congress passed the Medical Device Amendments, requiring that the FDA classify all medical and dental devices. FDA is operating under the mistaken assumption it has an indefinite period (or perhaps an infinite period) to do its duty and classify encapsulated amalgam. While FDA has taken steps – *via* bans, warnings, and other precautionary measures – to protect the public from a range of products with only trace amounts of mercury, it has failed to act on the product that, according to the World Health Organization and peer-reviewed scientific studies, poses the greatest risk of human exposure to mercury: dental amalgam. More than 28 years have passed since an FDA Commissioner ruled that amalgam is an implant – the most scrutinized of all devices -- and must be classified; 16 years since Congress set a five year deadline for FDA to complete its classifying; 14 years since FDA prevailed against a mandamus to classify amalgam in the United States Court of Appeals for the District of Columbia by promising good faith action; 12 years since an illegally constituted FDA Advisory Committee last met and voted on amalgam (since then, a plethora of bans on mercury products has occurred); and 11 years since the Congressional deadline passed. Meanwhile, many Federal and state agencies, as well as health agencies in countries where regulating dental amalgam is not under the control of the very profession that profits from its use (as is the case with FDA’s Dental Devices Branch)

have taken steps to protect vulnerable populations: 15 years ago, the World Health Organization declared dental amalgam to be the primary source of human exposure to mercury; 13 years ago, a U.S. Public Health Service report by the Committee to Coordinate Environmental Health and Related Programs identified “tremor, ataxia, personality change, loss of memory, insomnia, fatigue, depression, headaches, irritability, slowed nerve conduction, weight loss, appetite loss, psychological distress, and gingivitis” as ailments directly associated with major exposure to mercury, and noted that “even low-level or ambient exposure . . . is not likely to provide satisfactory protection for the sensitive portion of the population such as the young, the aged, and the chronically ill”; 10 years ago, the Canadian government directed that nation’s dentists to stop placing amalgam in the mouths of children and pregnant women (because of potential damage from exposure to mercury to the development of normal brain and neurological functions); eight years ago, the United Kingdom banned the use of mercury-based fillings for pregnant women; five years ago, California declared mercury amalgam to be a reproductive toxin and ordered dentists to post signs to warn patients; three years ago, FDA banned mercury in all veterinary products, and last year, the United States Centers for Disease Control declared mercury amalgam to be a major exposure to mercury. Decade after decade, FDA promises to classify dental amalgam. These promises are simply a smokescreen to hide FDA’s complicity in allowing dental interests within the organization – with direct financial ties to mercury producers and amalgam manufactures – to control the regulation of their product.

No Environmental Impact Statement: Mercury from amalgam is one of the three largest sources of this virulent neurotoxic pollutant in the U.S. **Organized dentistry accounts for 22% of the mercury purchases in the United States** (up from only 2% just 25 years ago, because other uses have been restricted or banned). According to the Environmental Protection Agency, one in seven American women of childbearing age has so much mercury in her system that she is at risk of having a brain-damaged child (630,000 babies out of 4 million). By the stroke of a pen, FDA could eliminate a primary source of this human toxin and environmental pollutant. This is precisely what FDA did with Mercurochrome – a product posing far less risk of exposure or environmental damage than amalgam. Ignoring its legal obligation, FDA does neither an Environmental Impact Statement (EIS) nor even a Finding Of No Substantial Impact (FONSI). In January 2006, via Executive Order 13101, a U.S. federal interagency task force recently developed a priority list of chemicals that were identified as potentially resulting in significant harm to human health and the environment and identified product categories where “Environmental Attribute Non-Mercury Alternatives” are available. Included among those product categories was “dental products.” (<http://www.mercurypolicy.org/new/documents/NonMercuryAlternativesUSMilitary0206.pdf>). FDA’s decision for the past three decades to neither classify nor to require independent pre-market approval is based in part on its efforts to try to avoid application of the National Environmental Policy Act – reason enough alone for this Court to order amalgam banned until FDA meets its obligations under law.

I. Bad faith actions by leadership at the Center on Devices

The problem is not a mere occasional error in judgment. **The deceptions, inaction, and malfeasance amount to a pattern of bad faith** -- a transparent agenda to support pro-mercury dentists at the expense of the science, the truth, and the very well-being of America’s children, born and unborn.

Here from (a) to (z) are 26 examples of actions by the Center on Devices and Radiological Health that show a multi-year pattern of bad faith:

- (a) Withholding from the American public that amalgam constitutes **a major exposure to toxic mercury** (according to the US Centers for Disease Control, 2005) or **the major exposure to toxic mercury** (according to the World Health Organization, Criteria #118, 1991, and Health Canada, 1996);
- (b) Avoiding doing an Environmental Impact Statement by claiming falsely and in bad faith that amalgam has no environmental impact, when in fact the mercury flushed from dental offices constitutes **the major source of mercury in America's wastewater** and 100% of the 1000 tons of mercury presently in the mouths of Americans today will end up in the environment eventually;
- (c) Abdicating its duty even to do a Finding Of No Significant Impact ("FONSI"), a condition precedent to avoiding an Environmental Impact Statement;
- (d) Deceiving the American public through issuing deceptive, incomplete, and outright false information in its Consumer Updates about the risks of mercury amalgam;
- (e) Granting veto power to the American Dental Association over language in its Consumer Update;
- (f) Granting veto power to the California Dental Association over language in its Consumer Update;
- (g) Echoing the American Dental Association propaganda that exposure to mercury from amalgam is similar to exposure to dust or pollen;
- (h) Engaging in pseudo-science by insisting that mercury amalgam must be safe because it has been used for a long time;
- (i) Deceiving the Congress by providing false information to Senator Smith and Senator Murray that the Canadian government approves of mercury amalgam instead of the truth: Canada issues contraindications for amalgam in children, pregnant women, and people with kidney problems;
- (j) Refusing to correct the above error despite repeated requests by the nonprofit group Consumers for Dental Choice;
- (k) Engaging in two consecutive bad faith in-house literature reviews on mercury amalgam, conducted by dentists or their handpicked friends to benefit dentistry instead of by toxicologists for the good of the public;
- (l) Violating the Federal Acquisition Regulation by: (a) engaging in a scheme to appoint a patently unqualified meetings coordinator to conduct a scientific review of amalgam literature; (b) handpicking as subcontractor a tobacco consultant; (c) directing that no panelist have experience in researching mercury toxicity; and (d) blueprinting the desired result in advance;
- (m) Accepting and promoting the consultant's report, when FDA knew or should have known the consultant dishonestly flipped the research question -- from the contractual agreement to determine whether evidence of risk exists, to a whimsical system of whether carefully-worded, amorphous hypotheses could prove harm;
- (n) Refusing to investigate these irregularities, even though the Director of the National Institutes of Health (a co-signer of the contract) was so concerned about the wrongdoing he appointed an independent CPA firm to investigate;
- (o) Promoting the above literature review to Congress as a bona fide study, even after being fully apprised of both the NIH investigation and evidence of wrongdoing;

- (p) Working in partnership with the American Dental Association to successfully hide the mercury content of amalgam from the American public through a concerted scheme to call these primarily mercury fillings “silver fillings” (a 2006 Zogby poll found that 76% of those surveyed did not know that mercury was the primary component of amalgams);
- (q) Allowing its Dental Products Panel to recommend a departure from a Class III classification for mercury amalgams without stating a scientific basis;
- (r) Making repeated sham promises of an intention to classify mercury amalgam;
- (s) Creating a sham classification scheme to continue the unapproved sale of unclassified mercury amalgam;
- (t) Unveiling, in 2002, a proposed regulation that could not under any remote scenario pass court approval, but one that allowed FDA’s obfuscating regulatory scheme to continue;
- (u) Adopting policies on mercury amalgam at odds with FDA policies on mercury in virtually all other products;
- (v) Adopting policies and practices on mercury amalgam at odds with the policies and practices on mercury amalgam in virtually all countries with advanced health systems;
- (w) Claiming, knowingly and falsely, that FDA’s policies on amalgam are consistent with the policies of other national health systems;
- (x) Putting dentists in charge of amalgam regulation – persons without the medical training or qualifications to determine the potential health risks from exposure to mercury via amalgam to the unborn child in the mother’s womb, or the child’s developing brain, or an aging person’s kidneys;
- (y) Putting dentists in charge of amalgam regulation – persons with an egregious conflict of interest, due to the ADA’s 150 years of financial interests in promoting amalgam and mercury-using dentists financial interests in continuing to use amalgam and avoiding liability for doing so;
- (z) Approving amalgam even when the manufacturers-applicants disclose and explain the neurotoxicity of their products. In 2005, FDA approved the amalgam product Silverfil, even though the applicant admitted that in its own country, the United Kingdom, **the amalgam product is banned for children;**

FDA regulators, manufacturers, and the ADA are fully aware that to classify amalgam would mean the demise of this dangerous product. Amalgam manufacturer Dentsply, in a 10-Q submission to FDA, concedes that if FDA required premarket approval for mercury amalgam, there would be “no assurance that the required approval would be obtained or that the FDA would permit the continued sale of amalgam filling materials.” Therefore, the pro-amalgam interests running FDA’s Dental Devices Branch have engaged in a joint industry-government campaign of disinformation, making official statements that are **false** (such as that Health Canada supports amalgam use without reservation), **deceptive** (withholding from the public the salient facts that amalgam is mainly mercury and that mercury vapor from the fillings is inhaled by unsuspecting patients), and **pseudo-scientific** (like the tobacco lobby, claiming length of use as proof of safety because amalgam has been around for 150 years). FDA has been complicit in the activities of its Dental Devices Branch, which has taken extraordinary and illegal steps to keep amalgam products on the market – such as appointing a dentist to the sole consumer position on the Dental Products Panel, or engaging in efforts to circumvent Federal bidding laws by handpicking an unqualified “conference planner” to head up a scientific review of amalgam, then directing the conference planner to appoint

a tobacco consultant to run the study. Throughout decades of malfeasance, FDA has granted carte blanche authority on the **regulation of amalgam** to the dental professionals who have profited from the sale and distribution of dental amalgam. The decision-making power about how mercury toxicity might affect the development of the brain or the neurological functions of a young child or a fetus in the mother's womb is in the hands of pro-amalgam dentists with **no medical or toxicological qualifications whatsoever**.

To keep amalgam on the market without ever classifying it, CDRH engaged in a fraudulent classification scheme. Years ago, It classified all other dental filling materials except encapsulated amalgam, then surreptitiously – without asking for public comment and without amending any regulation – decided that amalgam capsules are “substantially equivalent” to the powder, which is merely the non-mercury component (a powdered form of silver, tin, and other heavy metals). According to the traditional system, that powder gets mixed with the mercury in the dentist's office. (That system has now been banned by several state statutes and abandoned by the ADA because of mercury exposure to the dentist.) But what the Center for Devices chooses to call a capsule is not a capsule at all. So this regulation by definition excludes mercury as a component, covers a material that is not contained in a capsule, and does not even become an amalgam product until the dentist mixes it with mercury.

FDA's classification scheme is so convoluted and disingenuous that FDA officials cannot get their stories straight. In a bizarre sequence of e-mails with a consumer in 2003-04, FDA officials claimed three conflicting interpretations of how encapsulated amalgam is classified: classified as a single device substantially equivalent to the non-mercury amalgam alloy; classified as a dual device combining non-mercury amalgam device (Class II) and the dental mercury device (Class I); and, after further inquiry, not classified at all but rather “on hold.” That FDA officials themselves cannot properly reply to a simple consumer inquiry about a classification system with only three categories – I, II, and III – is reason enough for court intervention.

This combination of a sham substantial equivalence test, an apparent decision to delay classifying indefinitely, and the dissemination of false and deceptive information is decidedly at odds with government agency policies on mercury and with FDA policies on other mercury products. Indeed, FDA has acted aggressively to protect the public against other mercury exposures, even in products with only trace elements of mercury, by recommending removal of mercury in most children's vaccines], banning Mercurochrome, banning mercury in treating horses, and giving warnings about mercury in fish. Furthermore, the approach to mercury amalgam is contrary to FDA's *modus operandi*, in which FDA (as its governing statute requires) puts the burden on the manufacturers to prove that their products or devices are safe. Here, though, the FDA has permitted an extralegal operation, run by pro-amalgam dentists with long-standing organizational ties to amalgam, to sit and wait for absolute proof that this **mercury product is unsafe** before changing its regulatory netherworld. The anomalous treatment of mercury-based dental fillings is due to an inherent conflict of interest. The regulated industry is running the regulatory agency. Organized dentistry, with a huge financial stake in the continued use of amalgam, is in complete control of a fraudulent regulatory process, while the Secretary of Health and Human Services, the FDA's Acting Commissioner, and the FDA's Director of Devices and Radiological Health perpetuate a long history of supervisory neglect.

Because mercury is recognized as the most toxic nonradioactive substance on earth – a substance that the FDA has banned in virtually all other uses, including products for animals – the agency’s non-oversight of mercury amalgam is unique, and the consequences are alarming. It means that tons and tons of mercury are unnecessarily added to the environment each year, while FDA assiduously avoids its responsibility to do an Environmental Impact Statement. It means that low-income pregnant women are unaware that getting a “silver” filling results in greater exposure to mercury for their unborn child than eating dozens of tuna fish steaks. It means that a child with neurological problems is receiving an additional jolt of mercury to the brain, a factor that can produce additional, permanent harm.

FDA has now recognized the obvious, ordering these public hearings by a new joint committee to address toxicity – particularly **neurotoxicity** – associated with dental amalgam. The April 3, 2006, Federal Register announcement of these hearings is an acknowledgment that the dental amalgam “capsule” is a device that is **substantially different** from the non-mercury (powdered silver, tin, etc.) alloy, the device under which it is deemed **substantially equivalent**. The announcement is a tacit admission that the previous so-called “substantial equivalence” determinations have no merit. FDA, when it announced the hearing on mercury amalgam, should have simultaneously ordered a ban on mercury amalgam until it is classified or proven safe – or both. Instead, three decades after being mandated to classify, the agency has re-entered a time warp by blissfully returning to the starting point and initiating what may turn out to be more decades of obfuscation in dealing with this harmful, and completely unnecessary, mercury product.

The order of April 3, 2006, amounts to (a) a *sub silentio* admission that mercury amalgam capsules are **not** substantially equivalent to the powdered metals non-mercury components of amalgam; (b) a confirmation that FDA believes it can keep amalgam fillings in its current state of regulatory limbo; (c) recognition that the long-overdue Environmental Impact Statement must take place immediately, or FDA cannot allow sales of the product to continue under the current regulatory system.

Because FDA recognizes mercury is toxic in other uses, and has taken enforcement steps to stop it – even to protect horses – its approach to amalgam is unique and unjustifiable. FDA is violating its duty to classify a dental device – not an unknown or rarely used one, but the one that is placed 70,000,000 times a year in Americans and one that has been the central controversy inside dentistry for decades. FDA’s response – in absolute contrast to its response to mercury in medicines, in vaccines, in veterinary products, in foods – is: Do nothing; favoring pro-mercury dentists ... and grievously harming America’s children.

II. The Mercury Amalgam Controversy

To understand why organized dentistry and its advocates inside FDA fight to protect the marketing of a product that is 50% mercury, two fundamental points must be borne in mind. First, mercury-based amalgam has been the cornerstone of the world’s most powerful dental trade association since the middle of the 19th century. Second, dentistry and medicine began to follow separate – and in many ways opposite – tracks in the 20th century.

Efforts in the first half of the 19th century to establish dentistry as a research-based branch of medical practice appeared promising. In 1840, Dr. Chapin Harris, a staunch opponent of the use of mercury in medical or dental procedures, formed the first national dental organization, the American Society of Dental Surgeons, which was dedicated to the advancement of scientific methods – and opposed mercury use. But the development of mercury-based amalgam fillings changed all that. Unlike Dr. Harris, a significant percentage of the dentists of that time had no medical background and little training. They were often barbers or blacksmiths who filled teeth, or pulled them, on the side. In 1859, an enterprising group of these dentists formed the American Dental Association (ADA) — not to advance the science of dentistry, but for the specific purpose of promoting the commercial use of “silver amalgam-mercury use in dentistry.”

Since then, the ADA has marched in lock step with mercury producers and amalgam manufacturers, marketing the fillings as “silver” to an unsuspecting public (no mention of mercury) and never wavering from the company line that amalgam was “safe.” The product caught on quickly. It was cheap, easy to place, and immensely profitable. The demand for “silver” fillings eventually forced the American Society of Dental Surgeons out of business.

All health professions except dentistry abandoned mercury use. Physician criticism of the use of mercury in medicine – such as by Boston physician / poet Oliver Wendell Holmes Sr. – led to a re-thinking by the medical profession. By the early 20th century, the use of mercury in medicine was on an irreversible decline. While the Merck Manual listed numerous uses for mercury to treat illnesses in 1899, it lists none today. Teething powder containing mercury was banned at mid-century because it was causing “pink disease” in infants – the disease disappeared after the product was banned. Contact lens manufacturers, in cooperation with ophthalmologists and optometrist, pulled mercury preservatives out of contact lenses.

FDA banned Mercurochrome more than a decade ago and, under the “precautionary principle,” ordered mercury removed from most – but unfortunately not all – childhood vaccines.

The ADA has experienced no such scientific awakening. Despite mounting scientific evidence to the contrary, it has continued to insist that mercury fillings are safe, based on the 19th century standard of **length of use** – the same argument that enabled the tobacco industry to keep Federal regulators at bay for decades. The ADA has adopted a similar *modus operandi*.

The ADA is the deceptive promoter of mercury amalgam. Unlike the American Medical Association, the ADA has long been in the business of promoting specific products, the most prominent of which is mercury-based amalgam. The American Medical Association’s position on promoting commercial products is unequivocal: “The AMA does not sanction, endorse, approve, or disapprove products, procedures, hospitals, or clinics.” By contrast, every amalgam patent that has been awarded for decades has been produced according to ADA specifications.

Since the 1930s, the ADA has continuously promoted a wide variety of amalgam products as “safe and effective” through its Seal of Acceptance, **paid for by the amalgam companies with which the ADA has an economic partnership.** Although

the ADA advises dentists and the public that it has state-of-the-art laboratories to determine whether a product is safe, with regard to amalgam, that claim has no foundation. The ADA has never done a single test that it will reveal on the safety of amalgam. The ADA publishes promotional brochures describing the possibility of “rare allergic reactions” and making the scientifically absurd comparison of toxic mercury to substances like pollen or dust.

Due to its three-tiered mandatory membership system, the ADA has much greater market power over dentistry than the AMA has over medicine. No dentist may join a local dental society affiliate or the state dental association without also joining the ADA. Thus, the ADA claims almost 70% of U.S. dentists as members, a percentage greatly exceeding that of physicians in the AMA or lawyers in the American Bar Association. The ADA has used this control to block the emergence of criticism by dentists trying to communicate concerns to patients and the public. In 1988, in a move that protected the power of its existing patents on amalgam, the ADA promulgated within its “Code of Ethics” the infamous gag rule, forbidding dentists from volunteering information to patients about the toxicity of mercury. The gag rule is under challenge across the country, but organized dentistry keeps it in place as it can.

Today, all Federal government-funded research on the health risks of amalgam is run by dentists or other representatives of organized dentistry. The Dental Devices Branch at FDA routinely collaborates with the National Institute of Dental and Craniofacial Research at NIH. Some Members of Congress have voiced strong criticism, pointing out that research and regulation of amalgam’s toxicity is controlled by dentists – professionals whose training does not qualify them to determine the impact of mercury on the body and who have an inherent conflict of interest due to the ADA’s endorsement of amalgam. The pro-amalgam dentists at NIH run the research, and the pro-amalgam dentists at FDA make the rules.

III. FDA Carves Privileged Status for Just This One Mercury Product

Minority-led organizations express grave concern that pregnant women and children, especially at the lower end of the socioeconomic scale, still receive mercury fillings – without even a warning.⁶ Indeed, in this age of widespread awareness and concern about avoiding mercury exposure, the overwhelming majority of Americans don’t even know the fillings are mercury! A 2006 Zogby International poll shows that 76% of voters cannot identify the main component of amalgam. When told the truth, fully 92% said dentists should be required to disclose the mercury in “silver” fillings, and to tell patients they have a choice to get non-mercury fillings.

FDA do-nothing Center on Devices sole agenda is to protect the status quo:

- 1) Rather than correct misinformation that amalgam is “silver,” FDA does the opposite: its “Consumer Updates” cover up the fact that amalgam exposes patients to mercury;⁷

⁶ Resolution of national NAACP (2002).

Resolution of National Black Caucus of State Legislators (2001).

⁷ FDA’s “Consumers Update: Dental Amalgam” of March 2002 was such a puff piece for amalgam that consumer and mercury-free dental groups protested. On re-writing, FDA’s Dental Devices

- 2) Rather than classify amalgam, as the Food Drug and Cosmetic Act (“FDCA”) requires, FDA has “delayed” the decision for 20 years (see Part II);
- 3) Rather than require proof of safety, as the FDCA requires, FDA keeps amalgam on the market without such proof via a Byzantine regulatory scheme even its staff cannot explain the same two times in a row (see Part III):
- 4) Rather than comply with the National Environmental Policy Act to write an environmental impact statement about dental mercury – the largest source of mercury in America’s wastewater, and the nation’s #3 mercury use – FDA repeatedly refuses (see Part IV).

It is a credit to tens of thousands of men and women in the dental profession that they refuse to follow the company line. To protect their patients, their employees, their environment, and themselves from unnecessary mercury exposure, these U.S. dentists implant alternatives like resin; polls show the number of “mercury-free” dentists growing dramatically. **Modern dentists no longer place mercury amalgam**; that’s the good news. The sad news: **the mercury users in dentistry are the assembly-line profiteers who serve the working poor, minorities, and children.**⁸ Polls show a majority of dentists anticipate the demise of mercury fillings, but a plurality still use them because, well, because they’ve always done it that way. The presidents of three national dental societies have filed sworn statements that any cavity of any size or type, child or adult, may now be filled with alternative, non-toxic dental materials, such as resin or porcelain.

In its regulation of other products – drugs, vaccines, food, and even animal medications – **FDA adamantly opposes mercury exposures.** In 1998, FDA banned Mercurochrome, once a popular disinfectant, solely because it had mercury. Four years later, FDA acted to get mercury out of childhood vaccines, based on medicine’s Precautionary Principle. Two years after that, FDA issued warnings to pregnant women and parents of young children about mercury in fish. The reason for the privileged status for mercury fillings is not FDA ignorance – when pressed (e.g., by Congress), the agency admits that amalgam constitutes an exposure to mercury for the whole body, and that mercury from amalgams enters the brain.⁹

Extending its reach to stop mercury exposures, **FDA bans mercury in all veterinary medicines.**¹⁰ FDA ordered Miracle Leg Paint, a salve used for horse blisters, recalled for the sole reason it contained mercury. Contrast FDA’s felicitous concern with

Branch Director secretly allowed the pro-mercury interest groups to veto offending sentences, a fact not discovered until 2005 due to agency resistance to Freedom of Information Act requests.

⁸ See prefatory language to H.R. 4011, a bipartisan bill with over a dozen sponsors.

⁹ “Mr. Burton [Chairman, Committee on Government Reform]: You do agree though that mercury vapors leech out of the tooth?”

Dr. Feigal [Director, FDA Center on Devices]: Yes, we agree with that.

Mr. Burton: And that it is ingested into the body?

Dr. Feigal: Yes, we do agree.

Mr. Burton: And that it gets into the bloodstream?

Dr. Feigal: Yes.

Mr. Burton: And it goes to the brain and other organs of the body?

Dr. Feigal: Yes, we agree with that.”

Congressional hearing, “Mercury in Dental Amalgams,” *op. cit.* fn 1, at pp. 127-8.

¹⁰ http://www.fda.gov/ora/about/enf_story/archive/2002/ch5/cvm1.htm.

the traces of mercury on the outside of a horse's leg with its indifference about literally grams of mercury implanted three or four inches from a child's brain.

International and United States health agencies recognize the biggest bear in the woods when it comes to mercury – for indeed amalgam is that. It is the greatest source of mercury vapor in non-industrialized settings, says the World Health Organization;¹¹ it is the largest source of human mercury exposure, says the government of Canada.¹² In a seminal report on mercury, the U.S. Public Health Service¹³ says amalgams contribute up to 75% of a person's mercury exposure. The Centers for Disease Control¹⁴ warns amalgam constitutes a “major exposure” of mercury. The Environmental Protection Agency¹⁵ issued grim news urging young women to avoid all unnecessary mercury exposures, because one American woman of childbearing age in seven has so much mercury in her body she is at risk of having a brain-damaged child.

Although proclaiming itself the world's “gold standard” in consumer protection, FDA sits on the bottom rung on mercury fillings. One might think the Kerr manufacturer's warning listing a half dozen other countries which forbid amalgam for pregnant and nursing women (footnote 3, *supra*) would embarrass FDA into action. A Swedish government report authored by World Health Organization researcher Dr. Maths Berlin, citing hundreds of scientific studies, concludes,

“The safety factor thought to exist with respect to mercury exposure from amalgam has been erased... . **For medical reasons, amalgam should be eliminated in dental care as soon as possible.**”¹⁶

Health Canada (our northern neighbor's FDA equivalent) wrote every dentist in that nation to stop placing mercury fillings in pregnant women and children under six – not this year or last, but ten years ago.

How could this happen? How could FDA protect even **horses** from mercury exposure from a **salve** on the **outside of their legs** while being the world's slacker in protecting **children and pregnant women** from an **implant** of mercury in the **inside of their heads**? The answer is twofold: dentist control, and absolutely no oversight.

FDA hands regulatory control not to toxicologists or physicians but to persons unqualified to determine the impact of mercury on the fetus, the child's brain, and the

¹¹ http://www.who.int/water_sanitation_health/medicalwaste/mercurypolpaper.pdf; World Health Organization, Criteria #118 (1991).

¹² http://www.mercurypoisoned.com/health_canada.html

¹³ <http://www.atsdr.cdc.gov/toxprofiles/phs46.html>

¹⁴ <http://www.cdc.gov/exposurereport/>

¹⁵ “Estimate of Fetuses Exposed to High Mercury Doubles; The metal becomes more concentrated in umbilical cord blood, EPA notes,” *Los Angeles Times*, Feb. 6, 2004.

¹⁶ Full text -- www.social.regeringen.se/inenglish/publications/index.htm. (Scroll down cover page to “health and medical care,” then open the first item, by Maths Berlin.) FDA's Consumer Update on Amalgam falsely claims that Sweden's concerns are environmental. The National Institutes of Health asked Branch Director Runner to make a correction; she ignored it, choosing to keep this false information in FDA's Consumer Update where it has remained for the past four years.

adult's kidney – dentists. That decision is under fire from Capitol Hill.¹⁷ These dentists – even in formal documents like FDA's 2002 feigned rulemaking – cover up the emerging scientific studies and replace it with pseudo-scientific rhetoric. A prime example: FDA absurdly claims that amalgam's longevity proves its safety!¹⁸ Contrast the rear-guard action of dentistry with that of medicine: the California Medical Association's House of Delegates passed a resolution in 2002 calling for a ban on all mercury products used in health care. Here, then, is dentistry's hapless reality: **mercury amalgam is this nation's last remnant of pre-Civil War medicine.**

Whether due to professional courtesy or indifference, the supervisors at the Center on Devices provide no oversight whatsoever. The evidence of nonfeasance is uncontroverted: (1) Responses from three years of FOIA requests show not one single document to or from Dan Schultz, M.D., Director of the Center on Devices and Radiological Health – or to or from the Deputy Director either -- even though this explosive issue has included Congressional hearings, media attention, and petitions. (2) Letters signed by high-level officials – e.g., from FDA's Assistant Commissioner for Legislation to Senator Murray (Jan. 14, 2005) and to Senator Smith (Feb. 10, 2005) – contain deceptive comments and outright falsehoods about Health Canada, Sweden, the LSRO report, and mercury exposure from amalgam, a sign that the letters were drafted by the same hands writing the Consumer Updates. (3) Instead of vertical supervision, the way an agency should operate, policy has been made horizontally, with a coalescence of like-minded dentists from sister agencies, unfettered by participation by scientists or by supervision from FDA higher-ups.¹⁹

¹⁷ Senator Lautenberg wrote that dentists must be removed from their pre-eminent decision-making role in regulating mercury amalgam.

¹⁸ The “most notabl[e]” “scientific evidence” in favor of amalgam, FDA asserted as recently as 2002, is “the significant human experience with amalgam for over 100 years.” 67 Fed. Reg. 7626-27 (Feb. 20, 2002). No bona fide scientist would equate longevity of use with absence of risk – much less, as FDA does, make it the lead argument.

¹⁹ 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 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, known as 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 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. With the meetings planner acting as strawperson, this NIDCR-FDA cabal handpicked a consultant for the major tobacco companies to do the work, after presenting the latter with a blueprint of 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 director of NIDCR, Lawrence 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, had to invert the research question – from evidence of risk to proof of harm – and thus violate the contract. The report was result-oriented from start to finish. It is instructive to note that only NIH investigated. A letter from the above two Members of Congress to the FDA Commissioner raising these major concerns, not only went unanswered, but FDA, led by Branch Director Mary Susan Runner, DDS, tried to organize a team to advocate for the study, under the ill-named rubric “amalgam vigilance committee.”

IV. FDA's Twenty Years of Staunchly Refusing to Classify Amalgam.

Starting in 1976, Congress directed FDA to start classifying all devices,²⁰ including those already on the market.²¹ Class I and Class II devices may be sold by the manufacturer merely notifying FDA. Class III devices, however, require “premarket approval” by FDA, whereby the manufacturer must prove the device is safe. Implants, such as dental fillings, are presumptively Class III; they may be moved up the safety chain to II or I only under proof of “reasonable assurance of safety.” So while device regulation used different terminology than drug regulation, the conceptual starting point (especially for implants) is the same: manufacturers prove safety before the product is allowed to enter commerce.

Thus, the very act of classifying will mean the demise of mercury amalgam. Under today's rigorous concern about mercury exposure, manufacturers of a device 50% mercury implanted inside the head emitting mercury vapors could never, repeat never, prove “reasonable assurance of safety.” The amalgam advocates inside FDA realize **the only way to keep mercury fillings legal is not to classify them.**²²

Between 1986 and 1989 FDA duly classified all dental filling materials – that is, all but the controversial one, encapsulated amalgam; see fn 1, *supra*. Further proof they were working around amalgam: the agency even classified the accoutrements of amalgam (the capsule itself and the equipment to titrate it).²³ FDA has never sought to justify, or even explain, the privileged status accorded amalgam for 20 years.²⁴

Ever since, in predictable three-to-six year cycles, FDA promises to classify amalgams, then pulls back, finding an excuse to do nothing and start over. Perhaps if the issue were how to classify band-aids, the routine would be comical -- like cartoon character Lucy pulling up the football each autumn. But FDA is playing games with the most toxic nonradioactive element and the most volatile heavy metal, a virulent neurotoxin that can permanently damage the brain, the nervous system, or the kidneys.

First cycle of deception (1986-92): FDA classifies all filling materials except the most common one, amalgam, then adopts a clever scheme to keep amalgam on the market (see Part III, *infra*). After watching and waiting, the Foundation for Toxic-Free Dentistry and others, with the undersigned Robert E. Reeves as counsel, file a mandamus to classify before this Honorable Court. FDA wins on procedural grounds in January 1993.

Second cycle of deception (1993-96): Per the ruling by the D.C. Circuit, petitioners – as well as other citizens, dentists, and nonprofit organizations – file

²⁰ Until 1976, devices were unregulated. Hence the regulatory statute for FDA is known as the Food Drug and Cosmetic Act, covering the areas assigned to FDA decades earlier.

²¹ Devices on the market before 1976 are “preamendment devices.”

²² Another insurmountable barrier that will doom amalgam: the environmental impact statement, mandated before classifying; see Part IV, *infra*.

²³ Dental fillings are implants, which – since they remain in the body undissolved for more than 30 days – have a stricter system of scrutiny than devices which remain outside the body.

²⁴ When asked at a Congressional hearing why FDA refused to classify amalgam in the 1980s while classifying all other fillings, the Director of its Center on Devices replied, “To be honest, we do not know ...” “Mercury in Dental Amalgams,” *op. cit.* fn 1, at p. 125.

petitions to FDA to classify. FDA responds by doing a “literature review” (1993) – by a dentist-controlled group – and by throwing the issue to the Dental Products Panel (1994), a panel consisting of eight dentists, two manufacturers, and one consumer. (The sole consumer member was also a dentist, so its make-up was illegal.) Thereafter, action stalls again.

Third cycle of deception (1997-2000): Lawyers Reeves and James Turner press FDA to respond to the myriad petitions. FDA does a second “literature review” – by the same group. In November 1997 Deputy Director Elizabeth Jacobson, Center on Devices, writes Reeves and Turner with two unequivocal promises:

“**FDA [1] intends to classify** encapsulated dental amalgam alloy and dental mercury [and] [2] **intends to require certain warnings.**”

That was nine years ago. **FDA broke its promise to classify. FDA broke its promise to issue warnings.**

Fourth cycle of deception (2001-04): A movement to ban mercury amalgam ignites activism around the country. California, Arizona, Maine, and New Hampshire either enact or begin to enforce consumer disclosure statutes about health and environmental risks. Lawmakers in Congress and ten states introduce ban bills. To quash the movement, FDA proposes a sham regulation to **reduce** public awareness -- directing manufacturers to stop issuing warnings, trying to thwart state disclosure bills, and (to divert attention away from the mercury) audaciously directing a bold warning that amalgam contains (only) zinc!^{25 26} A public outcry erupts; thousands of submissions come in against the rule. In October 2002, FDA retreats. Director Feigal of the Center on Devices tells a House Committee that the proposed regulation is on hold pending – *no surprise here* – a **third** “literature review.”²⁷ At that point comes the LSRO debacle, footnote 19, *supra*.

Does the April 3, 2006, order²⁸ signal yet a fifth cycle? In October 2005, based upon concerns expressed by Senator Hatch and Senator Kennedy, FDA met with representatives of Consumers for Dental Choice, including the undersigned Charles G. Brown, in a meeting hosted by Associate Commissioner Lutter and Acting Associate Commissioner Brodsky. On April 3, 2006, the two Associate Commissioners take the positive step of acknowledging the neurotoxicity issue, convening a panel with neurological expertise, and ordering a public hearing. Whether this step is the start of good-faith action by FDA, or the start of a fifth cycle of deception, remains to be seen.

²⁵ <http://www.fda.gov/cdrh/ode/guidance/1192.pdf>

²⁶ No better evidence exists of FDA’s intent to deceive the public than the fact the agency proposed patients be warned about the small amount of zinc in amalgam but not the 43 to 54% mercury. Mercury is always toxic, in the tiniest doses, and is many, many times more toxic than zinc. Zinc is considered beneficial in small doses, provided limits are observed.

²⁷ *FDA Week*, Nov. 22, 2002.

²⁸ <http://www.fda.gov/oc/advisory/accalendar/2006/cdrh12518dd09060706.html>

V. How FDA Improperly Keeps Mercury Amalgam on the Market

FDA's Center on Devices used the following legerdemain to keep amalgam on the market while evading the triple mandates of classifying, proof of safety, and environmental impact statement: it invoked a "substantially equivalent" claim – doing so in secret and with no factual finding of equivalence. The classified device is "amalgam alloy," a material defined as having no mercury, which dentists once mixed in their offices. So FDA said a substance that is non-mercury, non-encapsulated and not even a completed dental material (and, not incidentally, obsolete), is "substantially equivalent" to an encapsulated completed dental material that is 50% mercury.

"Amalgam alloy" refers to a 19th-century technique: Dentists, like pharmacists of old, created the filling in their office, mixing the powdered alloy with liquid mercury. Since a handful of old-fashioned dentists still used this system a generation ago, FDA classified the alloy. The mixing involved such a reckless exposure to mercury that organized dentistry officially renounced it in the 1990s, and several states banned its use in the 2000s.²⁹ In 2002 FDA conceded the system is defunct.

In the Food, Drug and Cosmetic Act, a "substantially equivalent" determination requires meeting two precise prongs. First, clinical or scientific data must demonstrate that the unclassified device is as safe and effective as the classified one. FDA never produced such data; so it fails to meet this prong. Second, two devices must not raise different questions of safety and effectiveness. The agency *sub silentio* concedes that this prong is not met in its order in April that mercury's neurological risks must be evaluated. By definition (the alloy has no mercury) the two products raise different questions of safety. Both prongs must be met; neither is.

Both Senator Enzi and Senator Kennedy have challenged this substantial equivalence system in sharp-edged questions to the Acting Commissioner.

When pressed, Center officials cannot get their story straight on just how they regulate amalgam. In an astonishing e-mail exchange in 2003-04 between Georgia consumer Pamela Floener and FDA officials, FDA gave three sequential, competing explanations of their classification system for capsulated amalgam. First, they said, it is classified substantially equivalent as a single device (which is the official explanation, the one in the 2002 regulation). When Floener challenged them, they said no, it is a dual device, the alloy and the mercury bottle. When she again challenged them, they said no, it isn't classified at all, and that the decision to classify is on hold.

The recent application of Silverfil to sell amalgam aptly illustrates that FDA uses substantial equivalence as a ruse to keep amalgam unregulated. In its application, this British-based fillings manufacturer makes alarming concessions:

²⁹ The occupational warnings from manufacturer to dentist remain vivid for capsulated amalgam as well. The Sixth Circuit threw out a claim by a dentist who suffered major health damage from workplace exposure to mercury from amalgam – on the grounds that the manufacturer had repeatedly warned the dentist, in writing, of the severe risks of amalgam. *Barnes v. Kerr Corp.*, 418 F.3d 583 (6th Cir. 2005).

“In recent times, dental amalgam has had a bit of a rough ride. The mercury content has been cited as a cause for many illnesses, and, although the jury is still out on many of these claims, there is no getting away from the fact that **mercury and its vapours are indeed very dangerous, and direct contact with either is better avoided.**

“This has led to very strict guidelines regarding placing and handling the material. ... **In the UK** we have been advised to **avoid its use in children and expectant and nursing mothers. Several European countries have banned its use entirely.**”

With such extraordinary admissions, one might hope FDA would prick up its ears and demand proof of safety. But no, for amalgam, FDA’s gold standard equates to golden acquiescence for manufacturers and golden silence to the American public.³⁰

VI. Flouting Its Duty, FDA Refuses to Do Environmental Impact Statement

The U.S. Centers for Disease Control says mercury poisoning “primarily affects the central nervous system, causing parathesias, ataxia, dysarthria, hearing impairment, and progressive constriction of the visual fields.” Outside of the nervous system, the “most prominent effect” is damage to kidneys. Even more chilling, CDC warns of mercury’s “**well-characterized adverse reproductive effects.**” Pre-natal exposure may cause “mental retardation, ... sensory impairments, and cerebral palsy.”³¹ A “major exposure” of mercury is ... dental amalgam. *Id.*

Dental mercury’s **colossal impact on the environment is undeniable:**³²

- As long as amalgam remains legal, it adds 42 tons of mercury into commerce, and thus the environment, every year.
- Dental amalgam is by far the largest source of mercury in the wastewater.
- Enough mercury from fillings goes into human waste that dental amalgam is also the largest source of mercury from household waste.
- Dentists are the second or third largest purchasers of mercury, an astounding 22%. It was only 2% in 1980 -- while others are cutting mercury use, many dentists defend mercury use and refuse to do their share for the environment.
- With the growing choice of cremation, dental fillings are emerging as a major source of mercury in the air as well.

³⁰ The suggestion that since every child and adult is not impacted by mercury amalgam exposure means none are harmed is as preposterous as to suggest that everyone who smokes gets lung cancer. Scientists are unanimous, and FDA concedes, that a certain percentage of the population is hypersensitive to mercury exposure, and could have a grievous reaction from the slightest exposure. The estimates of mercury hypersensitivity average 15%, varying from 25% to 1%. But even 1% equals three million Americans. To this hypersensitive population must be added those at substantial risk because their mercury burden is already overloaded from other exposures – e.g., residence near a power plant, eating large quantities of fish, or workplace exposure (such as a dental office) –so the amalgam may constitute their tipping point.

³¹ Centers for Disease Control, *Third National Report on Human Exposure to Environmental Chemicals 2005*, pp. 45-48. www.cdc.gov/exposurereport/

³² “Dentists Biggest Mercury Polluters, New Study Finds,” *Los Angeles Times*, 6/6/02.

- More mercury is in Americans' mouths than all other products put together. Assuming proportionate release over 15 years, more mercury will be released yearly from Americans' collective mouths each year than from power plants.

*Taking a Bite Out of Dental Mercury Pollution / The 2005 Report Card on Dental Mercury Use and Release Reduction;*³³ *Dentist The Menace? The Uncontrolled Release of Mercury.*³⁴

Under the National Environmental Policy Act of 1969 (“NEPA”), any agency contemplating a decision that could have a major impact on the human environment must do an Environmental Impact Statement (“EIS”). The statutory term “proposal” requires the agency to incorporate environmental policy into its decision-making before it chooses between options or before it decides to take action. An agency may not simply dismiss the need for an E.I.S.; it must do an “Environmental Assessment” to determine if an E.I.S. is needed. Before it may decline to do an E.I.S., it must make specific findings that the action “will not have a significant effect on the environment.” The Food Drug and Cosmetic Act mandates FDA compliance with NEPA.

Yet, FDA has three times made clear that for amalgam it will do no E.I.S.

- In 1997, FDA refused to do an environmental assessment requested in a citizen petition from Dr. Cheraskin and Dr. Ringsdorf.
- In 2002, FDA proposed a regulation but refused to do an E.I.S. – even though the law requires an environmental impact statement when FDA proposes a regulation. 21 C.F.R. §25.20(g). Continuing its amalgam agenda of deny, deny, deny, FDA absurdly claimed that regulation of amalgam “does not individually or cumulatively have a significant impact on the human environment.”
- In 2006, FDA’s press response to an inquiry from *Water Policy Report* re this lawsuit shifted responsibility to the manufacturer to advise of the environmental impact -- in its pre-market approval application. But FDA requires no pre-market application for amalgam. Using a Catch 22 maneuver, FDA asserts the duty belongs to the premarket applicant – then arranges for there to be no premarket application!

The breadth required in an environmental impact statement illustrates why FDA shuns it. After spelling out the environmental impact, the agency must consider both how to “avoid” any adverse environmental effects and “alternatives to the proposed action.” Thus, an Environmental Impact Statement will almost certainly lead the abolition of mercury fillings, a step the staff at the Center is resolved to stop.

VII. Science, Law, and Public Policy Point to One Solution: Ban Amalgam

In a last-ditch effort to keep amalgam sales unregulated, the mercury advocates are framing the issue as a removal of a legally approved device from the market. That is

³³ By the New England Zero Mercury Campaign, composed of Clean Water Action New England, Health Care Without Harm, Mercury Policy Project, Natural Resources Council of Maine, and National Wildlife Federation (2005), at www.mercurypolicy.org (date 4/4/05).

³⁴ By the Mercury Policy Project, Health Care Without Harm, Sierra Club, and Toxics Action Center (2002), at www.mercurypolicy.org/new/documents/DentistTheMenace.pdf

not the issue. Indeed, several routes exist either to stop amalgam use immediately, or to stop its use immediately for the vulnerable populations – children and unborn children.

It's time to put the burden where the FDCA says it should be: prove its safety – for the first time.

One route to abolition: Amalgam has never been classified, has never been subject to proof of safety, and has never had an environmental impact statement. Therefore, today, its sale is illegal – until each of these three steps are taken .

Another route to abolition: When classified (as a III, the only realistic option), manufacturers must prove it is safe; they have already conceded they cannot do so.

Another route to abolition: Issue an order, today, that amalgam must no longer be given to children and pregnant women. Others could have it, but once they find out it's mercury, it's usage will cease rapidly.

Several legal paths exist, ones that can be implemented immediately. FDA has to choose whether its loyalty is to pro-mercury dentists, or whether science, public health, and children come ahead of the politically-connected dental association.

Ending the use of amalgam ends a major health risk and a colossal environmental impact – and it has no downside whatsoever. **No benefits exist for amalgam; it is not needed for any kind of cavity in any child or any adult..** Except that **it might temporarily dent the profits of the assembly-line and old-fashioned dentists**, there is no negative impact whatsoever:

- Dental product makers, already prepared for this development, will sell other filling materials in greater quantities, while the dwindling pro-mercury dentists will have to switch to non-toxic materials like resin. The dental product makers are prepared to exit amalgam; the historical remnants are the pro-mercury dentists.
- Dentists have been converting to mercury-free practices, but not rapidly enough. Many pro-mercury dentists – those who refuse to transition out of using this toxic product – will be momentarily inconvenienced by a requirement to implanting non-toxic fillings. But every dentist knows how to do it – 100% of them learned in dental school to implant resin and porcelain.
- No one will go without dental care. A 2006 study shows that all Medicaid programs already give patients the choice to get non-toxic alternatives to amalgam.