IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MOMS AGAINST MERCURY, CONNECTICUT COALITION for ENVIRONMENTAL JUSTICE, OREGONIANS for LIFE, CALIFORNIA CITIZENS for HEALTH FREEDOM, Kevin J. BIGGERS (Member of the Dental Board of California), Karen JOHNSON (Arizona State Senator), Linda BROCATO, R. Andrew LANDERMAN, D.D.S., Anita Vazquez TIBAU 1725 K Street, NW, Suite 511, Washington, D.C. 20006 Petitioners,	
v.	Petition for Review
Mike LEAVITT, Secretary, Department of Health and Human Services; Andrew VON ESCHENBACH, Acting Commissioner, Food and Drug Administration ("FDA"); Dan SCHULTZ, Director, Center for Devices and Radiological Health, FDA; and Mary Susan RUNNER, Director, Dental Devices Branch, Center for Devices and Radiological Health FDA, 200 Independence Avenue, S.W., Washington, D.C. 20201 Respondents.	

Petition (21 USC §360g) To Order Mercury Amalgam Withdrawn from Interstate Commerce

I. Parties and Jurisdiction

1. Four of the petitioners are nonprofit organizations that represent the breadth of concerns about the adverse health effects of FDA's protecting the use of mercury-based amalgam dental fillings. Their respective missions focus on: (i) mercury-damaged children (via mercury from amalgam accumulated in the mother's system and passed on through the bloodstream to the fetus in the mother's womb or through the mother's milk to the nursing child); (ii) environmental justice for those at lower socioeconomic levels, who are falsely informed that the cheaper fillings are "silver," when they are actually 50% mercury; (iii)

protection for the unborn child from, in this situation, harmful toxins; and (iv) consumer rights to informed consent and healthy medical choices.

2. The five individual petitioners include: two state officials – a state Senator and a public member of a state dental board – who are unable to fulfill their constitutional and statutory duties, respectively, to regulate the professions of dentistry and dental hygiene because FDA fails in its duty to classify and otherwise regulate mercury fillings; a mercury-free dentist aware that amalgam causes exposure to toxic mercury, an unstable substance that is completely unnecessary for oral health care (but which FDA allows to be sold solely for the profit and convenience of dentists); and two victims of mercury amalgam poisoning who were not warned about either the mercury content or its health risks, and who now are advocates for its abolition.

3. Moms Against Mercury, a North Carolina nonprofit corporation (55 Carson's Trail, Leicester, NC 28748, *at* www.momsagainstmercury.org), represents children suffering substantial neurological harm from mercury exposure. It joins this case because mercury vapors emanating from the mother's dental fillings are involuntarily inhaled, absorbed into the bloodstream, and passed into the body of her unborn baby in the womb. When the child is born, mercury continues passing from mother to child through her breast milk.

4. Connecticut Coalition for Environmental Justice, a Connecticut nonprofit corporation (10 Jefferson St., Hartford, 06145, *at* www.environmental-justice.org), is a state-based group representing the needs of lower-income and minority citizens. It joins this case because the burden of exposure to mercury *via* amalgam falls heavily on lower-income Americans – especially children – while its use by middle- and upper-income Americans is increasingly rare.

5. Oregonians for Life, an Oregon nonprofit corporation (1301 Highway 99W, McMinnville, OR 97128, *at* www.oregoniansforlife.org), has a mission to protect the unborn

from harm, whether via abortion or toxins. It joins this case because mercury from the mother's teeth poses a substantial risk of harm to the health and even life of unborn children.

6. California Citizens for Health Freedom, a California nonprofit corporation (8048 Mamie Avenue, Oroville, CA 95966, *at* www.citizenshealth.org), is a state-based group focused on making healthy choices available to Californians. Because mercury amalgam fillings expose Californians to mercury and are not a healthy choice, California Citizens for Health Freedom joins this case to protect consumer health.

7. Kevin J. Biggers (30141 Via Victoria, Rancho Palos Verdes, CT 90275) is a Public Member of the Dental Board of California, the state agency that licenses over 20,000 dentists, plus thousands of registered dental hygienists and registered dental assistants. He joins this case in his individual capacity and not on behalf of, nor is he alleging that he speaks for, the Board or its other members. Member Biggers, as a member of the Dental Board of California, has a duty under California law to regulate dentistry in the consumer interest; our federal system has generally divided the responsibility for regulating products between FDA and the states. Because FDA has failed to classify mercury amalgam, has published deceptive Consumer Updates, and has been unable to explain its classification system in response to consumer inquiries, neither Member Biggers nor the Board can effectively address the mercury amalgam issue, nor can they effectively regulate dentistry in the public interest.

8. Karen Johnson (1700 West Washington, Room 303A, Phoenix, AZ 85007), a Member of the Arizona Senate who chairs the Children and Families Committee, brings this case as an individual Senator. Senator Johnson has a constitutional duty to regulate the dental profession, and is under the same impairment to do so as petitioner Biggers. Whereas his duty is regulatory and administrative in California, Senator Johnson's duty in Arizona is to write laws to protect the

public health, including for the professions of dentistry and dental hygiene, to oversee enforcement of the laws, and to focus on her assigned role as a committee chairperson responsible for protecting children and families from toxins and other risks.

9. R. Andrew Landerman, DDS, a practicing general dentist (170 Sotoyome St., #4, Santa Rosa, CA 95405) realizes amalgam is about 50% mercury, that its toxic vapors emanate constantly from teeth, that manufacturers warn dentists against its use for pregnant women and children, that many dentists fail to communicate this information to patients, and that mercury is a 19th century approach to oral health care in the 21st century. Petitioner Landerman is concerned about FDA's failure to inform the public of amalgam's health or environmental impact.

10. Linda Brocato (Whitehall North of Deerfield, #264, 300 Waukegan Rd., Deerfield, IL 60015) is an advocate in her home state of Illinois to abolish mercury amalgam fillings. As a young woman, she suffered such severe neurological problems that she was diagnosed with Multiple Sclerosis confined to a nursing home. After the removal of her mercury-based fillings, her MS symptoms promptly disappeared and she substantially regained her health, except that her legs had atrophied and she remains in a wheelchair. This condition continues to make her life quite difficult; a recent fall has forced her back temporarily to assisted living. Petitioner Brocato received implants of amalgam fillings without being aware, or being advised, that they contained 50% mercury.

11. Anita Vazquez Tibau (P.O. Box 664, Newport Beach, CA 92661), who lives in Rio de Janeiro, Brazil, as well as in the state of California, is an international advocate for abolishing mercury-based fillings. Because of the placement of amalgam two decades ago, she suffered substantial and life-threatening symptoms of asthma, symptoms that dissipated rapidly when the

amalgam was removed. Petitioner Tibau received over a dozen implants of amalgam fillings at one time – the event that set off the asthmatic conditions – without being aware of or advised that they contained 50% mercury.

12. Petitioners collectively, and individually, are adversely affected by FDA's failure to classify, FDA's failure to do an environmental impact statement, and FDA's April 3 order which concedes its "substantial equivalence" standard for amalgam is a sham but fails to revoke it.

13. Respondents are (i) the Honorable Mike Leavitt, of Health and Human Services, and three officials of the Food and Drug Administration: (ii) Andrew Von Eschenbach, M.D., Acting Commissioner; (iii) Daniel Schultz, M.D., Director, Center on Devices and Radiological Health ("the Center"); and (iv) Mary Susan Runner, D.D.S., Dental Devices Branch of the Center.

14. The Agency has subject matter jurisdiction pursuant to 21 USC §393. The FDA is tasked with ensuring that devices are safe and effective, and must regulate devices in a way that is prompt, efficient, and timely. Petitioners also assert jurisdiction pursuant to 28 U.S.C. §1331 (federal question), 28 U.S.C. §1346 (United States as Defendant), and 28 U.S.C. §1361 (mandamus).

15. This court has jurisdiction over this petition to stop mercury-based dental fillings from entering interstate commerce pursuant to 21 U.S.C. 360g. On April 3, FDA ordered (http://www.fda.gov/oc/advisory/accalendar/2006/cdrh12518dd09060706.html) an open-ended hearing with no suggestion that regulatory action would occur -- continuing an unending 28-years of failing to classify mercury amalgam, failing to require proof of its safety, maintaining a sham classification scheme for its sale, and refusing to do an Environmental Impact Statement. For a product that is 50% mercury – a toxin FDA condemns in virtually every other use – this

order to freeze the illegal regulatory status quo for yet another six months (and perhaps years more) is plainly subject to appeal. See paragraph 45.

16. Alternatively, if the order of April 3 does not qualify for appeal to this Court, then FDA's decision not to classify is one that is continuing decade after decade to this day; thus the 30-day requirement is met.

17. Venue is properly vested in this court pursuant to 28 U.S.C. §1391(e) because the principal office of Respondent Mr. Secretary is located in the District of Columbia.

II. Case Summary: FDA's Decision To Ignore Its Duties To: (1) Classify Encapsulated Mercury Amalgam, (2) Require Proof of Safety, and (3) Prepare an Environmental Impact Statement

18. Although classifying all other dental materials two decades ago as required by 21 USC §360c(b), the Secretary 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 25% 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.

19. *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.

20. *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.

21. *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 – which has directly controlled all Federal Government research and regulation on amalgam for more than half a century – 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 US 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 in 1998 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, as a result of 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.

III. The Mercury Amalgam Controversy

A) The Simultaneous Emergence of Mercury Amalgam and Organized Dentistry

22. 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.

23. 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. This led to the founding of America's first school of dentistry, the Baltimore College of Dental Surgery. But the development of mercury-based amalgam fillings changed all that.

24. 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."

25. 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; membership in the ADA soared.

26. For 150 years, the very existence of organized dentistry has depended on suppressing any suggestion that implanting mercury in the mouth might create health problems. Today, the ADA remains the only national trade group of health professionals to endorse the use of a product that is primarily mercury.

B) The Abandonment of Mercury By All Health Professions Except Dentistry

27. 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.

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

29. 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*.

C) The Role of the ADA as Deceptive Promoter of Mercury Amalgam

30. 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.

31. 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 that the ADA represents**.

32. Although the ADA advises dentists and the public that it has state-of-the-art laboratories to determine whether a product is safe, the claim has no apparent 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.

33. 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 in a case pending in the Supreme Court of California, *Kids Against Pollution* v. *California Dental Association*.

D) Control by Dentistry Over Federal Regulation of Amalgam

34. In the period during and after World War I, the ADA began developing a partnership with the National Institute of Standards in the area of dental materials. Over the decades, members of the ADA and an ADA spin-off organization, the pro-amalgam American Association of Dental Research, have moved on to fill the dental research and regulatory leadership positions at the dental arm of the National Institutes of Health (NIH) and at FDA.

35. 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.

36. Respondent Schultz, a physician who heads FDA's Center on Devices, has either neglected or abandoned his supervisory responsibility over this corrupt system. Thus, he has been complicit in handing over medical decisions about the regulation of mercury-based dental products to dentists with close ties to the ADA and pro-amalgam interests. They in turn have established a unique and incongruous base of operations within FDA to protect their organization's cash cow – mercury amalgam.

37. It should come as no surprise that all government literature reviews on amalgam's toxicity have been managed by groups composed mainly of dentists. For example, a multimillion dollar grant to study amalgam was given to a dentist sitting on the ADA's Council of Scientific Affairs; that person chose a defenseless group – institutionalized Portuguese orphans – on which to experiment with mercury, **without disclosures of health risks**. The study is now under investigation by the Secretary's Office of Human Research Protections, the watchdog charged with stopping unethical medical experimentation.

38. Respondent Runner, a dentist, uses her powerful position as Director of the Dental Devices Branch to act as an advocate for, rather than a regulator of, amalgam. In addition to exculpatory statements for amalgam that misrepresent what international health agencies recommend, she twice issued Consumer Updates lauding amalgam, falsely claiming that neither the Canadian nor Swedish governments have health concerns about amalgam, and hiding from consumers the fact that amalgam constitutes a major exposure to mercury. In the second such FDA Consumer Update, she allowed the American Dental Association and the California Dental Association to veto two sentences (one for each group) that displeased them.

IV. Acts and Practices (I): FDA Protects – Rather than Regulates – the Sale of Mercury Amalgam

39. 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**.

40. To keep amalgam on the market without ever classifying it, officials within FDA's Dental Devices Branch have engaged in a fraudulent classification scheme. They 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 CFR §872.3050, 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 (CFR §872.3050) 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. Yet the FDA has falsely declared the capsule containing both mercury and the other powdered metal components to be "substantially equivalent" to the non-mercury CFR Section 872.3050 product. Clearly, the addition of mercury to the product makes it a substantially modified product that must be separately classified.

41. 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.

42. 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.

43. 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.

44. FDA has now recognized the obvious, ordering public hearings under a new joint committee to address toxicity – particularly **neurotoxicity** – associated with dental amalgam. (http://www.fda.gov/oc/advisory/accalendar/2006/cdrh12518dd09060706.html)

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 another three decades of obfuscation in dealing with this harmful, and completely unnecessary, mercury product.

45. 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. At its heart, the April 3, 2006, order is an admission that the sale of mercury amalgam capsules in interstate commerce has been, and continues to be, illegal. This Court should therefore grant interim relief, pursuant to 21 USC §360g(c), and immediately block the sale of these mercury products, unless or until FDA creates a bona fide classification and, based on substantial, credible, scientific evidence, finds them safe for any, some, or all classes of consumers.

V. Acts and Practices (II): A Plethora of Bad Faith Actions by FDA Officials

46. As set out in paragraph 41 above, FDA's classification of amalgam is so Byzantine that agency officials themselves will not coherently explain it. In a bizarre sequence of e-mails between Georgia consumer Pamela Floener and FDA officials (including respondent Runner), FDA kept jumping between three competing explanations: (1) that encapsulated amalgam is regulated solely under C.F.R. §872.3050 as a non-mercury amalgam alloy, (2) that encapsulated amalgam is regulated as a dual device under section 3050 (non-mercury amalgam alloy) and C.F.R. §872.3700 (dental mercury), and (3) that encapsulated amalgam is not yet classified, because that decision is now "on hold."

47. Since FDA itself can't decide how encapsulated amalgam is classified, it is time for the Courts to demand clear lines. It is a device; it must be classified; and as an implant with questions of neuro-toxicity, it must be classified as a class III medical device.

48. To keep this sham regulatory system going, FDA officials – acting in the name of the agency that is under the supervision of respondent Mr. Secretary – have engaged in a plethora of bad faith actions in order to protect, rather than classify and otherwise lawfully regulate, mercury fillings.

49. Taken together, these actions involving malfeasance and nonfeasance make it clear that while the FDA's official position is that it intends to classify amalgam – someday, in some distant year – its unofficial but real agenda is something different: Not to classify amalgam, but to continue to allow its sales via a sham classification system where the manufacturers of a product that is mainly mercury need never prove its safety. <u>This de facto decision not to classify is nonetheless a decision</u> – a decision to try to place mercury amalgam in a position of regulatory untouchability. FDA has chosen to keep amalgam fillings in a netherworld of non-regulation.

This Court must order amalgam sales stopped immediately. If FDA still believes that implanting mercury-based fillings in the mouths of pregnant women and young children is safe, it can then initiate a classification process that is open and transparent – not one cloaked in secrecy that protects the financial interests of organized dentistry.

50. Here are **27 examples of bad faith by FDA and FDA officials**:

(i) 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);

(ii) 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;

(iii) Abdicating its duty even to do a Finding Of No Significant Impact ("FONSI"), a condition precedent to avoiding an Environmental Impact Statement;

(iv) Deceiving the American public through issuing deceptive, incomplete, and outright false information in its Consumer Updates about the risks of mercury amalgam;

(v) Granting veto power to the American Dental Association over language in its Consumer Update;

(vi) Granting veto power to the California Dental Association over language in its Consumer Update;

(vii) Echoing the American Dental Association propaganda that exposure to mercury from amalgam is similar to exposure to dust or pollen;

(viii) Engaging in pseudo-science by insisting that mercury amalgam must be safe because it has been used for a long time;

(ix) 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;

(x) Refusing to correct the above error despite repeated requests by the nonprofit group Consumers for Dental Choice;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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);

(xvii) Violating law, by installing a dentist as the sole Consumer Representative on the Dental Products Panel, exceeding the statutory mandate for the number of dentists;

(xviii) Violating law, by allowing its Dental Products Panel to recommend a departure from a Class III classification for mercury amalgams without stating a scientific basis;

(xix) Making repeated sham promises of an intention to classify mercury amalgam;

(xx) Creating a sham classification scheme to continue the unapproved sale of unclassified mercury amalgam;

(xxi) 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;

(xxii) Adopting policies on mercury amalgam at odds with FDA policies on mercury in virtually all other products;

(xxiii) 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;

(xxiv) Claiming, knowingly and falsely, that FDA's polices on amalgam are consistent with the policies of other national health systems;

(xxv) 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;

(xxvi) 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;

(xxvii) Approving amalgam even when the manufacturers-applicants disclose and explain the neurotoxicity of their products. In 2005, FDA approved the amalgam product Silverfill, even though the applicant admitted that in its own country, the United Kingdom, **the amalgam product is banned for children**;

VI. Acts and Practices (III): FDA Bans or Warns Against Other Mercury Exposures for People and Animals – While Protecting Amalgam Even from Disclosure of the Mercury

51. 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, unjustifiable and unlawful.

52. 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 -- has been to do nothing, favoring pro-mercury dentists and grievously harming America's children.

53. FDA's substantial equivalence system to keep mercury fillings on the market – classifying it "temporarily" (for two decades) as a powdered metal non-mercury component of a dental filling -- is a sham – which the agency now apparently realizes, since it ordered hearings on mercury's toxicity.

VII. CAUSES OF ACTION

(1) Violations of the Federal Food, Drug, and Cosmetic Act

(A) 21 U.S.C. §360g(a)(8): Encapsulated amalgam is being marketed via a deceptive, unlawful, and sham classification.

(B) 21 U.S.C. §360g(a)(4): Encapsulated amalgam is being marketed despite never having been classified, and this failure to classify, far from being inadvertent, represents a calculated FDA decision to keep selling amalgam with no safety review.

(C) 21 U.S.C. §351: Encapsulated amalgam is an adulterated device, as its major component is mercury, a recognized neuro-toxin, but the classification under which it was sold, §872.3050, may not, by definition, contain mercury.

(D) 21 U.S.C. §352: Encapsulated amalgam is a misbranded device, as its major component is mercury, a recognized neuro-toxin, but the classification under which it was sold, §872.3050, may not, by definition, contain mercury.

(E) 21 U.S.C. §393: Encapsulated amalgam has never been regulated despite a statutory mandate that FDA "promote the public health by promptly and efficiently" reviewing the safety of amalgam and "protect[ing] the public health by ensuring that" there is a reasonable assurance that amalgam is safe as a filling material.

(2) Violation of the National Environmental Policy Act

21 USC §379o: The Food Drug and Cosmetic Act mandates FDA to conduct both an environmental assessment and an environmental impact statement (EIS) for any action falling within the National Environmental Policy Act, 42 USC §4332(2)(C). 21 CFR §25.21 requires that FDA at a minimum perform an environmental assessment where available data indicates that there is the potential for serious harm to the environment, or where Agency action could harm a species or critical habitat. Even though the widespread use of amalgam means dentists account for 22% of all mercury purchased each year (the second or third largest category of purchasers), and even though there is more mercury residing in Americans' mouths than in all other products combined, FDA did not do an environmental assessment or EIS. Much waste mercury from dental offices finds its way into our wastewater, streams, and larger waterways.

(3) Violations of the Administrative Procedure Act

(A) FDA's arbitrary regulation of mercury amalgam is totally at odds with the prevailing science, and its own policies, that seek to reduce or eliminate unnecessary exposure to mercury.

(B) 21 U.S.C. §360c: FDA's Dental Products Panel failed to find reasonable assurance of safety, especially reasonable assurance of safety for children and unborn babies, before issuing its recommendation.

(C) 21 U.S.C. §360c: FDA's Dental Products Panel met so long ago (12 years) that its recommendation, if ever valid, is obsolete.

(D) Respondents (excluding respondent Mr. Secretary and respondent Acting Commissioner) have engaged in an arbitrary and capricious pattern of bad faith actions in order to protect and advance the sale of amalgam.

VII. REMEDY

(A) Petitioners pray for interim relief, as permitted in 21 U.S.C. §360g(c):

- An immediate ban on the interstate sales or shipment of encapsulated amalgam, until respondents, using lawful procedures, adopt a classification wherefore.
- An immediate ban on the interstate sales or shipment of encapsulated amalgam until each manufacturer submits an application for pre-market approval, and respondents, using lawful procedures, approves each.
- An immediate ban on encapsulated amalgam entering interstate commerce until respondents, using lawful procedures, write an Environmental Impact Statement on the colossal environmental effects of mercury amalgam – a product for which such interchangeable alternatives exist that it is no longer used in modern dentistry.

- An immediate ban on the interstate sales or shipment of capsulated amalgam because, in its current classification, C.F.R. §872.3050, it is an adulterated product – being 50% toxic mercury while the classified device is defined as having no mercury.
- An immediate ban on the interstate sales or shipment of capsulated amalgam, because, in its current classification, C.F.R. §872.3050, it is a misbranded product – being 50% toxic mercury while the classified device is defined as having no mercury.

(B) Permanent equitable relief incorporating the above.

(C) A cease-and-desist order against the issuance of false, deceptive, or misleading information by respondents about mercury amalgam.

(D) Attorney fees and litigation costs.

(E) Issue such other relief as it may deem necessary and proper.

Respectfully submitted by counsel for petitioners this ___ day of April 2006

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