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

No. 06-1147

MOMS AGAINST MERCURY, et al.

Appellants,

v.

FOOD & DRUG ADMINISTRATION,

Appellees.

ON PETITION FOR REVIEW OF REGULATORY INACTION BY
THE FOOD AND DRUG ADMINISTRATION

BRIEF OF APPELLANTS MOMS AGAINST MERCURY, CONNECTICUT COALITION FOR ENVIRONMENTAL JUSTICE, OREGONIONS FOR LIFE, CALIFORNIA CITIZENS FOR HEALTH FREEDOM, KEVIN J. BIGGERS, KAREN JOHNSON, LINDA BROCATO, R. ANDREW LANDERMAN, AND ANITA VAZQUEZ TIBAU

Charles G. Brown, Esq.
1725 K Street, NW
Suite 511
Washington, DC 20006
202-884-0315

Counsel for Appellants

Robert E. Reeves
REEVES LAW OFFICE
167 West Main St., Suite 1310
Lexington, KY 40507
859-226-0700

Counsel for Appellants

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), petitioners Moms Against Mercury, et al., (hereinafter called "Moms") submit the following information:

(A) Parties

APPELLANTS

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 mother to child through her breast milk.

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.

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.

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. Mercury fillings expose Californians to mercury and are not a healthy choice. California Citizens for Health Freedom joins this case to protect consumer health.

Kevin J. Biggers (30141 Via Victoria, Rancho Palos Verdes, CA 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 he speaks for, the Board or its other members. Board Member Biggers has a statutory duty to regulate dentistry in the consumer interest (FDA primarily regulates medical products, while states primarily regulate the professionals who administer them). Because FDA has failed to classify mercury amalgam and publishes deceptive information about its health risks, neither Member Biggers nor the Board can effectively address the mercury fillings issue nor effectively regulate dentistry.

Karen Johnson (1700 W. 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 Board Member 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 to focus on protecting children and families from toxins and other risks.

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. He is concerned about FDA's failure to inform the public of amalgam's health or environmental impact.

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 fillings. As a young woman, she suffered such severe neurological problems she was confined to a nursing home; after the removal of her mercury fillings, 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. Plaintiff Brocato received implants of amalgam fillings without being aware, or being advised, that they contained 50% mercury.

Anita Vazquez Tibau (P.O. Box 664, Newport Beach, CA 92661), who lives in Rio de Janeiro as well as in the state of California, is an international advocate for abolishing mercury fillings. Because of the placement of amalgam two decades ago, she suffered substantial and life-threatening symptoms of asthma, symptoms that dissipated rapidly when her amalgam was removed. Plaintiff 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 being advised, that they contained 50% mercury.

APPELLEES

Food & Drug Administration (FDA), established by the Department of Health and Human Services, is responsible for regulating the nation's food, drugs, cosmetics, and medical devices. It is tasked with "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner. (emphasis added*). 21 U.S.C. § 393* (2006). Add. at 30. Regarding medical devices, the FDA must "protect the public health by ensuring that…there is reasonable assurance of safety and effectiveness of devices intended for human use." *Id*.

(B) **Ruling under Review**

(1) The ruling of which review is sought is the FDA decision not to classify the device encapsulated mercury amalgam, nor to do an environmental assessment.

(2) This decades-long policy best exemplified by the *Order* in question, *Joint Meeting of the Dental Products Panel of the Medical Devices Advisory Committee of the Center for Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research* (the "*Order*") App. at 1. Ordering another hearing on the safety of mercury amalgam only served to extend the three-decade-old FDA policy of ignoring the classification and environmental provisions of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

(C) **Related Cases**

This case has not previously been before this Court or any other court. The Appellants are not aware of any related cases pending in this Court or any other court.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

RELEVANT STATUTORY PROVISIONS AND REGULATIONS

GLOSSARY

CENTER or **CENTER FOR DEVICES:** FDA's Center for Devices and Radiological Health

COMMISSIONER: Commissioner, Food & Drug Administration

EIS: Environmental Impact Statement

FDA: Food & Drug Administration

FDCA: Federal Food, Drug, & Cosmetic Act

FOIA: Freedom of Information Act

FONSI: Finding of No Significant Impact

NEPA: National Environmental Policy Act

NIH: National Institutes of Health

NIDCR: National Institute of Dental and Craniofacial Research

ORDER: FDA's April 3, 2006 Order

PANEL: Dental Products Panel

JURISDICTIONAL STATEMENT

The FDA has subject-matter jurisdiction over medical devices pursuant to the FDCA. *See* 21 U.S.C. §393(b) (stating that FDA is responsible for the safety and effectiveness of medical devices). Add. at 30. Appellants cite three paragraphs under the Judicial Review section of the FDCA, §360g: subsection (a)(4), "the promulgation of a regulation under [21 U.S.C. §360e(b)(3)] requiring a device to have an approval of a premarket application"; subsection (a)(8), an order of substantial equivalence (21 U.S.C. §360c(i)); and subsection (a)(9), a regulation under 21 U.S.C. §360e(i)(2), where Congress directed FDA to speed up and finish classifying devices by 1995. Add. at 28. For subsection (a)(4), jurisdiction is invoked because FDA refuses, decade after decade, to write the required regulation to classify. For subsection (a)(8), FDA is approving applications based on an invalid substantial equivalence test. For subsection (a)(9), Congress directed in the early 1990s that the Secretary complete the process by 1995. The non-action now, 11 years after that deadline as well as 20 years after classifying all other dental filling materials and 30 years after Congress initially directed classifying all devices, adds weight to the point that now is the time for judicial review.

Alternatively, Appellants filed this petition on April 27, 2006, to seek review of FDA's most recent action, an order/notice of April 3, 2006, to convene two scientific panels to discuss, but not to act on, amalgam. Rather than ask the Panels to recommend a classification, a step required by law to classify, FDA convened the meeting to seek approval of a "white paper," a stalling tactic designed to continue FDA policy of not classifying amalgam.

Alternatively, this case is brought under 5 U.S.C. §703, a jurisdictional catch-all which allows for judicial review of actions of federal agencies like FDA in circumstances which do not precisely fit the "special statutory review" section of the statute covering that agency. Add. at 2.

Congress directed that appeals addressing classification and substantial equivalence decisions go to this Court, and it is clear that the standard of review contained in 21 U.S.C. §360g contemplates those instances where a federal agency has simply refused to take action when its statutory duty to act is unequivocal. Add. at 28.

Finally, Appellants reasonably believe their standing is self-evident. The Government did not raise the issue of standing before the Motions Panel, and Appellants do not expect standing to be in question. Appellants submit, in the Appendix, sworn statements from eight of the nine Petitioners establishing the parties' injuries. App. at 155-162.

STATEMENT OF ISSUES PRESENTED FOR REVIEW

I. Whether FDA may, while refusing to classify for 30 years the pre-amendment implant encapsulated mercury amalgam, allow this device to remain in commerce.

II. Whether FDA may evade judicial review of its approval process for encapsulated mercury amalgam by refusing repeatedly to classify it.

III. Whether FDA, while acting to protect the public from other sources of mercury exposure and acknowledging the environmental harm of mercury from amalgam, may refuse to do an environmental assessment while it considers regulatory options on encapsulated mercury amalgam.

IV. Whether a classification panel may recommend a class I or II designation for an implant if it does not also issue a statement explaining why premarket approval (proof of safety) is not necessary.

V. Whether FDA has such untrammeled discretion in determining substantial equivalence, therefore bypassing proof of safety, that it may equate (i) a device which is 50% mercury, ready for use, and a capsule, to (ii) a device defined as containing no mercury, is not ready for use until mixed, and is a powder.

STATEMENT OF THE CASE

On April 3, 2006, in its latest stalling tactic to avoid its duty to classify encapsulated mercury amalgam, FDA issued a notice calling for another advisory Panel meeting to review the literature. FDA called a similar meeting over a decade ago, and in the time in between has done three so-called literature reviews while repeatedly promising to classify. At that meeting on September 6-7, 2006, the Panels decisively rejected the premise that amalgam is safe, delivered to them yet another FDA diversion, a "white paper."

Since that April 3 notice – an order in the Federal Register -- promised more delay, Appellants took steps to end this charade. Since "orders" for the purpose of appellate review include negative parts of an Agency's final disposition of a matter, *see* 5 U.S.C. §551(6), Add. at 2, Appellants Moms Against Mercury, et al., filed a petition on April 27, 2006, to review FDA's inaction on amalgam with the Circuit Court of Appeals, D.C. Circuit. On June 1, 2006, Moms filed a Motion for Interim Relief, asking that this Court halt amalgam sales in commerce until the resolution of this case.

On June 28, FDA moved to dismiss the petition for a lack of jurisdiction. Additionally, on June 30, 2006, FDA filed an opposition to Moms' Motion for Interim Relief. On July 19, Moms responded to FDA's motion to dismiss, and replied to the Agency's opposition to Moms' motion for emergency relief.

The Motions Panel rejected both motions – FDA's motion to dismiss on jurisdictional grounds, and Petitioners' motion for emergency relief. On November 1, 2006, the Merits Panel ordered that a briefing schedule be established, and further, that Moms' opening brief be submitted by December 11, 2006.

STATEMENT OF FACTS

Although mandated since 1976 to classify all medical devices (including dental fillings) into one of three categories to reflect relative risk, the Food and Drug Administration has never classified encapsulated mercury dental amalgam. After classifying all other dental filling materials in the 1980s, FDA over the past two decades has repeatedly responded to citizen requests, formal petitions, and even litigants that it will classify amalgam -- then just as often breaks its promise.

The decision not to classify mercury amalgam is no oversight. Testifying before Congress four years ago, FDA's lead regulator of devices had no excuse or explanation for classifying all other dental filling materials while ignoring the oldest and probably best-known type of filling:

> "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 for Devices and Radiological Health, FDA]: That is correct."
>
> --- "Mercury in Dental Amalgams," Hearing before the House Committee on Government Reform, Nov. 14, 2002, Serial No. 107-159, at p. 125 (emphases added). App. at 138.

Four years after this November 2002 hearing, encapsulated amalgam remains unclassified.

(A) FDA's Protective and Unique Status for **This** Mercury Product

Marketed to the public as "silver" since the 1840s, this primitive device is actually about 50 percent mercury, App. at 90, a deadly neurotoxin that was phased out of medical drugs a century ago and is now outlawed by FDA in animal drugs. App. at 163. (The silvery coloring comes from the presence of mercury – quicksilver.)

The World Health Organization and the Canadian government identify dental amalgam as the primary source of human exposure to mercury, with fish consumption and industrial pollution trailing as second and third. App. at 164, 190. The scientific community is unanimous in recognizing that exposure to mercury can permanently impair the nervous system of fetuses within the mother's womb, damage the developing brain of young children, and exacerbate kidney disease in adults; the Centers for Disease Control warns of that mercury's "**well-characterized adverse reproductive effects**." Pre-natal exposure to mercury may cause "mental retardation, … sensory impairments, and cerebral palsy." Outside of the nervous system, the "most prominent effect" is damage to kidneys, with other damage including "parasthaesia, ataxia, dysarthria, hearing impairment and progressive constriction of the visual fields." App. at 166.

Amalgam arrives at the dentist's office in sealed containers with  above the words "POISON, CONTAINS METALLIC MERCURY." Mercury, the warning states, is a "potentially hazardous substance" with "neurotoxic [poison to the brain and nervous system] and nephrotoxic [poison to the kidneys] effects."

- 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.) App. at 199.

- Dentsply, the second largest manufacturer, and Vivadent, the third largest manufacturer, go farther, issuing contraindications [*N.B.*: "Contraindication" is a directive to forbid, not just a "warning."]. They state dentists should not put mercury fillings in the following patients:
    - In patients with impaired renal function.
    - In children 6 and under.
    - In pregnant or nursing mothers.

  App. at 200-206.

Yet **these stark manufacturer warnings are not reaching the American public**. A 2006 Zogby poll found that less than one American in four can identify mercury as the main component of amalgam – while over three in four would pay more to get a filling with no mercury. App. at 207.

With the growing use of substitutes like resin, amalgam is no longer needed in modern dentistry. App. at 222-223. Indeed, many dentists no longer use amalgam at all. "Mercury-free" dentistry (dentists who implant only non-toxic materials) is growing rapidly. Industry polling puts the number of such dentists at over 30%. App. at 230. Meanwhile, mercury amalgam's use is declining, with resin now being used more often than amalgam. No dentist need place amalgam any longer; any cavity in any child or adult may be filled with alternatives, such as resin for small cavities and porcelain for large ones. App. at 222-223. Dentists who still use amalgam are those engaged in factory-style operations, where they can make more per chair per day using amalgam; even Medicaid now will cover alternatives. App. at 224. The motivation to keep amalgam is therefore dentist profits and dentist convenience (they being the quickest and easiest to implant). App. 222-223.

Who still gets amalgam is now a growing public policy concern. Minority-led organizations note that the recipients are heavily minority and poor. They have expressed grave concern that pregnant women and children, especially at the lower end of the socioeconomic scale, still receive mercury fillings – without even a warning. Resolution of national NAACP (2002); Resolution of National Black Caucus of State Legislators (2001), App. at 231-233.

FDA's response to this widespread consumer ignorance has been contrary to its mission as the nation's protector of health. Instead of acting to make sure Americans learn that silver fillings are really mercury fillings, and to try to warn parents and young women about mercury exposure from amalgam, FDA partners with organized dentistry to **conceal** this from consumers. In 2002, FDA proposed a regulation that would overturn manufacturer warnings and thwart state "fact sheet" laws. In the place of manufacturer warnings, FDA proposed mandating in large print that amalgam contains zinc, but no warning at all that amalgam contains mercury. App. at 90. Zinc is in fact a nutriment necessary for the body in small quantities, while mercury is a xeno-toxic, meaning toxic at any level and of no benefit. The disclosure of the zinc while covering up the mercury was a further surprise because amalgam is 50% mercury, about 30% silver, and only a small amount of zinc. App. at 126.

For other mercury-containing products, FDA protects the public from exposure or at least acts to warn it. For example, (1) FDA bans mercury in veterinary medicines to protect animals from toxic exposure; (2) FDA bans mercury in disinfectants (e.g., Mercurochrome); (3) FDA removed mercury from childhood vaccines as a precautionary step. (4) FDA issues warnings to pregnant women and parents about mercury in fish. App. at 163, 235, 245, 251.

When evaluating mercury toxicity from amalgam, FDA writes conclusions at odds with its dire health concerns about mercury toxicity from disinfectants, medicines, or fish. Although

accepting that those with hypersensitivity or previous mercury exposure may be at risk of neurological damage from mercury amalgam, and acknowledging that Health Canada concludes that mercury amalgam is the largest source of mercury to human beings, FDA nonetheless concludes the major risk of mercury from amalgam is "allergic reactions." App. at 90. No paper by any toxicologist can be found by Appellants that concludes the primary risk of mercury exposure is allergies. Also, FDA concludes that the "most notabl[e]" evidence of the "safety and effectiveness of dental amalgam is … the significant human experience with amalgam for over 100 years." App. at 90. The hypothesis that longevity of use equates to safety has, to Petitioners' knowledge, no scientific validity.

FDA's protection of mercury-based amalgam is also at odds with all other federal agencies operating in this arena: the Centers for Disease Control warns that mercury amalgam constitutes a "major exposure" to toxic mercury. App. at 166. The United States Environmental Protection Agency warns young women against any exposure to mercury, because one in eight already has so much mercury in their body that they are at risk of having brain-damaged children. App. at 254.

FDA's inaction on amalgam is in sharp contrast to health oversight agencies elsewhere. Back in 1996, Canada wrote its dentists directing that they cease placing mercury amalgam in children under six, in pregnant women, in those with kidney disease, in those with braces, and with those with mercury hypersensitivity. App. at 190. The United Kingdom followed suit with regard to pregnant women in 1998. App. at 256. The Scandinavian countries are phasing out mercury fillings altogether. App. at 150.

(B) Through Five Cycles of Inaction FDA Promises to Classify, Then Pulls Back

For 20 years, in predictable three-to-six year cycles, FDA repeatedly promises to classify amalgam … then finds an excuse to divert its resources … then puts classifying on the shelf.

First cycle of deception (1986-92): FDA classified all filling materials except the most common one, amalgam, then adopted a means to keep amalgam on the market with no proof of safety (see Part (D) *infra*). After watching and waiting, the Foundation for Toxic-Free Dentistry, et al. with the undersigned Robert E. Reeves as counsel, filed a mandamus to classify before this Honorable Court. Held: Relief denied based on failure to exhaust of administrative remedies. *In Re Foundation for Toxic-Free Dentistry*, 1993 Westlaw 1415. App. at 258.

Second cycle of deception (1993-96): Per the above ruling by the D.C. Circuit to exhaust administrative remedies, a group of citizens, dentists, and nonprofit organizations filed petitions to FDA to classify. App. at 90. FDA responded by doing a "literature review" (1993) – by the very people who controlled the process; they in turn affirmed their previous position. App. at 90. Upon staff request in 1994, the Dental Products Panel provided a recommendation to classify as a "II" – but did not issue any findings stating why it should not be a "III." App. at 5. Then the Secretary, rather than considering the panel recommendation and either classifying or publishing a notice not to classify, did nothing.

Third cycle of deception (1997-2000): Lawyers Reeves and James Turner press FDA to respond to the myriad petitions. FDA's response: a second "literature review" – by the same group. But this time, FDA made a specific promise to classify. On November 10, 1997, Deputy Director Elizabeth Jacobson, Center on Devices, wrote Reeves and Turner with two unequivocal promises:

> "**FDA intends to classify** encapsulated dental amalgam alloy and dental mercury [and] intends to require certain warnings.
>
> --- App. at 66.

That was **nine years ago**.

Fourth cycle of deception (2001-05): In the midst of a movement to ban mercury amalgam, App. at 260, 263, FDA at last proposes a regulation -- to **reduce** public

awareness. The draft rule directed manufacturers to stop issuing warnings, tried to thwart state disclosure laws, and (to divert attention away from the mercury) audaciously directing a bold warning that amalgam contains (only) zinc! App. at 126. A public outcry erupted; thousands of submissions came in against the rule. In October 2002, Director Feigal, Center for Devices, put the proposed regulation on hold; in November, he advised a House Committee that the proposed regulation is on hold pending – *no surprise here* – a **third** "literature review." App. at 266. The controversial LSRO Report was released in 2004, and immediately was put under federal investigation by the National Institutes of Health, App. at 229. FDA's Center for Devices, put on notice that its third literature review is under investigation by NIH, agreed to cooperate. App. at 153. In 2005 Acting Commissioner Crawford informed Senator Kennedy that the proposed FDA regulation was "on hold." App. at 140.

Fifth cycle of deception (2006-20??): On April 3, 2006, FDA ordered that two scientific panels convene for a public meeting on the neurotoxicity of mercury amalgam, but not to ask for a recommendation. App. at 90. Instead, FDA presented its legally extraneous "white paper," which after two days of hearings, the scientists, on September 7, decisively rejected -- both the staff's methodology and the staff's conclusion that mercury fillings are safe: Quoting from the FDA's own record, App. at 145:

> "Does the draft FDA White Paper objectively and clearly present the current state of knowledge about the exposure and health effects related to dental amalgam?
> Yes 7, **No 13**.
>
> "Given the amount and quality of information available for the draft FDA White Paper, are the conclusions reasonable?
> Yes 7, **No 13**." [1]

Advised their "science" was wrong, FDA has done nothing since. However, the sequence of announcing the panel meeting, limiting the agenda to a white paper, then asking for another round of comment – has meant FDA has spent another year keeping amalgam unclassified.

[1] Transcript of testimony: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=668

(C) FDA's Refuses to Require Proof of Safety of Amalgam

Manufacturers acknowledge that they could probably never prove that amalgam is safe. App. at 267. Yet FDA relieves them of that burden, allowing amalgam – which is 50% mercury and emanates toxic vapors – in commerce with no proof of safety.

To get and keep mercury-based fillings on the market, FDA invokes a "substantial equivalence" test – but equates such fillings to a material having no mercury! The latter, known as the predicate device, is defined thusly (21 C.F.R. 872.3050):

> An amalgam alloy is a device that consists of a metallic substance intended to be mixed with mercury to form filling material for treatment of dental caries.

This alloy is not even a device by itself; in the past, dentists use to mix it in their offices with mercury to create personalized amalgam. This 19th-century system is absolutely discredited in all dental circles. App. at 268. Thus, FDA has equated encapsulated mercury amalgam (a capsule, a product containing 50% mercury, and a complete device) with amalgam alloy (a powder, a product with zero mercury, and an incomplete device).

FDA is using this substantial equivalence test repeatedly, approving ten applications under this system in the past six years. App. at 144. Yet Acting Commissioner (now Commissioner) Von Eschenbach, replying to a written question from Senator Kennedy on how such an incongruous comparison could be made, denied that FDA was using such a test. The Commissioner wrote: "We have not cleared the dental amalgam devices as substantially equivalent to non-mercury powder alloy." App. at 147.

A continuing controversy is whether dentists should continue to control amalgam regulation and research at FDA. In 2002, Senator Lautenberg wrote NIH to stop having dentists in charge, noting that dentists have an "inherent conflict of interest" in the use of amalgam, and are far less qualified than toxicologists or physicians to determine the impact of

dental mercury on the fetus, the child's brain, or the adult's kidneys. App. at 271. FDA attempted to justify dentist control, in a 2006 letter to Senator Kennedy, by claiming that the issue in the continued use of mercury in dentistry is placement (how they fit in the teeth), not toxicity. App. at 147.

(D) FDA Refuses To Do An Environmental Assessment

Three times, FDA has rejected doing an environmental impact statement or an environmental assessment:

- In 1997, FDA refused to do an environmental assessment requested in a citizen petition from Dr. Cheraskin and Dr. Ringsdorf. App. at 34.

- In 2002, when FDA proposed a regulation, it refused even to do an environmental assessment, claiming – without supplying an iota of support or referring to any staff research – that amalgam "does not individually or cumulatively have a significant impact on the human environment." 67 Fed. Reg. 7628 (Feb. 20, 2002).

- 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. App. at 273. 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!

That mercury from dental amalgam has a **colossal impact on the environment** is a point FDA could easily find out by reading reports on the national data, or a plethora of studies on cities or regions. App. at 275, 276.

- 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.
- 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.

Sources: Taking a Bite Out of Dental Mercury Pollution / The 2005 Report Card on Dental Mercury Use and Release Reduction, 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); and Dentist The Menace? The Uncontrolled Release of Mercury, by the Mercury Policy Project, Health Care Without Harm, Sierra Club, and Toxics Action Center (2002). App. at 279, 287.

The rest of FDA, in sharp contrast to the pro-amalgam Center on Devices, cuts square corners on the environmental impact question. In its proposed rule on the sugar substitute "sucralose" (unlike amalgam, hardly a raging environmental issue), FDA concludes no Environmental Assessment is needed – but only after doing an initial analysis and referring the regulation reader to that staff research.

> "The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch." Vol. 64, p. 43909, 8/12/99. App. at 292.

Actually, FDA's Center for Devices **does** know of the environmental harm from amalgam, and admits it. In its 10/31/06 public statement on mercury fillings, the Center concedes that some countries are phasing out mercury amalgam use for environmental reasons alone. App. at 150.

(E) FDA Has No Valid Panel Recommendation and Seeks None

Back in 1994 – an earlier scientific era, before FDA began its sequence of bans and restrictions on virtually all other mercury-based products, and before the vaporizing tendency of mercury fillings was well-known – FDA's Dental Products Panel recommended that encapsulated mercury amalgam be upgraded to a Class II device. Although mercury amalgam is an implant, the Panel failed to issue a statement of why premarket approval is not necessary to ensure that amalgam is safe and effective. App. at 5. The Commissioner failed to respond to the panel recommendation, and amalgam remained unclassified. FDA staff finally proposed a rule in 2002, but then moved the regulation to inactive status while it handpicked a meetings planner and a tobacco consultant to do a literature review. In September 2006 the Dental Products Panel, joined with a panel specializing in neurotoxicology issues, voted 13 to 7 to reject a staff white paper which claimed mercury fillings are safe. App. at 145.

FDA did not request a classification recommendation at that 2006 meeting, and has requested none since.

(F) Rather than Classify, Require Proof of Safety, or Do an Environmental Assessment, FDA Assumes Role as Cheerleader for Amalgam

Whether mercury amalgam should continue to be used in oral health care has been and remains the leading controversy in dentistry. Thus the nation's overseer of health could not disregard the issue. But as a course of action, FDA chose rhetoric – being the nation's advocate for mercury fillings instead of the regulator. But the agency's campaign is filled with spurious and error-ridden propaganda. Its flood of consumer updates, white papers, literature reviews, and news releases are replete with outright scientific errors (e.g., the risk of mercury is "allergies," not neurological damage); debatable anecdotal evidence (the reason amalgam is good

is because it has been used for over 100 years, the same case the tobacco industry made for its claim cigarettes are safe); false claims (denying that Canada and other countries have warned against amalgam for health reasons); and misstatement of FDA's mission (saying it would act if amalgam is proved unsafe rather than reversing the burden). App. at 90.

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" (because that consultant had an existing contract) to act as strawperson, then directed the latter to handpick as subcontractor a consultant for the major tobacco companies to do the actual work, and presented the latter with a blueprint of result that the FDA desired. To block scientists with real expertise, NIDCR-FDA ordered that no panelist be appointed who had done research on mercury (the opposite of what government panels are supposed to have). 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, and who put FDA on notice of it. App. at 153, 227, 229.

FDA has never even sought to justify the unique regulatory status for mercury fillings – unique in terms of mercury products, unique in terms of dental fillings, unique in terms of

defining of what constitutes substantial equivalence. When asked by Chairman Burton why FDA would choose not to classify amalgam in the 1980s while classifying all other fillings, Director Feigal of its Center for Devices replied,

> "To be honest, we do not know." App. at 138.

FDA has announced its plans for amalgam – which includes neither classifying, nor an environmental assessment, nor seeking a panel recommendation. On October 31, 2006, FDA issued "Questions and Answers on Dental Amalgam, FDA answered its own question, "What is the next stop for FDA?" by listing only one option: labeling. App. at 150.

SUMMARY OF ARGUMENT

Thirty years after being directed to classify all devices, 20 years after classifying all other dental fillings materials, 13 years after being mandamused to classify but winning on exhaustion grounds, nine years after specifically promising (in writing) to classify, four years after pleading no excuses to Congress for not classifying, it's clear that FDA's policy is **not to classify encapsulated mercury amalgam**. To say FDA ignores this issue is incorrect: FDA's public relations machine is has been in high gear, as the Center for Devices bobs and weaves about its duty to classify through three "literature reviews," three "consumer updates," one "white paper," and a plethora of sound bites.

The decision not to classify – a plain violation of the statute – is thus a reviewable decision.

FDA's choice of cheerleader for amalgam, instead of regulator of amalgam, is not acceptable. FDA otherwise bans, limits, and warns against other products, drugs, or foods containing mercury, while other federal health agencies and the health regulators of other nations condemn mercury amalgam.

FDA not only ducks classifying, but also refuses to do an environmental assessment, which would plainly indicate the need for an environmental impact statement. Nor will FDA seek a timely and valid panel recommendation – the previous one being too old (1994), procedurally invalid (no statement for departing from Class III), and sub silentio overruled in September 2006. The writing is on the wall in both cases: An environmental assessment will plainly indicate the need for an environmental impact statement, which report would show alternatives to toxic mercury can be used in fillings, thereby eliminating the major source of mercury in the nation's wastewater – amalgam. In September, the FDA panel decisively rejected

the FDA staff's pseudo-science about amalgam (e.g., it is safe because it's been used for a long time), so FDA ducks asking the panel for formal action.

FDA keeps amalgam on the market via a sham substantial equivalence test, pretending that a powder half-device containing no mercury equates to a full device capsule that is 50% toxic mercury. When asked by Senator Kennedy why this practice is allowed, Commissioner Von Eschenbach in writing denied that FDA considers the two devices to be substantially equivalent. Since the staff has ten times approved amalgam under this test in the past six years (and many times before that), perhaps the Center for Devices is engaged in rogue activity unknown to the Commissioner's office.

The correct recourse is not a mere order to classify, allowing an unclassified, unregulated device – with 50% mercury and for which substitute materials are legal and available for any dentist to place – to remain in commerce, but to remove it from commerce temporarily until FDA complies with its legal duties.

STANDARD OF REVIEW

FDA's failure to regulate amalgam in accordance with the Food Drug and Cosmetic Act is reviewable by this Court under Section 706 of the Administrative Procedure Act, as indicated by 21 U.S.C. 360g(c). Add. at 2, 28.

ARGUMENT

I. FDA's Decision Not To Classify Encapsulated Mercury Amalgam Means the Device May Not Remain in Commerce

A. FDA Refuses to Classify Mercury Dental Amalgam

No other inference other than refusal to classify is reasonable.

FDA has not classified encapsulated amalgam during the 30 years since it was ordered to, nor in the 20 years since it classified all other dental materials, nor in the 13 years since it dodged a previous ruling on the merits via the exhaustion issue, nor in the nine years since specifically promising (pursuant to a petition) to classify, nor in the four years since pleading *nolo contendere* before a Congressional committee, nor in the 18 months since then-Commissioner Crawford advised Senator Kennedy that classification is "on hold," nor in the three months since two scientific panel turned thumbs down on FDA's "but this mercury is safe" mantra.

FDA can hardly say the issue got lost in the bureaucracy – or that it's too insignificant to give attention. FDA banned, limited the use of, or warned against all other major sources, and many not-so-major sources, of mercury exposure. FDA protects animals from mercury exposure by banning the toxin from every single veterinary medicine. Meanwhile, the Center for Devices, aware that this is the major dispute inside dentistry, doggedly sticks to a public relations strategy.

To say FDA has been inactive on the mercury amalgam issue is incorrect. FDA has been a whirlwind of activity, all in the public relations field. As FDA ducks its legal duties, it engages in a plethora of legally extraneous activities – three consumer updates, three literature reviews, a white paper, speeches, etc. Meanwhile, amalgam apologists at FDA's Center for Devices put forward bizarre medical theories: (1) the risk from the most virulently toxic heavy metal is an "allergic reaction" (as if a skin rash should be of greater concern that permanent neurological damages); and (2) taking a page from the cigarette companies (it must be safe because people

have smoked for so long), FDA reassures Americans that the "most notable" evidence of amalgam safety is that it has been in widespread use for over 100 years.

B. The Decision Not To Classify Is a Decision.

The Secretary **must** classify **all** devices, 21 U.S.C. §360c(b)(1). Add. at 3. No exceptions. Providing specific guidance to address agency inaction is *Cobell v. Norton*, 240 F.3d 1081, 1095-1097 (D.C. Cir. 2001). The Court affirmed a ruling that the Bureau of Indian Affairs unreasonably delayed the discharge of their fiduciary obligations. As with the petition at bar, the agency had discretion on what to do – but it could not fail to act. In reviewing a claim for agency inaction, the D.C. Circuit considered four factors:

(1) how much time has elapsed since coming under a duty to act. In the case at bar, FDA has had 30 years, since the 1976 amendments; in *Cobell*, the agency had likewise failed to do an accounting for "decades."
(2) the reasonableness of the delay. FDA has proffered no excuse.
(3) the consequences of delay. Amalgam is a device that is no longer needed in dentistry, and is so controversial its use has been banned in pregnant women and children by other governments, such as Britain and Canada. The balancing of risk to fetal and child health vs. dentists' profits should be an easy one.
(4) the practical difficulties in carrying out its statutory mandate. If amalgam is as safe as FDA's dentists claim (which petitioners doubt), FDA should have scant difficulty jumping through hoops it jumps through for thousands of other devices.

In *Cobell*, this Circuit holds:

> "[Where] an agency is under an unequivocal statutory duty to act, failure so to act constitutes, in effect, an affirmative act that triggers final agency action review. …**Were it otherwise, agencies could effectively prevent judicial review … by simply refusing to take final action.**" *Ibid.* (Emphasis added.)

C. All Devices Must Be Classified, So a Device FDA Chooses Not To Classify May Not Remain In Commerce.

Having failed to classify, having failed to require proof of safety, having failed to seek timely or respond timely to a Panel recommendation to classify, and having rejected doing the environmental assessment before classifying, **FDA has done none of its primary duties to regulate with this device**. **An unclassified, unregulated device, never proved safe but composed 50% of mercury, is in commerce**. Under FDCA requirements, amalgam must be temporarily removed from commerce, until FDA lawfully classifies this implant.

If a private sector entity were to try to sell an unclassified product that was never subject to proof of safety, that contained 50% mercury, stopping its sale would not be a close call. Because the facilitator is a unit of FDA should not deter a remedy.

First, mercury fillings are no longer needed for oral health care. The emergence of resin as the major filling component, available for any kind of filling eliminates any valid reason for amalgam. The latter exists solely for dentist convenience – fast and easy work for old-fashioned or profit-centered dental offices that have not transitioned.

Second, the agency's choice to propagandize rather than to regulate must not be rewarded. This case is not about an agency trying to comply with the law but falling short. It concerns a bureaucracy choosing to disregard **all** its major legal duties regarding a controversial health product, substituting a bully pulpit role to covers up its failures.

Third, in sharp contrast to other FDA Centers who try to warn and otherwise protect the public against mercury exposure, FDA's Center for Devices is an active participant in covering up the mercury in amalgam. In 2002, the Center recommended that a bold warning issue on one material in amalgam – but not the mercury. Rather, the Center wants to highlight the small presence of zinc, a nutriment required in small quantities for human health. This flagrant

diversionary tactic allows the pro-amalgam interests to present the appearance of "disclosure" while hiding the fact that amalgam fillings are mostly mercury.

Fourth, even acting in good faith, FDA couldn't classify encapsulated amalgam in under a year. Due to noncompliance with its duties regarding the panel recommendation and the environmental study – plus rescission of its sham substantial approval process in favor of proof of safety – FDA would have to start from scratch.

In sum, Moms respectfully asks that this Court order the removal of amalgam from commerce temporarily – pending FDA compliance with the FDCA and the NEPA –a necessary step to reign in a rogue bureaucracy. It is not a product ban.

II. FDA May Not Evade Judicial Review On the Grounds that It Has Not Classified Amalgam.

FDA must not be allowed off the hook by asking this Court to await its decision to classify, nor to duck compliance by claiming it must first classify before being reviewed. FDA has made its decision – not to classify. It's time for FDA to stop defending the indefensible, and remove amalgam from commerce while it takes steps to comply with the law.

FDA does not have the discretion to do nothing; it has choices on how to classify, but it must classify. *Norton* v. *Southern Utah Wilderness Alliance*, 542 U.S. 55 (2004). For a unanimous court, Justice Scalia allowed that while the agency has discretion on what course of action to take, it must act.

III. FDA Must Perform an Environment Assessment Forthwith.

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"). 42 U.S.C. §332 (C). Add. at 31. The statutory term

"proposal" requires the agency to incorporate environmental policy into its decision-making before it chooses between options (and thus long before it decides to take action) 40 C.F.R. §1508.23. Add. at 33. 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, 40 C.F.R. §1508.9. Add. at 34. 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," known as a FONSI statement (Finding Of No Significant Impact), 40 C.F.R. §1508.13. Add. at 34.

The Food Drug and Cosmetic Act mandates FDA compliance with NEPA; 21 USC §379o. Add. at 30. FDA has a specific set of regulations to ensure agency compliance; FDA must do at least an environmental assessment when considering, among other tasks, regulations and premarket notifications. 21 C.F.R. §25.20(g) and (n). Add. at 31. An E.I.S. is required, too, where there exists a "potential for serious harm to the environment." 21 CFR §25.21. Add. at 33.

Contrast that with the Center on Devices' arrogating to itself the power to make decisions without process, without facts, and without an iota of public input: a mere announcement, a conclusion without an analysis, no offer of back-up material, not a shred of evidence – this about a toxin known to all to cause gigantic environmental damage.

As shown in the Statement of Facts, amalgam is the largest source of mercury in the wastewater – mainly from dental offices-- and a growing source in the air as well (due to the increase in cremations).

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." 42 U.S.C. §332(C)(ii) and (iii). Add. at 31. Plainly, the route to "avoid" adverse environmental effects is to direct

dentists to alternatives, what over one-third of U.S. dentists are already doing every day. The agenda of FDA's rogue Center on Devices is clear: **To keep amalgam on the market by refusing to do an environmental assessment**.

Therefore, Moms respectfully asks that this Court compel FDA to immediately assess the environmental impact of dental mercury on the environment.

IV. FDA Has No Valid Panel Recommendation To Classify Encapsulated Mercury Amalgam

Before classifying a preamendment implant, the Secretary must seek and obtain a classification recommendation from an advisory panel. 21 U.S.C. §360c(c)(1). Add. at 3.

The 1994 Panel recommendation is invalid for **any** of these four reasons:

(1) it did not provide a statement as to why to depart from the presumption of Class III for preamendment implants, 21 C.F.R. §860.84(d)(6) Add. at 33;

(2) the Commissioner failed to publish or otherwise respond to the recommendation within a reasonable period of time, 21 U.S.C. §360c(d) Add. at 3;

(3) the passage of times makes it inoperative for scientific reasons – it being done before FDA recognized the impact of minute exposure to mercury exposure and began to ban, limit, or warn against mercury in virtually all other products; or

(4) it has been superseded by the September 7, 2006, vote to reject the staff position, which equates to the panel position in 1994.

At the 1994 proceeding, the Dental Products Panel simply voted to recommend that encapsulated mercury amalgam be a Class II. The Panel ignored the statutory mandate to provide specific reasons why a pre-amendment implant should not be a Class III. 21 U.S.C. §360c(c)(2)(C). Add. at 3. Now that the Dental Products Panel is on record warning about

mercury fillings, FDA stands in equipoise – it won't bring the matter back to them for a formal recommendation. FDA's Center for Devices knows that it cannot continue its unregulated posture for mercury fillings once it complies with this legal requirement.

Therefore, Moms respectfully requests that this Court set aside the Panel's class II classification recommendation, for it is not in observance of procedure required by law.

V. FDA's Substantial Equivalence Test for Encapsulated Mercury Amalgam Is Invalid

Since proof of safety for a product that is 50% mercury seems, at best, dubious, the amalgam advocates at FDA discovered a way around it: They sought out an existing classified device, in order to shoehorn mercury fillings into commerce as a "substantially equivalent" product. The device they chose was a curious one. Until the first half of the 20th century, dentists (like pharmacists of old) mixed amalgam in their offices – combining liquid mercury that came in a bottle and a powdery non-mercury alloy material. Despite the enormous health risks of having a bottle of mercury around, and exposing staff to such a severe exposure, a few older dentists continued to use it until recent decades, when the American Dental Association directed its use be stopped, and several states followed suit with statutory bans. But the old powder was classified, 21 C.F.R. 872.3050, so FDA staff trotted it out this obsolete material for a different use: as a substantially equivalence marker.

The two materials are so incongruous in nature that one wonders if FDA's pro-amalgam Center on Devices assumed no one would ever challenge them. "Substantial Equivalence," 21 U.S.C. §360c(i), Add. at 3, a route whereby FDA may bypass proof of safety for a new device if it mirrors an existing one, has rigid standards. Since the two devices plainly lack "the same technological characteristics," the second device must be demonstrated to be "as safe and

effective as a legally marketed device," and must "not raise different questions of safety and effectiveness than the predicate device."

One wonders if the Center ever told the Commissioner's office what it was doing. In August 2006 Acting Commissioner (now Commissioner) Von Eschenbach denied in writing to Senator Kennedy that FDA has ever made this determination of substantial equivalence in the premarket notification process. With the Center repeatedly approving mercury amalgam under this test, and the Commissioner denying that these two devices have been determined to be substantially equivalent, further questions arise as to its propriety and legality. In determining the degree of deference owed an agency determination, courts have distinguished between claims that an agency's action is *ultra vires* and claims that an agency's interpretation of the act it administers is legally unsound. *Utah Power & Light Co. v. Environmental Protection Agency*, 553 F.2d 215, 218 (D.C. Cir. 1977). The FDA practice of equating mercury amalgam to alloy powder is legally unsound, contravenes the purpose of the substantial equivalency function, and cannot be awarded any judicial deference.

Moms respectfully asks this Court to set aside and hold as unlawful the FDA practice of allowing new mercury amalgam products to be marketed by concluding that they are substantially equivalent to the device identified in 21 C.F.R. 872.3050, dental alloy. Add. at 33.

CONCLUSION

This Court must direct FDA to start being amalgam's regulator instead of amalgam's cheerleader.

Whether by intention or lethargy, FDA's Center for Devices has protected the marketing of mercury fillings by doing none of its regulatory duties – neither classifying nor requiring proof of safety nor doing an environmental assessment nor seeking a valid recommendation from

the scientific panel. Since they have ducked and dodged classifying encapsulated amalgam after classifying all other dental filling materials in the 1980s, the mercury apologists at the Center for Devices by now realize that completing any of these tasks will lead straight to the end of mercury in dentistry.

Thus, an order to classify is not enough. The legal prerequisites (environmental impact statement and Panel referral) mean the process will take months; the record of bad faith suggests it will take years. Amalgam is illegally in commerce. It must be removed from commerce forthwith, temporarily, until FDA chooses to complete its regulatory duties.

Respectfully submitted,

Charles G. Brown, Esq.
1725 K Street, NW
Suite 511
Washington, DC 20006
202-884-0315
Counsel for Appellants

Robert E. Reeves --
REEVES LAW OFFICE
167 West Main St., Suite 1310
Lexington, KY 40507
859-226-0700
Counsel for Appellants

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of December 2006, I caused copies of the foregoing brief of Moms Against Mercury, et al. to be served on the parties indicated below by first-class, postage-prepaid United States mail:

Mark B. Stern
Attorney, Appellate Staff
Civil Division, Room 7236
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

Catherine Y. Hancock
Attorney, Appellate Staff
Civil Division, Room 7236
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

_____
Charles G. Brown

CERTIFICATE OF COMPLIANCE

I hereby certify on this 11th day of December 2006, that the foregoing Brief of Moms Against Mercury, et al., complies with this Court's orders establishing the number of words to be contained in said brief.

_____
Charles G. Brown