IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MOMS AGAINST MERCURY, 55 Carson's Trail, Leicester, NC 28748; CONNECTICUT COALITION for ENVIRONMENTAL JUSTICE, 10 Jefferson St., Hartford, CT 06145; OREGONIANS for LIFE, 1301 Hwy 99W, McMinnville, OR 97128; CONSUMERS for DENTAL CHOICE, 316 F St., N.E., Suite 210, Washington DC 20006; Michael BENDER, 1420 North St., Montpelier, VT 06520; Karen JOHNSON, 1700 West Washington, Phoenix, AZ 85007; Karen PALMER, 1314 West Union Blvd.) Bethlehem, PA 18018; Corrie CROWE, 10640 Windsor Ct., Orlando, FL 32821; Anita Vazquez TIBAU, P.O. Box 664, Newport Beach, CA 92661; R. Andrew LANDERMAN, 145 Pleasant Hill Ave. North, Sevastopol, CA 95472; Linda BROCATO, 940 East Old Willow Rd. #112,) Prospect Heights, IL 60070;
Plaintiffs,
v.
Andrew von ESCHENBACH, Commissioner, Food and Drug Administration ("FDA"); Randall LUTTER, Deputy Commissioner, FDA; Norris ALDERSON, Associate Commissioner, FDA: Dan SCHULTZ, Director, Center for Devices and Radiological Health ("The Center"), FDA; Chiu LIN, Director, Anesthesiology, General Hospital, Infection Control and Dental Devices, The Center, FDA; and Mary Susan RUNNER,) Director, Dental Devices Branch, The Center, FDA, 5600 Fishers Lane, Rockville, Maryland 20847
Mike LEAVITT, Secretary, Department of Health and Human Services;
Defendants.

Case: 1:07-cv-02332
Assigned To : Huvelle, Ellen S.
Assign. Date : 12/28/2007
Description: Admn. Agency Review

Complaint

Introduction

A. Encapsulated amalgam ("silver fillings") arrives at a dentist's office with  affixed next to the words "POISON, CONTAINS METALLIC MERCURY." Mercury, the warning states, is a "potentially hazardous substance" with "neurotoxic/nephrotoxic effects"; "a chemical known to the state of California to cause birth defects or other reproductive harm." Amalgam makers advised dentists in writing not to place amalgam in pregnant women, nursing mothers, children under six, and anyone with kidney disease.

B. Neither the U.S. Food and Drug Administration ("FDA") nor its independent scientists claim that mercury amalgam is safe. In September 2006 two FDA Scientific Advisory

Committees voted 13 to 7 that an FDA staff "white paper's" conclusion that mercury amalgam is safe is incorrect. In February 2007 FDA admitted five times in a brief to the Court of Appeals, in an earlier version of this case, that FDA doesn't know if mercury fillings are safe or unsafe: "there is a lack of conclusive evidence regarding the health effects of mercury fillings"; "complex issues and intense disagreement [exist] about the scientific evidence regarding mercury and its potential health effects."

C. Yet FDA has for 31 years ignored its duty to classify this device, and worse, allows untrammeled sales and no warnings about the mercury. In 2002 FDA actually launched a campaign to conceal the mercury, even from pregnant women, via a subterfuge warning that "amalgam contains zinc" (zinc is a nutrient, mercury a neurotoxin).

D. Time and again, a rogue bureaucracy inside FDA sabotages pronouncements from the Commissioner's office that FDA will act on amalgam. FDA leaders repeatedly promise to classify – to litigants (1997), to Congressman Burton (2002), to Senator Kennedy (2005), to the Court of Appeals (February 2007). In June 2007, facing a lawsuit by these plaintiffs, FDA promised to announce an Advanced Notice of Proposed Rulemaking. The promise was a sham to buy more time to keep mercury fillings on the market. Meanwhile, in the style of the British Queen, Commissioner Eschenbach chooses to reign but not rule, allowing this bureaucracy to set policy while he and Deputy Commissioner Lutter blithely ignore repeated warnings of lawlessness beneath.

I. JURISDICTION

This action arises under the provisions of 21 U.S.C. §360c, and is filed pursuant to the judicial review provisions contained in 5 U.S.C. §§ 701 to 706. The Court has jurisdiction

under 28 U.S.C. §§ 1331 and 1361, and venue lies in this Court by virtue of the provisions of 28 U.S.C.A. § 1391(e).

II. PLAINTIFFS

A. Moms Against Mercury, a North Carolina nonprofit corporation (*at* www.momsagainstmercury.org), represents children suffering substantial neurological harm from mercury exposure and their families, and works to end those risks in the future, with amalgam being one such major exposure of mercury.

B. Connecticut Coalition for Environmental Justice, a Connecticut nonprofit corporation (*at* www.environmental-justice.org), is a state-based group representing the needs of lower-income and minority citizens. Its central mission is to address the disproportionate impact of toxins on the poor, the urban, and minorities, and it has been active in trying to end the use of mercury amalgam.

C. Oregonians for Life, an Oregon nonprofit corporation (*at* www.oregoniansforlife.org), has a mission to protect the unborn from harm, whether via abortion or toxins. Its mission to protect human life from conception includes a major focus on toxins that harm unborn babies, and its work has included a focus on mercury from dental fillings as a risk to such babies.

D. Consumers for Dental Choice, a Delaware nonprofit corporation (*at* www.toxicteeth.org), has as its sole mission to end the use of mercury in dentistry. The group has petitioned FDA several times, held meetings with FDA officials, written letters to officials at all levels of leadership, assisted with Congressional oversight hearings,

organized submissions by injured consumers and mercury-free dentists, and otherwise taken steps to invite FDA to comply with the Food Drug and Cosmetic Act.

E. Michael Bender was appointed by the Governor of Vermont to the state Advisory Committee of Mercury Pollution (*at* www.mercvt.org/acmp/index.htm). Plaintiff Bender enters this case on his own behalf, and is neither representing nor speaking for any other Member of the Committee nor for the Committee as a whole. His statutory duties, including to "advis[e] the general assembly, the executive branch, and the general public on matters relating to the prevention and cleanup of mercury pollution, and the latest science on remediation of mercury pollution," cannot be done effectively or efficiently with FDA's policy of covering up the impact of mercury amalgam and disseminating incorrect information about it.

F. Karen Johnson is a Member of the Arizona Senate and chairs the Children and Families Committee. Senator Johnson has a constitutional and statutory duty to regulate the dental profession, and a delegated role to lead efforts to protect children and families from dangers such as neurotoxins. She has been active in efforts to limit the use of mercury amalgam.

G. Karen Palmer, Certified Dental Assistant, is disabled because of mercury exposure from working at dental offices. The risk of mercury exposure was hidden from her, a fact due to defendants' cover-up of the mercury and its risks.

H. Corrie Crowe, D.D.S., practices mercury-free dentistry in a public health clinic, but other dentists in that same clinic do not. Due to FDA's failure to warn, dental personnel

have employed imprudent practices that led to much greater mercury exposure for Dr. Crowe. Due to such mercury exposure, she has suffered two tragic miscarriages.

I. R. Andrew Landerman, DDS, a practicing general dentist, does not implant mercury fillings, but he and his staff are constantly exposed to such mercury in the workplace because of its continued use.

J. Linda Brocato is an advocate in her 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 and confined to round-the-clock care, due to the impact of the mercury on her neurological system.

K. Anita Vazquez Tibau, 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.

L. Plaintiffs are interested persons suffering legal wrong as contemplated by 5 U.S.C. §702 and 21 C.F.R. §10.45

III. DEFENDANTS

A. The six defendants from the Food and Drug Administration (FDA) are sued in their official capacities only – pending discovery regarding whether they engaged in their nonfeasance and misfeasance in a malicious, bad faith, or reckless manner.

B. Andrew von Eschenbach, M.D., is Commissioner of FDA. He is aware that FDA staff classified all dental filling materials but will not classify mercury amalgam, but he refuses to follow through when his orders are ignored. For example, he promised Senator Enzi in August 2006, during his confirmation hearings, that the Scientific Advisory Panels convening in September "will be asked to answer specific questions concerning any possible adverse health effects of dental amalgam." Such questions never took place; defendant Alderson sabotaged the order, turning the hearings instead into a referendum on a mysterious staff "white paper" (a vote Alderson lost). No record exists of Eschenbach taking corrective action when he broke that confirmation promise to Senator Enzi – either an apology to Enzi or discipline within the agency. Eschenbach remains indifferent on whether FDA complies with its legal duty to classify mercury amalgam.

C. Randall Lutter, Ph.D., is Deputy Commissioner of FDA for Policy, and is charged with classifying devices. He has repeatedly been warned – at a meeting he presided at in 2005, at a meeting where he directed his assistant Williams McGonagha to preside in 2007, and via receiving a plethora of letters – of lawlessness at the Center for Devices and Radiological Health. He is indifferent to whether FDA complies with its statutory duties on mercury amalgam, or whether directives to the bureaucracy are complied with.

D. Norris Alderson, Associate Commissioner for Science, who presided at the meeting of the two Scientific Advisory Committees in September 2006, sabotaged the confirmation promise from the Commissioner to Senator Enzi. Rather than ask the scientists questions about the toxicity of mercury amalgam, Alderson orchestrated a "white paper," promoted it to the press as if it were an official FDA position, then

presented it to the Panels on a take-it-or-leave-it vote. When not only the "white paper" but also staff's methodology to propagandize for mercury amalgam were rejected by twin 13 to 7 votes, Alderson acted again to sabotage orders. Aligning with defendants Schultz and Runner, he embarked on a disinformation campaign to claim they won the vote they actually lost – astonishingly, they actually claim the scientists voted favorably to the white paper claim that amalgam is safe. First they caused this false information to be posted on the Center's website in 2006, then Alderson testified to Congress deceptively about the vote of the Panels.

E. Daniel Schultz, M.D., Director, Center on Devices and Radiological Health ("the Center"), conspired with his deputy director, Linda Kahan, to keep dentists in charge of decision-making on amalgam, despite knowing that the damage from mercury toxicity is neurological, not tooth decay, hence dentists are not nearly so qualified to decide the issue – plus dentists have a colossal conflict of interest. Schultz and Kahan conspired further to keep toxicologists and neurologists out of policy-making. He approved the website posting in 2006 that falsely claimed the Scientific Advisory Committees voted that amalgam is safe.

F. Chiu Lin, Ph.D., Director, Anesthesiology, General Hospital, Infection Control and Dental Devices, The Center, conspires with defendant Runner to approve encapsulated mercury amalgam, with no limits and no warnings, despite no legal authority to do so. He has assumed the power to rule on substantial equivalence when he lacks the authority to do so; the impact is to allow mercury amalgam to enter the market unclassified and without controls or warnings, creating a health risk to children and unborn children.

G. Mary Susan Runner, D.D.S., Director, Dental Devices Branch, Center, sabotaged a 2002 order from former Center Director David Feigal to contract for an "independent literature review" of mercury amalgam's toxicity issues. Instead, working with dentists in other agencies, she handpicked an unqualified meetings planning company in order to avoid competitive bidding, directed that company to appoint a Beltway tobacco consultant to do the study with whom she or her conspirators had conducted secret meetings to obtain an agreed-upon result. Fully aware that mercury can permanently harm the fetus or the developing brain of a child, Runner nevertheless led the effort in 2002 to conceal forever from dental patients (even pregnant women and parents of young children) the presence of the mercury, via a subterfuge of naming zinc as the controversial product. This outrageous conspiracy to use zinc to cover up the mercury has been joined by defendants Alderson and Schultz.

I. The final defendant, in case required for the remedy, is the Honorable Mike Leavitt, Secretary, Department of Health and Human Services.

IV. PATTERN OF LAWLESSNESS

A. Operating under a collectivist theory of unaccountability, where if everyone does it no one may be held to task, defendants Alderson, Lin, Runner, and Schultz have abused their high-ranking positions by willfully and wantonly defying their statutory duty to regulate mercury amalgam. They have engaged in, or supported the others within the cabal, by engaging in the following acts and practices:

i. Conceal the mercury content from patients, including even pregnant women and parents, most notably by trying to put into effect a 2002 proposal by defendant

Runner mandating that all warnings be banned except the specious one that amalgam contains (the nutrient) zinc;

ii. Conceal the mercury content from patients even though all defendants are aware that most Americans do not know that amalgam is mainly mercury (a fact confirmed by a 2006 Zogby poll), most notably by conspiring with organized dentistry to allow its marketing under the deceptive term "silver fillings";

iii. Sabotage directives from the Commissioner's Office, most notably a 2003 deal initiated by Runner to do a "literature review," enlisting a patently unqualified consultant (a meetings planning company), and appending a tobacco consultant with whom Runner's group had held secret meetings as subcontractor, who in turn flipped the contractual research question to give Runner the result she sought;

iv. Falsely represent via website, Congressional testimony, and other means that two Scientific Advisory Committees voted to support the safety of mercury fillings, when in fact the scientists took just two votes: (1) to condemn FDA's conclusion that mercury fillings are safe, and (2) to condemn the methodology used by FDA staff;

v. Block any meaningful role by real scientists in decision making, most notably, a decision by defendants Schultz and his deputy Kahan to keep dentists in control of making neurological decisions;

vi. Illegally block an Environmental Assessment on regulating dental mercury, the largest source of mercury in the wastewater, the third largest use of mercury, and the largest source of mercury currently in products -- in flagrant disregard of the National Environmental Policy Act;

vii. Illegally block requesting a legitimate and timely classification recommendation by the Scientific Advisory Committee, because defendants Alderson, Schultz, and Runner are fully aware that the Committee would likely recommend a III Classification and effectively put mercury fillings out of business;

viii. Repeatedly approve mercury amalgam for sale, without limits or warnings, under a sham "substantial equivalence" test, one condemned (in *dicta*) by the Court of Appeals in *Moms against Mercury v. FDA* (2007).

ix. Repeatedly promise in bad faith that they intend to classify mercury amalgam when in fact they have no such intention, most notably to plaintiffs in June 2007 for the specific purpose of avoiding getting sued, a step that caused plaintiffs to assume defendants acted in good faith and hence which delayed this lawsuit for six months.

V. MERCURY AMALGAM CONTROVERSY

A. The Simultaneous Emergence of Mercury Amalgam and Organized Dentistry

i. 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.

ii. 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.

iii. 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."

iv. 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.

v. 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

i. 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.

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

iii. 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

i. 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.

ii. 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 historically by the amalgam companies that the ADA represents.

iii. 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.

iv. 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

i. 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.

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

iii. 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, <u>without disclosures of health risks</u>. The Secretary's Office of Human Research Protections, the watchdog charged with stopping unethical medical experimentation, found that this

experiment denied the children and their guardians the basic disclosures of risks required in all research on human beings – making it both unethical and immoral.

VI. STEPS TO EXHAUSTION, MATCHED BY FDA's CASCADE OF FALSE PROMISES TO CLASSIFY

A. In 1976, Congress, via passage of the Medical Devices Amendments Act, required FDA to classify all devices, not just new ones coming into the marketplace (post-amendment devices), but also those already on the market (pre-amendment devices). The Commissioner ruled that dental fillings are implants, a more heavily regulated kind of device than those which are not placed inside the body.

B. From the start, FDA staff – with dentists in charge of the decision -- was determined to avoid classifying the one controversial dental material, encapsulated amalgam. In the 1980s, FDA classified all other dental filling materials but did not classify encapsulated mercury amalgam – even though it was then, by far, the most heavily used dental material by dentists. In February 2002 FDA staff speciously claimed the failure to classify encapsulated mercury amalgam was "inadvertent," but when questioned by Congressman Burton at a Congressional hearing in November 2002, Center Director David Feigal withdrew the claim that the failure to classify was "inadvertent."

C. Classification of pre-amendment devices requires a number of procedural steps, including seeking and receiving a recommendation from one of FDA's Scientific Advisory Committees. FDA sought such a recommendation in 1993, but the Scientific

Advisory Committee failed to comply with the statute, issuing a recommendation without stating the reason(s) it recommended departing from a Class III.

D. A variety of consumer groups and anti-mercury dental societies, led by undersigned counsel Robert E. Reeves and James Turner, later counsel for plaintiff Consumers for Dental Choice, tried to get FDA to classify mercury amalgam; rebuffed, they filed a mandamus. In 1994, the Court of Appeals denied the mandamus on the grounds of exhaustion, whereupon Reeves, Turner, and others filed a petition to FDA to classify. After sitting on the petition for three years, FDA wrote Reeves and Dr. Michael Baylin of Baltimore, in separate letters, promising to classify encapsulated mercury amalgam.

E. With the heat off – having made the promise to classify and therefore being able to duck court review --- FDA did nothing. Nothing, for five years. By that time, a movement had begun in the states to pass fact sheets to be given to consumers about the health risks of mercury; four states passed such laws, and a dozen more were considering it. The government of Canada in 1996 advised dentists to stop placing mercury amalgam in (1) pregnant women, (2) children, and (3) persons with kidney ailments. Manufacturers quickly issued contraindications to U.S. dentists for all three categories. Faced with a movement against mercury, FDA staff acted --- to protect amalgam and to block warnings. FDA proposed a rule to block those manufacturer warnings, to pre-empt state laws, and to tell consumers one thing: that amalgam contained zinc. Since zinc is a nutrient and exists only in minute amounts if at all in amalgam, and since mercury is a neurotoxin that is 50% of amalgam (and the reason for the controversy in the first place),

the move was a patent effort to cover up the mercury on behalf of dentists and manufacturers. The proposal was accompanied by a "consumer alert" that so full of braggadocio about amalgam that FDA later had to revoke it for being untrue.

F. Public comment against this cover-up proposal was so severe that FDA backed off, promising an "independent" literature review – a promise that morphed into the notorious contract defendant Runner engineered with a meetings planner and a tobacco consultant, with pre-cooked results.

G. In 2005, at his confirmation hearing, Commissioner-designate Lester Crawford promised Senator Kennedy that FDA would classify mercury amalgam. Later in 2005 Consumers for Dental Choice petitioned FDA to change its policies, including to discard the 2002 regulation and start over.

H. In 2006 FDA convened the Scientific Advisory Committees, but cleverly not to ask for a classification recommendation. FDA continues to refuse to convene the panels for a recommendation, obviously fearing a repeat of this panels' vote condemning the FDA staff position that mercury amalgam is safe.

I. In April 2006, plaintiffs sought an order from the Court of Appeals to declare mercury amalgam unregulated and therefore not validly sold. In its brief filed in February 2007, FDA said it was right in the midst of classifying mercury amalgam and simply needed some time to act.

J. In April 2007 plaintiffs were rebuffed on jurisdictional grounds, the Court stating the District Court was the proper forum (*Moms Against Mercury, et al., v. FDA*). Immediately notified that plaintiffs would sue in the District Court, FDA counsel asked for a meeting with plaintiffs' counsel instead, a meeting held in May. Plaintiffs announced they would wait just 30 days, so FDA promised prompt attention to the issue. In June 2007, FDA counsel promised that FDA would issue an Advanced Notice of Proposed Rulemaking. FDA also told reporters for two professional publications, *FDA Week* and the Bureau of National Affairs' *Medical Device Reporter*, that it would promptly issue an Advanced Notice of Proposed Rulemaking.

K. A Congressional subcommittee chaired by Congressman Kucinich convened a hearing in November 2007, where defendant Alderson said FDA will not agree to do an Environmental Assessment. Alderson in his testimony refused to indicate whether FDA's promise in June to issue an Advanced Notice of Proposed Rulemaking is still operative. Instead of promising to move forward, Alderson stonewalled, indicating that FDA was under no obligation to take any steps on mercury amalgam.

L. Thirty-one years after Congress ordered all pre-amendment devices to be classified, 20 years after FDA classified all other dental fillings except this controversial one, 15 years after winning a mandamus based on exhaustion of remedies, ten years after promising in writing to classify mercury amalgam, five years after a sequence of meetings began between plaintiffs and FDA officials that have continued year after year,

five years after promising a House committee it will classify, two years after promising a Senate confirmations committee it will classify, two years after plaintiff Consumers for Dental Choice filed a sequence of petitions for FDA to act, one year after two Scientific Advisory Committees voted decisively that FDA's claim of mercury amalgam's safety is mistaken, ten months after FDA conceded to the Court of Appeals that it does not know if amalgam is safe or unsafe … FDA refuses to classify mercury amalgam.

M. But FDA staff has adopted yet another "safeguard" to ensure it cannot classify mercury amalgam in the near future. To ensure that if any directive (from the Courts, from Congress, or from the Secretary) will take years and years, defendants refuse to do even the conditions precedent to classifying: request a valid and timely recommendation from the scientists, and conduct an environmental assessment on the mercury damage. Refusal to begin even the requisite steps to classify is proof of bad faith by defendants, suggesting a belief that they are somehow above the law when it comes to making product decisions.

VII. STATEMENT OF ALLEGATIONS: VIOLATIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

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

(ii) 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.

(iii) 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.

(iv) 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.

(v) 21 U.S.C. 379(o): With the National Environmental Policy Act applicable to FDA, defendants must do an environmental assessment, followed by an environmental impact statement.

(vi) 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.

VIII. REMEDY

Defendants have unlawfully withheld and unreasonably delayed the classification of encapsulated mercury and amalgam alloy. As FDA has done so many times before, it predictably will come before this Court and announce it intends to classify, but simply needs more time. FDA has had 31 years to classify mercury amalgam, and classified all other filling materials – that is, the noncontroversial ones – 20 years ago.

For ten years, FDA has been promising to classify – it has told the Court of Appeals, litigants, petitioners, Congressman Burton, and Senator Kennedy that it is on the

verge of classifying. It promised plaintiffs six months ago it would take the first step toward classifying, a ruse that held plaintiffs off from filing this suit six months ago.

For a device that is 50% toxic mercury; for a device about which FDA confessed to the Court of Appeals it no longer knows if it is safe or unsafe; for a device that two panels of distinguished outside scientists voted overwhelmingly against the staff position that amalgam is safe -- and for a device about which FDA is immobilized from classifying – there is but one fair, equitable, and proper remedy:

Pursuant to 5 U.S.C. §706, this Court should remove encapsulated mercury amalgam from the marketplace and order that FDA comply forthwith with its statutory duty to assemble a classification panel and request a classification recommendation, to publish said recommendation with comments, to publish a proposed rule, and finally – after 31 years – to classify mercury amalgam.

The alternative – to allow FDA to weasel out of this case with yet another promise to classify, when FDA refuses even to the conditions precedent to classifying – would be an injustice to plaintiffs, allow a continued concealment of the mercury, and send a message that FDA has no accountability to the American people. Plaintiffs also request attorneys fees and other remedies permitted by law and as are just and equitable.

Respectfully submitted by counsel for plaintiff this 28th day of December 2007

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