UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INTERNATIONAL ACADEMY OF ORAL MEDICINE & TOXICOLOGY, INC., an Oklahoma non-profit corporation; MOMS AGAINST MERCURY, INC., a North Carolina non-profit corporation; COMED, INC., a Delaware non-profit Corporation; DAMS, INC., a New Mexico non-profit corporation; AMY M. CARSON, guardian ad litem for KIT D. CARSON; REV. LISA SYKES, guardian ad litem for WESLEY SYKES; LINDA BROCATO; KRISTIN HOMME, PE, MPP, MPH; MICHAEL G. BURKE; HOLLIS HUGHES ROGER WALLER; KENNARD W. WELLONS; DAVID BARNES, DDS; PAULA KAVANAGH; ROBERTA VOSS; JOY CHMIELENSKI, RN; DORICE A. MADRONERO; ERIC EDNEY; KAREN PALMER; and KAREN BURNS,	)	
Plaintiffs,	)	
v.	)	CASE NO.: 1:14-cv-00356
THE U.S. FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue Silver Spring, MD 20993;	)	
DR. STEPHEN OSTROFF, M.D., Acting Commissioner of the U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993	)	
THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W. Washington, D.C. 20201	)	

SYLVIA MATHEWS BURWELL)
Secretary of Health and Human Services)
U.S. Department of Health and Human)
Services)
200 Independence Avenue, S.W.)
Washington, D.C. 20201)
)
Defendants.)

SUPPLEMENTAL COMPLAINT REQUESTING JUDICIAL REVIEW UNDER THE ADMINISTRATIVE PROCEDURE ACT AND FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, the International Academy of Oral Medicine & Toxicology, Inc., an Oklahoma non-profit corporation and others,[1] allege and state as follows:

NATURE OF THE ACTION

1. This is an action to review and set aside a final action of the United States Food and Drug Administration ("FDA") pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 702 et seq., and for related declaratory relief under 28 U.S.C. § 2201-02, and an injunction.

2. This Complaint supplements Plaintiffs' action for declaratory and injunctive relief filed on March 5, 2014. The action arose out of the failure of the FDA to respond within a reasonable time to the Petitions[2] concerning mercury fillings challenging the FDA's July 28, 2009, Final Order classifying mercury amalgam dental filling material as a Class II device.

[1] Moms Against Mercury, Inc., a North Carolina non-profit corporation; CoMeD, Inc., a Delaware non-profit corporation; DAMS, Inc., a New Mexico non-profit corporation; Amy M. Carson, guardian ad litem for Kit D. Carson; Rev. Lisa Sykes, guardian ad litem for Wesley Sykes; Linda Brocato; Kristin Homme, PE, MPP, MPH; Michael G. Burke; Hollis Hughes; Roger Waller; Kennard W. Wellons; David Barnes, DDS; Paula Kavanagh; Roberta Voss; Joy Chmielenski, RN; Dorice A. Madronero; Eric Edney; Karen Palmer; and Karen Burns.

[2] A Supplemental Petition was filed in March 2013 that updated the administrative record with relevant new science that had been published since the 2009 Petitions were filed.

3. The Plaintiffs' Petitions requested that FDA provide the following relief: (1) formally ban the use of mercury fillings as a dental restorative material pursuant to section 516 of the Medical Device Amendments of 1976 (21 U.S.C. § 360f) and 21 C.F.R. § 895, or in the alternative; (2) place encapsulated mercury fillings into Class III pursuant to section 513(3) of the Medical Device Amendments; (3) demonstrate proof of safety and effectiveness; (4) promulgate restrictions for the use of dental amalgam in certain individuals; (5) require that an Environmental Impact Statement ("EIS") or at least an Environmental Assessment ("EA") be prepared pursuant to 21 C.F.R. § 25.40; and, (6) provide meaningful informed consent to dental patients, or their parents, of the amalgam mercury content and potential risks associated with mercury exposure from amalgam fillings. (The citizens' petitions and supplemental petition at issue are referred to below as the "Petitions.")

SUPPLEMENTAL INFORMATION

4. On January 27, 2015, after an order was entered imposing a stay on this litigation, the FDA submitted three individual responses to the Petitions and essentially rejected all of the actions/remedies sought by Plaintiffs. The pertinent 2015 FDA Responses are attached hereto as Exhibits A1, A2, and A3.

5. Pursuant to the APA, Plaintiffs now seek an order enjoining the enforcement of the July 28 , 2009, Final Order of FDA, as modified and further explained by the information contained in the 2015 Responses to the Petitions on mercury amalgam fillings, as arbitrary, capricious, an abuse of discretion, and not in accordance with law, and in excess of statutory jurisdiction, authority and limitations, within the meaning of 5 U.S.C. § 706(2)(A) through (F), and declaring that the Class II classification of mercury amalgams is unlawful and a nullity. Further, Plaintiffs seek injunctive relief from the Court to require FDA to obey its laws and

regulations insofar as they apply to the classification status of mercury amalgam fillings, and to enjoin the release of information about the "safety" of mercury fillings based on the absence of evidence of harm.

REGULATORY FRAMEWORK

6. Under the Federal Food, Drug, and Cosmetic Act ("FD&C Act")[3], devices are classified into one of three regulatory classes that describe the controls necessary *to provide reasonable assurances of safety and effectiveness*. *See* 5 U.S.C. § 513(a)(l)(A)-(C) (21 U.S.C. § 360c(a)(l)(A)-(C)). Class I devices are the least risky and the FD&C Act's general misbranding and adulteration controls are adequate to provide such an assurance. Class II devices range from the most risky to those of considerably less risk for which Class I controls are inadequate and *sufficient information exists to establish special controls to reasonably assure safety and effectiveness*. Class III devices represent the most risky devices, *i.e*., those devices that are life-supporting or life-sustaining, of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury, and *for which not enough is known to place them into Class II to provide a reasonable assurance of safety and effectiveness*. All three classes require an affirmative FDA finding of reasonable assurance of safety and effectiveness based on the existence of sufficient information to support such an affirmative finding. Plaintiffs assert that the 2015 FDA Responses violate this framework.

7. The regulatory framework requires FDA to classify as a dental or medical device any device that "(i) is intended to be implanted in the human body …." Dental amalgam, when utilized as a dental filling is a medical/dental device that must be classified as an implant under existing law. [43 FR 32994, July 28, 1978] When a device is identified as an implant it is

[3] As amended by The Medical and Dental Device Amendments of 1976, 21 U.S.C. §§360c, *et seq*.

automatically placed in the Class III category **requiring scientific proof of safety unless certain steps and proof is presented to classify the device in a different classification.** [43 FR 32988, July 28, 1978] In 1978, the FDA Dental Device Panel requested that dental amalgam be exempted from the FDA definition for "implant." [42 FR 46035, Sept. 13, 1977] The FDA Commissioner denied that request and ruled that a mercury filling was an implant. [43 FR 32988, July 28, 1978] In 1980, the FDA altered the definition, stating that, "a dental implant as a device that is surgically placed into, or in opposition to, the maxilla or mandible and which protrudes through the mucosa of the oral cavity." According to the Panel, "restorative materials placed in the teeth, such as amalgams…are not implants." [45 FR 85962, Dec. 30, 1980] However, upon belief and knowledge, the FDA did not allow an opportunity for public comments and rulemaking at that time. In the 2009 Final Rule, the FDA again improperly determined that a mercury filling is not an implant, stating that "dental restorative materials such as amalgam do not protrude through the mucosa of the oral cavity and, therefore, are not considered implants." [74 FR 38686, FN. 32] The FDA's own findings evidence the flaws of the 1980 determination that mercury amalgams are not implants. The FDA admits that mercury from dental amalgams crosses the mucosa membrane and is absorbed into and circulated throughout the body, ultimately being excreted through urine and feces. [*See, e.g.,* 74 FR 38686, at 38687 and 38701] Because FDA admits mercury is absorbed into the blood stream, FDA implicitly admits that mercury fillings fit the definition of an implant and should be regulated as such. Federal statutes and FDA regulations require that implants be regulated in Class III unless the Commissioner takes appropriate steps to justify the classification of the implant in Class I or II. These steps have not been taken.

SUPPLEMENTAL FACTS

8. History leading to this lawsuit: The legal controversy underlying this lawsuit commenced in 1992 when several parties represented by attorneys Robert Reeves and James Turner, including some parties to this case, sued FDA seeking an order compelling FDA to classify mercury fillings. These parties requested that the Circuit Court of Appeals for the District of Columbia accept original jurisdiction and issue a writ of mandamus compelling FDA to classify dental amalgam fillings. (*Foundation for Toxic Free Dentistry. et al. v. David Kessler, Commissioner of the FDA*, Case No. 92-1469.) The Court accepted original jurisdiction but ultimately dismissed the case on the basis that the plaintiffs had not exhausted their administrative remedies.

9. In 2008, some of these same parties sued FDA again demanding that FDA classify mercury fillings. (*Moms Against Mercury, et al. v. Andrew Von Eschenbach, Commissioner of the FDA*, in the United States District Court for the District of Columbia, Case No. 1:07-cv-02332-ESH-JMP.) The case settled when FDA agreed to complete the classification process by July 28, 2009. As part of the settlement, FDA also agreed to and did post a warning on its website providing the following warning: "[D]ental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses."

10. The Honorable Ellen Huvelle was assigned to the *Moms Against Mercury* case and found that the plaintiffs in that case had standing to bring their lawsuit. [*See* Transcript of hearing, Exhibit B.] The parties to this case continued to press FDA to classify mercury amalgam fillings, finally receiving classification on July 28, 2009. It is this classification, later discussed in the FDA's 2015 Responses to the Petitions, that is the subject of this lawsuit.

11. On July 28, 2009, in conjunction with issuing its Final Rule on mercury fillings, the FDA issued its "Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy". That document stated, "FDA is issuing this guidance in conjunction with a Federal Register (FR) notice announcing the final rule classifying dental amalgam, mercury, and amalgam alloy into Class II (special controls). The classification regulation designates this guidance document as the special control for these three devices." The Final Rule referred to here is the subject of Plaintiffs' Petitions and the Complaint in this case. Plaintiffs seek an amendment to this FDA Class II Special Controls Guidance Document if mercury amalgam fillings remain available to dental consumers.

12. In investigating the safety of mercury fillings, FDA commissioned two Scientific Advisory Committees to address mercury fillings. The two FDA committees refused to endorse the safety of mercury fillings. An FDA advisory panel in 2006 voted 13-7 to state that an FDA "white paper" failed to demonstrate the safety of mercury fillings. In 2010 another FDA advisory committee of experts hand-picked by the FDA expressed concerns that the agency had not gone far enough to protect vulnerable subpopulations.

13. The chief device regulator at the FDA, Dr. Jeffrey E. Shuren, publicly assured the Plaintiffs and the public that a decision on mercury fillings would be coming forth by December 31, 2011. This decision would be in response to the Petitioners' Petitions. No decision was forthcoming from FDA until January 27, 2015, and then only as a direct response to the instant action. Contemporaneously with the issuance of its Final Rule, FDA removed from its web site the warning, "dental amalgams contain mercury, which may have neurotoxic effects on the

nervous systems of developing children and fetuses." that it agreed to post as part of the settlement of the *Moms Against Mercury* litigation.

14. Sometime in 2011, FDA completed its scientific review of the literature presented by the Plaintiffs and drafted a response to Plaintiffs' Petitions bearing a January 2012 date. [The "2012 Response," attached as Exhibit C.] FDA forwarded the 2012 Response to the Department of Health and Human Services ("HHS") for approval. The 2012 Response ruled that significant restrictions were to be placed on amalgam use. Alternative materials, such as composite resins that do not contain mercury, were to be the material of choice. "The FDA believes that these alternative materials would best be offered as the first line of restorative care minimizing the use of dental amalgam." Moreover, mercury fillings were contraindicated in the following subpopulations: pregnant and nursing women; infants and children age six and younger; people with neurological disease; people with kidney disease; people with allergy or sensitivity to mercury (hereinafter, the "Protected Subpopulations.")

15. Despite the promise to publish its response no later than December 31, 2011, and despite the preparation of its 2012 Response, which was suppressed, HHS and/or FDA, collectively or separately, ultimately chose not to respond to the Plaintiffs' Petitions. Only after the Plaintiffs herein sued to compel a response did FDA prepare different Responses, which it submitted on January 27, 2015.

16. In its 2015 Responses, FDA repeatedly argued that Plaintiffs failed to demonstrate reliable evidence of harm caused by mercury fillings while repeatedly acknowledging a dearth of evidence of safety. The record clearly and repeatedly demonstrates that FDA failed to identify substantial evidence of safety or make a required finding that scientific evidence demonstrates a reasonable assurance of safety. The 2015 Responses removed the restrictions on the use of

mercury fillings in the Protected Subpopulations. It also explicitly shifted the FDA's legislatively mandated burden to demonstrate safety. The FDA asserted that the burden to demonstrate potential harm now rested on the Plaintiffs.

17. The 2015 FDA Responses clearly placed the burden of proof on the Plaintiffs to demonstrate that amalgam fillings pose a "substantial deception or an unreasonable and substantial risk of illness or injury." [Exhibit A1 at 5] For example, Plaintiffs presented a study demonstrating that amalgam fillings increase the risk of hearing loss. FDA rejected the study because it did not have enough study subjects, but FDA did not cite a study demonstrating that amalgam fillings do not cause hearing loss. Additionally, FDA admitted that there "was limited to no clinical information concerning the effects of prenatal exposure from maternal sources of mercury vapor at relevant concentrations." [Exhibit A1 at 18] Despite the evident and admitted lack of data demonstrating safety, FDA took no steps to legally restrict the use of dental amalgam in pregnant women or inform them of the potential risks. Moreover, if amalgam use is inappropriate in pregnant women, as FDA admits, it is also inappropriate for use in women who may bear children in the future. Obviously, women (birth to menopause) may become pregnant any time after mercury fillings are placed. As the Plaintiffs' Petitions demonstrate, mercury biologically accumulates over the life of a mother and presents an ever-increasing threat to her fetus. These are only a few examples of FDA's arbitrary and capricious conduct in responding to the Petitions. In addition the agency completely ignored petitioners' presentation of the law concerning device implants and refused to properly characterize mercury fillings as implants, claiming that they do not penetrate the oral mucosa and are therefore excused from the classification requirements applicable to implants.

18. Despite multiple admissions concerning health risks associated with mercury fillings in its 2015 Responses, and despite its previous findings that amalgam use was inappropriate for use in the Protected Subpopulations, FDA declined to restrict dental amalgam in any meaningful way, failed to place mercury fillings in Class III, and failed to make meaningful and relevant information available to the general public so that dental patients could make truly informed decisions. [The FDA admissions culled from the January 27, 2015, Responses are summarized in Exhibit D.]

19. The Petitions requested that, if FDA was not going to restrict the use of mercury amalgam fillings, then it should require sufficient information be provided to dental patients who are candidates for mercury filling therapy so that they can make a reasonably informed decision concerning this treatment. Despite making all of the admissions set forth in Exhibit D, FDA placed mercury amalgam fillings into Class II and declined to require that information about the FDA's acknowledged health risks associated with mercury fillings be made directly available to dental patients.

JURISDICTION

20. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1346 (United States as Defendant).

21. The relief requested is specifically authorized pursuant to 28 U.S.C. § 1651 (writs) and 28 U.S.C. §§ 2201-02 (declaratory relief). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201 (declaratory judgments).

22. Plaintiffs have a right to bring this action pursuant to the APA, 5 U.S.C. §§ 551, *et seq*., 702-706. Each Plaintiff has standing to bring the claims asserted herein by virtue of

injuries that they have suffered that will or should be redressed by the relief sought in this Complaint.

VENUE

23. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because Defendants in this Action are considered to reside in the District of Columbia for purposes of this Action, as their official duties are performed in Washington, D.C.

24. Defendant Dr. Stephen Ostroff, M.D, is sued in his official capacity as acting FDA Commissioner. As Commissioner, acting Dr. Ostroff bears ultimate responsibility for FDA's activities and policies. Dr. Ostroff and the Food and Drug Administration are collectively referred to herein as “FDA” or “the Agency.”

25. Defendant Sylvia Mathews Burwell is sued in her official capacity as Secretary of Health and Human Services. As Secretary, Ms. Burwell bears ultimate responsibility for HHS’s activities and policies. Ms. Burwell and the U.S. Department of Health and Human Services are collectively referred to as “HHS.”

CLAIMS FOR RELIEF

26. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 25 herein.

27. The Administrative Procedure Act, 5 U.S.C. § 553(3), requires agencies to “give an interested person the right to petition for the issuance, amendment, or repeal of a rule.” *See also* 5 U.S.C. § 551(4) (defining “rule” as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy"). The APA right to petition encompasses the right to petition for a new, revised, or final rule, or repeal thereof, concerning FDA's regulation of mercury fillings.

28. The APA, 5 U.S.C. § 702, grants a right of judicial review to "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." Plaintiffs, including the named individuals, entities, and members of those entities, are adversely affected by FDA's rule-making and 2015 Responses.

FIRST CLAIM FOR RELIEF

FDA impermissibly shifted the burden of proof to require plaintiffs to demonstrate that amalgams were unsafe for use.

29. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 28 herein.

30. The FDA is charged with ensuring the safety of medical and dental devices. Mercury amalgams are regulated by FDA as a dental device.

31. In its 2015 Responses, FDA imposed the burden of proof on the Plaintiffs, expressly requiring them to demonstrate that "dental amalgam presents a substantial deception or an unreasonable and substantial risk of illness or injury."

32. The instances described below further illustrate the FDA's pattern of rejecting the Plaintiffs' proffered studies and reaching an opposing conclusion without identifying scientific studies or evidence to support its position:

a. Plaintiffs presented numerous published and peer-reviewed studies demonstrating the substantial risks of illness or injury posed by mercury fillings. For various reasons, the FDA dismissed these studies but did not identify studies demonstrating that the opposite conclusion could and should be reached. For example, Plaintiffs cited to Rothwell, J., *et al*., *Amalgam dental fillings and hearing loss*, Int J Audiol. 2008 Dec., 47(12):770-6, for the proposition that amalgam fillings had the potential to cause hearing loss. In response, FDA stated that a larger study was needed to

corroborate the effects seen in this study. FDA did not cite to a study demonstrating that mercury fillings do not cause hearing loss.

b. FDA concedes that "[v]ery limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed." Nevertheless, FDA has not provided any meaningful controls requiring patients to be informed that there are very limited to no clinical information on which to reach a conclusion that amalgam fillings are safe for a developing fetus or a child under the age of six.

c. In the "Information for Use" section for recommended professional labeling for dental amalgam, the FDA admitted that "the developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor." Despite acknowledging this risk of harm, the FDA did not contraindicate against implanting amalgams in pregnant women and young children, even though FDA explicitly admitted that "very limited to no clinical information is available regarding the long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed." [Exhibit A1 at 18] However, Plaintiffs presented at least three published studies demonstrating that mercury from maternal dental amalgam fillings places developing fetuses and infants at risk. [Exhibit A1 at 17]

d. The FDA agreed that the people with certain genetic polymorphisms indicated that the "calculated exposure limits may be insufficient to protect individuals with genetic polymorphism to relevant enzymes involved in the toxicodynamics of mercury." [Exhibit A1 at 18-19] The FDA further found that, "individuals with certain

genetic polymorphisms maybe at a higher risk for adverse health effects due to mercury from dental amalgam risk for adverse health effects due to mercury from dental amalgam." [Exhibit A1 at 18] Nevertheless, FDA refused to issue any contraindication, and instead stated that more studies were needed. FDA presented no evidence that people with certain genetic polymorphisms are

e. The FDA concluded that there are "few studies that evaluate a link between dental amalgam and Multiple Sclerosis." However, Plaintiffs proffered five such studies linking dental amalgams with MS. The FDA refused to accept any of Plaintiffs' studies, but without the support of a single study supporting a contrary conclusion, concluded that there was no link between amalgams and MS. [Exhibit A1 at 23-25]

f. The FDA concluded that there are "few, if any, controlled studies that evaluate a link between dental amalgam and ALS." Plaintiffs proffered five such studies linking dental amalgams with ALS. However, similar to MS, the FDA refused to accept any of Plaintiffs' studies, and without the support of a single study, concluded that there was no link between amalgams and ALS. [Exhibit A1 at 25-26]

g. Plaintiffs offered nine studies supporting the proposition that amalgams contribute to kidney dysfunction. FDA concedes that the evidence indicates that mercury exposure from dental amalgams result in increased mercury levels in kidneys that, at high levels, can result in adverse health effects. However, the FDA concluded that the risks posed to kidneys from mercury amalgams are not unreasonable or substantial. [Exhibit A1 at 28-30]

h. Plaintiffs identified five studies indicating that a significant percentage of the population is at risk for hypersensitive reactions to amalgams. The FDA acknowledged that some individuals are hypersensitive or allergic to mercury, but believes that such reactions are rare. However, the FDA did not identify the study it relied on to reach such a conclusion. [Exhibit A1 at 31-33]

i. Plaintiffs put forth evidence that mercury is more toxic in the presence of other metals. In response, the FDA stated that it did not "discount the possibility of synergism or additivity when patients are simultaneously exposed to more than one chemical or drug." [Exhibit A1 at 7] However, the FDA considered the issue "complex" and refused to consider the Plaintiffs' evidence. The FDA did not identify a single study indicating that Plaintiffs position was incorrect.

WHEREFORE, the Plaintiffs pray for the relief hereinafter requested.

SECOND CLAIM FOR RELIEF

The FDA acted arbitrarily and capriciously in refusing to adopt the conclusions reached in the 2012 FDA Response to the Petitions.

33. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 32 herein.

34. As stated above, the FDA agreed to provide responses to the Petitions by the end of 2011 or early 2012. FDA made a final determination that was based on all of the science it reviewed, proceeded to prepare the 2012 Response, and forwarded its scientific conclusions to Defendant, the Department of Health and Human Services ("HHS"). This 2012 Response represented the last word from the FDA on the dental amalgam issue until its 2015 Responses to the Petitions which are the subject of this Supplemental Complaint.

35. Despite reaching its conclusions regarding dental amalgam in late 2011 or early 2012, HHS made the decision to not release the FDA's findings and conclusions to the public. Instead, the FDA remained silent for over three years until, after being sued in this lawsuit, it issued its 2015 Responses.

36. The 2015 Responses removed protections for the Protected Subpopulations and eliminated the call to use mercury fillings only as a secondary treatment material, which restrictions were contained in its 2012 Response. However, during the three-year period between the 2012 Response and the 2015 Responses, FDA did not review or consider any additional evidence that would have justified the alteration of its findings and opinions on mercury fillings. Therefore, it was arbitrary and capricious for the FDA to reach a contradictory conclusion in 2015 based on the same science it reviewed for its previous decision in 2012.

37. The following partial list of the discrepancies between the published 2015 Responses and the 2012 Response is extensive and concerning:

a. Most noteworthy, the 2012 Response admits that the use of alternative materials (*i.e.*, non-mercury containing fillings) should be best offered as "the first line of restorative care." [Exhibit C at 4] This restriction was eliminated from the 2015 Responses.

b. The 2012 Response stated that although there was "no direct evidence of harm from dental amalgam in the general population, information reviewed by FDA over the past year presents concern for certain sensitive subpopulations, such as pregnant women and their developing fetuses, children under six-year-old and other higher risk subgroups who may be more susceptible to potential adverse effects of mercury exposure." Based on this information, the FDA declared that amalgams should not be

placed in any of the Protected Subpopulations. [Exhibit C at 3-4] However, in 2015, the FDA completely changed course, stating that the available scientific evidence relating to potentially sensitive subpopulations did not reveal a health risk for sensitive populations except in persons with a known mercury allergy, for which the FDA has already recommended a contraindication. [Exhibit A2 at 5] However, despite acknowledging this allergy, the FDA did not create a special control that instructed dentists to check patients for an allergy to mercury before placing mercury fillings in their teeth.

38. The contradictory conclusions reached in the 2012 and 2015 Responses based on identical scientific evidence demonstrates that FDA's 2015 Responses were arbitrary and capricious and not supported by substantial evidence. Therefore, this Court should deem the FDA's 2015 Responses to be unlawful under 5 U.S.C. § 706(2)(A).

WHEREFORE, the Plaintiffs pray for the relief hereinafter requested.

THIRD CLAIM FOR RELIEF

The FDA acted arbitrarily and capriciously in its 2015 Responses by determining that the established minimum safety limits for mercury may be exceeded by a factor of ten.

39. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 38 herein.

40. FDA touted risk assessment principles in its 2009 Responses and argued that the mercury absorbed by amalgam bearers was below the safety limits established by the U.S. Agency for Toxic Substances and Disease Registry ("ATSDR") (called a "minimum risk level" or "MRL") and by the U.S. Environmental Protection Agency ("EPA") (called a reference concentration or "RfC"). In their Petitions, Plaintiffs identified twenty-seven points of error in the risk assessment promulgated by FDA regarding amalgam fillings. In its 2012 Response, FDA did not respond to these allegations of error and abandoned any discussion of risk

assessment principles, opting instead to limit the use of amalgam in the Protected Subpopulations.

41. In its 2015 Responses, FDA again changed course by removing the restrictions on the use of amalgam in treating the Protected Subpopulations and claiming for the first time that it was acceptable for the safety limits to be exceeded by a factor of ten. [Exhibit A1 at 38] FDA offered no evidence demonstrating that it was safe for dental patients, and particularly the Protected Subpopulations, to be exposed to mercury in quantities up to ten times the safety limits established by ATSDR and EPA that FDA endorsed in 2009. (Certainly the EPA and ATSDR have never authorized exposure to mercury that exceeds the safety limits that FDA now relies on.) Indeed, the EPA and ATSDR documents that establish the safety limits endorsed by the FDA do not allow the published mercury safety limits to be exceeded. FDA's conclusion that the ATSDR and EPA safety limits may be exceeded by a factor of ten is arbitrary and capricious and is not based on substantial evidence.

WHEREFORE, the Plaintiffs pray for the relief hereinafter requested.

FOURTH CLAIM FOR RELIEF

Patients receiving amalgam fillings are entitled to information explaining the potential risks involved and alternative treatment options.

42. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 41 herein.

43. FDA's current position is that patients are not required or entitled to receive warning information regarding the safety of amalgams prior to receiving amalgam implants. The Final Rule states that:

> [T]he recommended labeling statements in the special controls guidance document will provide dentists with important information that will improve their understanding of the devices and help them make appropriate treatment decisions

> with their patients. In addition, FDA notes that dental amalgam is a prescriptive device and, therefore, patients cannot receive the device without the involvement of a learned intermediary, the dental professional. [Thus,] FDA has concluded that it is unnecessary to require that dentists provide [the warning] information to patients in order to provide reasonable assurance of the safety and effectiveness of the device.

[Exhibit A2 at 11]

44. Plaintiffs requested that FDA change its policy and provide warnings and information directly to dental patients (and parents of young dental patients) detailing the potential health risks posed by exposure to mercury. In support, Plaintiffs set forth specific and compelling reasons why patients are entitled to such information. FDA declined to provide dental patients with information concerning these fillings.

a. Despite expressly and implicitly admitting that it does not have substantial evidence of safety, FDA concludes that it is not necessary for dentists to discuss potential risks of mercury fillings with dental patients or to discuss the availability of alternative restorative materials. Instead, FDA states that the special controls developed for mercury fillings will provide information that is disseminated only to dentists, and there is no requirement that the dentist impart any information to the patient. Indeed, the FDA special controls are not legally binding on dentists.

b. The 2015 Responses and the Final Rule are contrary to FDA's mission to provide the public with accurate, science-based information.

c. FDA declines to assure that patients will be provided with accurate and factual information regarding mercury fillings. As a result, patients and parents are likely to become confused. Roughly fifty percent of dentists do not use mercury fillings any more, many citing the health risks associated with those fillings. (Plaintiff IAOMT's

organizational mission is to eliminate the use of these fillings because of the documented health risks associated with their use.)

d. Neither the 2015 Responses nor the Final Rule require dentists to inform their patients that mercury fillings contain mercury that is emitted in significant quantities over the life of the filling, and that eighty percent of the mercury inhaled into the lungs is absorbed into the bloodstream. Moreover, the American Dental Association's model ethical code, widely adopted into law by state dental boards around the country, forbid dentists from advising their patients that mercury fillings are toxic. There are scores of instances where state chapters of the ADA and/or state dental boards have threatened professional sanctions against dentists who make such representations to their patients. In its Guidance document, FDA provides certain information "in order to help dental professionals plan appropriate treatment recommendations for their patients by providing them with FDA's analysis of the most current, best available evidence regarding potential risks to health from mercury vapor released from dental amalgams." [Exhibit A1 at 38] However, dental professionals cannot speak candidly with their patients about the health risks associated with mercury fillings, so the patient remains unprotected and does not receive information sufficient to give true informed consent. Ironically, the 2012 Response called for "informed consent" and "informed choice" and stated that "the ultimate decision about what dental restorative material to use is one that should be made between patient and their dentists." [Exhibit B at 4] The FDA 2015 Responses referred to a learned intermediary (the dentist) as the primary protection for the individual patient.

45. The FDA has no reasonable explanation for refusing to provide dental patients with factual information about mercury fillings. Moreover, it is completely illogical for the FDA

to conclude that patients are not entitled to receive the information necessary to enable them to receive adequate information about this treatment and give truly informed consent concerning their use, especially where FDA concedes this material emits toxic mercury vapors.

WHEREFORE, the Plaintiffs pray for the relief hereinafter requested.

FIFTH CLAIM FOR RELIEF

The FDA acted arbitrarily and capriciously in its 2015 Responses by ignoring the fact that mercury amalgam fillings should be characterized as implants, thus requiring them to be placed in Class III requiring manufactures to provide affirmative proof of safety and efficacy.

46. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 45 herein.

47. In 1978, the FDA Dental Device Panel requested that mercury fillings be exempted from the FDA definition for "implant." [42 FR 46035, Sept. 13, 1977] The FDA Commissioner denied that request and ruled that mercury fillings were an implant. [43 FR 32988, July 28, 1978] In 1980, the FDA Dental Device Panel again proposed that mercury fillings be excluded from the definition of an "implant." This Panel changed the definition of a "dental implant" to constitute a "device that is surgically placed into, or in opposition to, the maxilla or mandible and which protrudes through the mucosa of the oral cavity. According to this Panel definition, restorative materials placed in the teeth, such as amalgams, gold alloys, silicates, and cements, are not implants." [45 FR 85962] The FDA reaffirmed this determination in the 2009 Final Rule. 48. The FDA's 1980 alteration of the definition of an implant is at odds with Congress's definition of an "implant." In the Medical and Dental Device Amendments of 1976, 21 U.S.C. §§360c, *et seq*., Congress required FDA to classify dental and medical devices as follows:

> (C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

> (i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and
>
> (II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type, such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

21 U.S.C. §§360c. A similar and conforming definition can also be found at 21 C.F.R. § 860.3(d), which provides that "[i]mplant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health. Under the Medical and Dental Device Amendments of 1976 and Section 860.3(d), mercury fillings are clearly implants, and under statutory requirements, are to be placed in Class III until and unless there are steps taken to reclassify the fillings in another classification based on a finding that classifying the device in Class III is not necessary to provide reasonable assurances of its safety and effectiveness. No such finding has been entered.

49. The FDA's alteration of the definition of an implant is contrary to the clear Congressional intent set for in the Medical and Dental Device Amendments of 1976 and is incompatible with Section 860.3. Accordingly, FDA should be required to classify mercury fillings in Class III until such time as it takes statutorily mandated steps to classify mercury fillings in a different classification.

50. FDA Rules state that, "[a]lthough no device can be regulated adequately in Class I or Class II unless there are adequate data and information establishing its safety and effectiveness, a device for which there are such data and information may nevertheless require regulation in Class III because of the public health concerns posed by its use." [42 FR 46030, 13 Sep 1977] Moreover, 21 C.F.R. § 860.93 states that in order for a device to "be classified in any other class, the Dental Device Panel must file a full statement of the reasons for such classification, including 'supporting documentation and data satisfying the requirements of sec. 860.7.'" 21 C.F.R. § 860.93(b). The Dental Device Panel has not entered such a statement. Clearly, no administrative record exists on which the FDA Commissioner or the Dental Device Panel could rationally conclude that there are demonstrable and reasonable assurances that mercury fillings are safe and that the Commissioner could issue a waiver for the legislative requirement that mercury fillings be placed in Class III. It is arbitrary and capricious for FDA to place mercury fillings in any other category than Class III.

51. In its 2015 Responses to the Petitions, FDA acknowledges that, in connection with certain subpopulations, there is little to no data to support a finding of safety. [*See, e.g.*, Exhibit A1 at 18] Nevertheless, FDA classified mercury fillings in Class II anyway.

52. Even if FDA is legally permitted to alter the definition of an "implant," it is still clear that mercury fillings are implants. The FDA contends that mercury fillings are not implanted across the oral mucosa. However, it admits in its Final Rule that mercury, a constituent of the fillings, is absorbed into and circulated throughout the body, ultimately being excreted through urine and feces. [*See, e.g.*, 74 FR 38686, at 38687 and 38701] This admission undermines FDA's contention that a mercury filling is not an "implant."

WHEREFORE, the Plaintiffs pray for the relief hereinafter requested.

SIXTH CLAIM FOR RELIEF

FDA is required to publish an Environmental Impact Statement or an Environmental Assessment detailing the effects mercury amalgams have on the environment.

53. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 52 herein.

54. The National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. § 4321, *et seq*., requires a federal agency to prepare a detailed Environmental Impact Statement ("EIS") in connection with any major federal action that "significantly affects the quality of the human environment." 42 U.S.C. § 4332(3)(C).

55. Under the Council of Environmental Quality's (CEQ) implementing regulations, an agency may first prepare an Environmental Assessment ("EA") to determine whether the environmental impact of the proposed action warrants an EIS. *See* 40 C.F.R. § 1508.9. If an EA establishes that the agency's action "may have a significant effect upon the…environment, an EIS ***must*** be prepared." *Id*. (emphasis added). If the proposed action is found to have no significant effect, the agency must issue a finding of no significant impact, and set forth a "convincing statement" of the reasons that explain why the agency action will impact the environment no more than insignificantly. *Id*.

56. It is clear that mercury fillings have an extremely detrimental impact on the environment. According to one EPA estimate, the United States consumes at lease thirty-four (34) tons of mercury per year for dental preparation and use. *See* US EPA Office of Research and Development, *Mercury Use and Release of Mercury in the United States*, at 13, 34 (Dec. 2002) (EPA/600-R-02/104) (epa.gov/mercury/eco.htm) (hereinafter "Mercury Use Report"). Dental mercury waste typically will be captured for recycling, discarded as municipal waste or medical waste, or discharged into the general municipal wastewater system. The amalgam in wastewater

from dental offices is the largest direct contributor of mercury to water in the United States. [*Mercury Use Report* at 6] Mercury from spills, scrap and vacuum pump systems in dental offices release mercury pollutants into the air. Therefore, due to the significant impact mercury has on the environment, the FDA should be required to produce an EIS, or at the very least an EA.

57. Despite the evident concerns dental mercury fillings pose to the environment, the FDA has refused to provide an EIS or an EA, claiming that rulemaking regarding dental mercury fillings qualifies for a "categorical exclusion." In 1987, the FDA refused to produce an EIS or EA based on its contention that it was categorically excluded because its action would not result in the production or distribution of any substance, and, therefore, will not result in the introduction of any substance into the environment. 21 C.F.R. § 25.24. This categorical exclusion was amended in 2005 to categorically exclude any "classification or reclassification of a device…including the establishment of special controls, if the action will not result in increases in the existing levels of the device, or changes in intended use of the device or its substitutes." 21 C.F.R. § 25.234(b).

58. Plaintiffs submit that dental mercury fillings are not subject to this categorical exclusion. However, even if the exclusion applies, the FDA is still required to produce an EIS or EA. The Council of Environmental Quality ("CEQ") requires that an environmental assessment ordinarily excluded under a categorical exclusion be conducted if "extraordinary circumstances" exist that indicate that the proposed action may have a "significant affect" on the quality of the human environment. 40 C.F.R. § 1508.4. What significantly affects the environment involves considerations of both "context" and "intensity." 40 C.F.R. § 1508.27. A consideration of context "means that the significance of an action must be analyzed in several contexts such as

society as a whole (human, national), the affected region, the affected interests, and the locality." § 1508.27(a). An evaluation of "intensity" refers to the severity of the impact, and includes a consideration of numerous factors. Section 1508.27(b). The obvious detrimental effects of mercury, including the harms to the environment detailed above, greatly tip the scale in favor of requiring a detailed EIS. Accordingly, mercury fillings are not categorically excluded, and FDA is legally obligated to produce an EIS, or at the very least, an EA.

WHEREFORE, the Plaintiffs pray for the relief hereinafter requested.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

(1) Enjoining the enforcement of FDA's 2009 Final Rule, including the FDA's 2015 Responses written in support thereof, concerning mercury fillings;

(2) Enjoining the use of mercury fillings in the Protected Subpopulations in which the use of mercury fillings was cited as dangerous by the FDA's 2012 Response unless and until such time as FDA convenes a fact-finding proceeding wherein it identifies substantial evidence that mercury fillings are safe for use in these subpopulations;

(3) Requiring FDA to instruct the dental profession to minimize the use of mercury fillings in favor of alternative restorative materials, which should be used as the first line of restorative care, as asserted by FDA in its 2012 Response;

(4) Mandating that FDA provide and/or require appropriate warnings be submitted to patients, and parents of minor patients, explaining the potential harms and risks associated with mercury fillings, including information contained in Exhibit D, and including the availability of alternative restorative devices;

(5) Directing the FDA to amend its "Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy"

[Exhibit E] to include the information contained in Requests for Relief two, three, and four above, to include all the information contained in the FDA's 2012 Response [Exhibit C], to include all acknowledgements and admissions of health risks as set forth in the 2015 FDA Responses to Plaintiffs' Petitions [Exhibits A1 and A2], and to include directions for information that are made available to the public by manufacturers and dentists;

(6) Requiring FDA classify dental mercury fillings as implants and to designate such fillings as Class III devices requiring the manufacturers of mercury fillings to affirmatively prove the safety and efficacy of such fillings;

(7) Requiring the FDA to require that an EIS or at least an EA be prepared pursuant to 21 C.F.R. § 25.40;

(8) Awarding the Plaintiffs a reasonable attorneys' fee and all other court costs incurred in pursuit of this action;

(9) Granting other such relief as this Court deems just and proper.

Respectfully submitted,

_____

James S. Turner, DC Bar #82479
Swankin & Turner
1400 16th Street, NW, Suite 101
Washington, DC 20036
Tel: 202-462-8800
Email: jim@swankin-turner.com

Of Counsel

James M. Love
Titus Hills Reynolds Love
Dickman & McCalmon, P.C.
3700 First Place Tower
15 East Fifth Street
Tulsa, Oklahoma 74103-4334
Tel: 918-587-6800
Email: jlove@titushillis.com

Robert E. Reeves
Reeves Law Office
227 Albany Road
Lexington, Kentucky 40503
Tel: (859) 226-0700;
Email: robertereeves1@gmail.com