UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INTERNATIONAL ACADEMY OF ORAL MEDICINE & TOXICOLOGY, *et al.*, **Plaintiffs,** **v.** **THE U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,** **Defendants.**	**Civil Action No. 14-356 (JEB)**

MEMORANDUM OPINION

Dental amalgam is a metallic compound that dentists use to fill cavities and repair structural deformities in teeth. One of its constituent parts is mercury. The Plaintiffs in this suit, which include a number of individuals and several not-for-profit organizations, fear that mercury renders the compound physically harmful, both for the individuals obtaining fillings and for the dentists responsible for installing and removing them. They are also concerned that the removal of such fillings (also known as silver fillings) may cause environmental harm, as they assert that dental-amalgam particulate travels from patients' mouths to sinks and then to sewers, ultimately contaminating the nation's water supply.

Hoping to take a large bite out of the prevalence of dental amalgam, some of the Plaintiffs asked the Food and Drug Administration to either ban it outright or classify it as high risk, thereby triggering a greater degree of regulatory scrutiny. The FDA rejected these various entreaties. Plaintiffs then brought suit here, asking this Court to compel the FDA to take a considerably stronger regulatory position, including conducting an evaluation of amalgam's

environmental impact. Before getting to the root of Plaintiffs' claim, however, the Court must determine whether they have standing to sue. Concluding that they do not, the Court will grant Defendants' Motion to Dismiss.

I. Background

As the FDA's duties play an important role in this suit, the Court will first summarize the agency's responsibility for regulating dental devices and set out the regulatory history of dental amalgam. It will then recount the various efforts taken by some of the Plaintiffs to seek recourse directly from the FDA and end with a summary of the case's procedural history, including events that transpired subsequent to the filing of the Complaint.

A. Statutory Framework

Ever since passage of the 1976 Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA), see Pub.L. No. 94–295, 90 Stat. 539 (1976), the FDA has had authority to regulate devices that, among other things, are "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(h)(3). Under the statute, any device may be categorized into one of three classes: I, II, or III. "A device's classification is determined based on 'the degree of regulation thought necessary to provide reasonable assurance of each device's "safety and effectiveness."'" Ivy Sports Med., LLC v. Burwell, 767 F.3d 81, 83 (D.C. Cir. 2014) (quoting Contact Lens Manufacturers Association v. FDA, 766 F.2d 592, 594 (D.C. Cir. 1985), itself quoting 21 U.S.C. § 360c). Pursuant to the MDA, the FDA has classified a variety of tools and materials used in dentistry as "devices." See generally 21 C.F.R. Part 872 (1988).

The minutiae of the classification regime are immaterial for present purposes, and it is sufficient to explain that "Class I and II devices are considered to pose fewer risks," Ivy Sports Med., 767 F.3d at 83, meaning they demand fewer and less taxing regulatory controls. "The

devices receiving the most federal oversight," in contrast, "are those in Class III," which consist of "devices that present great risks [but] nonetheless offer great benefits in light of available alternatives." Riegel v. Medtronic, Inc., 552 U.S. 312, 317, 318 (2008).

Class I devices are regulated by the imposition of "'general controls,' such as labeling requirements." Id. at 316. Class II devices are, in addition to "general controls," subject to "'special controls' such as performance standards and postmarket surveillance measures." Id. at 316-17. Finally, Class III devices require rigorous pre-market evaluations and assessments to determine the product's safety, see id. at 317, and to ensure that the device "be made with almost no deviations from the specifications [furnished in the device's] approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." Id. at 323.

B. Dental Amalgam

"Dental amalgam" is a single device, but it is made up of two component parts, both of which are FDA-regulated devices in their own right: (a) elemental or "dental" mercury, and (b) amalgam alloy, which is mostly composed of silver, tin, and copper. See Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy, 74 Fed. Reg. 38686, 38696 (Aug. 4, 2009). Manufacturers of dental amalgam prepare and sell pre-dosed capsules containing those two components, which allows a dentist to mix them together in her office when installing a filling. See id. at 38696. The FDA formerly referred to this composite device as "encapsulated amalgam alloy and dental mercury," 67 Fed Reg. 7620, 7621 (Feb. 20, 2002), but it is now known more pithily as "dental amalgam." 74 Fed. Reg. at 38686.

Shortly after Congress enacted the MDA in the late 1970s, the FDA began the process of classifying the two sub-components of dental amalgam separately. See Classification of Dental Devices; Development of General Provisions, 45 Fed Reg. 85962 (Dec. 30, 1980) (Proposed Rule). In 1987, the agency promulgated a final rule classifying elemental mercury – then known as "dental mercury" – as a Class I device, and amalgam alloy as a Class II device. See Dental Devices; General Provisions and Classifications of 110 Devices, 52 Fed. Reg. 30082, 30084-85 (Aug. 12, 1987).

Unfortunately, "[d]ue to an inadvertent error," the FDA neglected to propose classification of the combined form, dental amalgam, in the 1980s rulemaking process. See 67 Fed. Reg. at 7621. It nevertheless decided at that time to treat dental amalgam as a Class II device, since one of its components, amalgam alloy, was regulated as Class II, even though the remaining components were regulated as Class I. See id.; 52 Fed. Reg. at 3099, 30102; see also Moms Against Mercury v. FDA, 483 F.3d 824, 825 (D.C. Cir. 2007) (recounting history of dental amalgam); Comm. of Dental Amalgam Mfrs. & Distributors v. Stratton, 92 F.3d 807, 811 (9th Cir. 1996) (recognizing and approving FDA's treatment of dental amalgam as a regulated device even though it had not been classified separately from its "component parts" dental mercury and amalgam alloy).

C. Plaintiffs' Citizen Petitions

Plaintiffs comprise a hodgepodge of individuals and organizations, all of whom in some way oppose the use of mercury in dental fillings. The Court will not provide extensive details on these various entities and individuals until later in this Opinion, as the briefing has clarified that only a subset of the full list of Plaintiffs possesses a colorable argument that they have standing to sue. Suffice it to say that at various points in the recent past, certain members of the present

group of Plaintiffs – which includes both natural persons and organizations – have attempted to steer the FDA away from using mercury in fillings.

The prologue to the present suit began in the 1990s, when various individuals and organizations (including some named Plaintiffs here) filed what are known as "Citizen Petitions" with the FDA asking it to reconsider its treatment of dental amalgam. See Mot. at 4-5; 21 C.F.R. § 10.25(a) ("An interested person may petition the Commissioner [of the FDA] to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action . . . (2) in the form for a citizen petition in § 10.30."). The Petitions prompted the agency to consult with the Dental Products Panel of the Medical Devices Advisory Committee, after which it issued a notice of proposed rulemaking in 2002, suggesting that it would formally classify dental amalgam as Class II. See 67 Fed. Reg. at 7624.

Although the 2002 proposed rule marked the beginning of the FDA's notice-and-comment process, some of the Plaintiffs named here believed the agency was moving too slowly. They filed two separate lawsuits to force the FDA to take final action. The first was an unsuccessful direct petition to the D.C. Circuit in 2006. See Moms Against Mercury, 483 F.3d at 824. The second was a district-court case initiated in 2007. See Moms Against Mercury v. Eschenbach, No. 07-2332 (D.D.C.). In settling the latter, the FDA agreed to issue a Final Rule classifying dental amalgam by July 28, 2009, see Mot. at 6, which set the stage for the instant dispute.

The first action relevant here came just days before the FDA was scheduled to publish its Final Rule. On July 25, 2009, a subset of the named Plaintiffs submitted a Citizen Petition asking the FDA to, *inter alia*, ban dental amalgam or, alternatively, regulate it as a Class III device. See Mot., Exh. 1 (July 25, 2009, Citizen Petition) at 1. The Petition also included less-

desirable alternatives in the event the device remained as Class II, such as restricting its use in various subpopulations (like young children and pregnant women). It also asked the FDA to require manufacturers to prepare environmental assessments. Id.

The stipulated deadline came and went with no news from the FDA. But in early August 2009, the agency finally published its Final Rule in which it formally classified dental amalgam as a Class II device. See 74 Fed. Reg. 38686 (Aug. 4, 2009) (Final Rule). In doing so, it addressed safety concerns raised in the voluminous submissions received during the seven-year notice-and-comment process, concluding that Class II special controls would properly balance any potential health risks against the device's benefits. See 74 Fed. Reg. at 38686-87. It also addressed environmental concerns raised by commenters, concluding that under the National Environmental Policy Act of 1969, there was no need to prepare an Environmental Assessment or Environmental Impact Statement, since the classification of dental amalgam would not "increase[] . . . the existing levels of use of the device or change[] . . . [its] intended use." Id. at 38704 (citing 21 C.F.R. § 25.34, which sets forth the conditions under which FDA need not complete an EA or EIS, as would ordinarily be required by NEPA).

Another Citizen Petition followed swiftly thereafter. On September 2, 2009, one of the named Plaintiffs, Karen Burns, signed on to a "petition for reconsideration" of the August 2009 Final Rule. (For technical reasons unimportant here, the petitioners later converted their grievance into a properly filed Citizen Petition in June 2014.) Unlike the July 25, 2009, Citizen Petition, this one did not seek an outright ban on dental amalgam, nor did it request the device be classified as a Class III device. Instead, it asked the FDA to require various forms of warnings pertaining to the device's mercury content, and to contraindicate the device for use in sensitive

subpopulations – *e.g.*, children under six, pregnant women, and nursing mothers. See Mot., Exh. 2 (September 2, 2009, Citizen Petition) at 1-2.

The final relevant action came one day after the September 2, 2009, Citizen Petition. On September 3, the same group of Plaintiffs that filed the July 25, 2009, Citizen Petition also filed a "petition for reconsideration" of the Final Rule, which was later supplemented in March 2013. See Mot., Exh. 5 (September 3, 2009, Citizen Petition), as amended by Mot., Exh. 6 (Supplement to Sept. 3, 2009, Citizen Petition). (As with the September 2, 2009, Citizen Petition, this action required some procedural finagling.) This Petition sought nearly the same relief as the first one (filed on July 25, 2009).

D. Procedural History & FDA Responses

After hearing nothing but crickets from the FDA for some time, Plaintiffs filed suit on March 5, 2014, alleging the agency had unreasonably delayed responding to the three Petitions. See Compl., ¶¶ 1, 41. The parties subsequently entered into negotiations, which included a proposal by the FDA that the case be stayed while it acted on the Petitions, which it agreed to do by January 2015. See ECF No. 18 (Joint Motion to Stay) at 1. The Court acquiesced. See Minute Order of Nov. 5, 2014.

On January 27, 2015, the FDA issued its three responses. It denied the July 25, 2009, Citizen Petition in full. See Supp. Compl. (ECF No. 30), Exh. A3. As to the September 2, 2009, Petition, it granted a portion – agreeing to require publication of some information regarding the presence of elemental mercury in silver fillings – but denied the remainder. See Supp. Compl., Exh. A2 at 2 & 12. It also denied the September 3, 2009, Citizen Petition in full. See Supp. Compl., Exh. A1 at 1 & 40.

After several more months, Plaintiffs filed a Supplemental Complaint here, which challenged the 2009 Final Rule and the FDA's January 2015 responses. See Supp. Compl., ¶ 4. They set forth six counts, the particulars of which are immaterial at present, and sought as a remedy an order that would (a) enjoin the 2009 Final Rule; (b) require the FDA to, among other things, ban the use of amalgam fillings in various subpopulations, "instruct the dental profession to minimize the use of mercury fillings in favor of alternative restorative materials," provide added warnings, and increase various regulatory controls; (c) order the FDA to reclassify dental amalgam as a Class III device, and (e) order it to complete an Environmental Impact Statement or at least an Environmental Assessment regarding the effect of dental amalgam as a pollutant of water and air. See Supp. Compl. at 27-28.

FDA now moves to dismiss the Supplemental Complaint for lack of standing, which request is ripe for this Court's analysis.

II. Legal Standard

In evaluating Defendants' Motion to Dismiss, the Court must "treat the complaint's factual allegations as true . . . and must grant plaintiff 'the benefit of all inferences that can be derived from the facts alleged.'" Sparrow v. United Air Lines, Inc., 216 F.3d 1111, 1113 (D.C. Cir. 2000) (quoting Schuler v. United States, 617 F.2d 605, 608 (D.C. Cir. 1979)) (internal citation omitted); see also Jerome Stevens Pharms., Inc. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005). This standard governs the Court's considerations of Defendants' Motion under both Rules 12(b)(1) and 12(b)(6). See Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) ("[I]n passing on a motion to dismiss, whether on the ground of lack of jurisdiction over the subject matter or for failure to state a cause of action, the allegations of the complaint should be construed favorably to the pleader."); Walker v. Jones, 733 F.2d 923, 925–26 (D.C. Cir. 1984) (same). The Court

need not accept as true, however, "a legal conclusion couched as a factual allegation," nor an inference unsupported by the facts set forth in the Complaint. Trudeau v. Fed. Trade Comm'n, 456 F.3d 178, 193 (D.C. Cir. 2006) (quoting Papasan v. Allain, 478 U.S. 265, 286 (1986) (internal quotation marks omitted)).

To survive a motion to dismiss under Rule 12(b)(1), Plaintiffs bear the burden of proving that the Court has subject-matter jurisdiction to hear their claims. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992); U.S. Ecology, Inc. v. U.S. Dep't of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000). A court has an "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority." Grand Lodge of the Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). For this reason, "'the [p]laintiff's factual allegations in the complaint ... will bear closer scrutiny in resolving a 12(b)(1) motion' than in resolving a 12(b)(6) motion for failure to state a claim." Id. at 13-14 (quoting 5A Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1350 (2d ed. 1987) (alteration in original)). Additionally, unlike with a motion to dismiss under Rule 12(b)(6), the Court "may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction." Jerome Stevens, 402 F.3d at 1253; see also Venetian Casino Resort, L.L.C. v. E.E.O.C., 409 F.3d 359, 366 (D.C. Cir. 2005) ("[G]iven the present posture of this case—a dismissal under Rule 12(b)(1) on ripeness grounds—the court may consider materials outside the pleadings."); Herbert v. Nat'l Acad. of Sciences, 974 F.2d 192, 197 (D.C. Cir. 1992).

III. Analysis

Article III of the United States Constitution limits the jurisdiction of federal courts to resolving "Cases" and "Controversies." U.S. CONST. art. III, § 2, cl. 1. A party's standing "is an essential and unchanging part of the case-or-controversy requirement of Article III." Lujan v.

Defenders of Wildlife, 504 U.S. 555, 560 (1992). To maintain standing, a plaintiff must, at a constitutional minimum, meet the following criteria. First, it "must have suffered an injury in fact — an invasion of a legally-protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or hypothetical . . . ." Id. (citations and internal quotation marks omitted). Second, "there must be a causal connection between the injury and the conduct complained of — the injury has to be fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." Id. (alterations in original) (citation and internal quotation marks omitted). Third, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" Id. at 561 (citation omitted). A "deficiency on any one of the three prongs suffices to defeat standing." U.S. Ecology, Inc., 231 F.3d at 24. In addition, "a plaintiff must demonstrate standing for each claim he seeks to press. . . ." DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352 (2006).

Plaintiffs advance several different theories of standing, each of which depends on the particular Plaintiff involved. Before setting those theories out, the Court notes that Plaintiffs no longer maintain that the full panoply of individuals and organizations named in their Supplemental Complaint has standing to sue. They make no affirmative case in their Opposition that the following individuals or entities have standing under any theory: Moms Against Mercury, Inc., Linda Brocato, Amy Carson (guardian *ad litem* for Kit D. Carson), Karen Palmer, Lisa Sykes (guardian *ad litem* for Wesley Sykes), Roberta Voss, Karen Burns, David Barnes, Michael G. Burke, Eric Edney, Kristin Homme, Paula Kavanagh, Dorice A. Madonero, Joy Chmielenski, James Hollis Hughes, and Kennard W. Wellons. Their reticence compels the Court to dismiss these Plaintiffs for lack of standing. See Rainbow/PUSH Coal. v. FCC, 396

F.3d 1235, 1239 (D.C. Cir. 2005) ("'[A] petitioner whose standing is not selfevident [*sic*] should establish its standing by the submission of its arguments and any affidavits or other evidence appurtenant thereto at the first appropriate point in the review proceeding'—either 'in response to a motion to dismiss for want of standing' or, in the absence of such motion, 'with the petitioner's opening brief.'") (quoting Sierra Club v. EPA, 292 F.3d 895, 900 (D.C. Cir. 2002)).

Only four Plaintiffs remain: (1) International Academy of Oral Medicine and Toxicology, Inc. (IAOMT), a group of dentists, dental students, scientists and others who advocate against the use of mercury in dentistry; (2) the Coalition for Mercury-free Drugs (CoMeD), an organization dedicated to reducing the level of mercury in drugs; (3) Roger Waller, an incarcerated individual who wants to have his silver fillings removed; and (4) Dental Amalgam Mercury Solutions (DAMS), an organization dedicated to educating individuals about the dangers of dental mercury. Their arguments raise four separate legal issues. First is the standing of IAOMT and CoMeD to bring suit as organizations. Second is the standing of a single individual, Roger Waller, to sue in his own name. Third is the standing of IAOMT and DAMS, as associations of individuals, to bring suit on behalf of their respective members – a theory of standing known as "representational standing." Last is the narrower question of whether IAOMT has standing to bring suit on its own behalf and on behalf of its members in demanding that the FDA complete an Environmental Assessment or Environmental Impact Statement. The Court will treat each theory separately, concluding that Plaintiffs have failed to establish standing across the board.

A. Organizational Standing: IAOMT and CoMeD

1. *Legal Framework*

Plaintiffs assert that two organizations (IAOMT and CoMeD) have each suffered harm on account of the FDA's actions and thus have standing to bring suit on their own behalf. In order

to assert such "organizational standing," the organization in question, just like any natural person, must show an "actual or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be redressed by a favorable court decision." People for the Ethical Treatment of Animals v. U.S. Dep't of Agric. (PETA), 797 F.3d 1087, 1093 (D.C. Cir. 2015) (citations omitted); see Havens Realty Corp. v. Coleman, 455 U.S. 363, 378-79 (1982) (organizational-standing inquiry is "the same inquiry as in the case of an individual: Has the plaintiff alleged such a personal stake in the outcome of the controversy as to warrant his invocation of federal-court jurisdiction?")).

Stated in such broad terms, the inquiry appears deceptively simple. But identifying what counts as a cognizable injury to an organization is no easy feat, in part because of the difficulty of applying the D.C. Circuit's distinction between a "concrete and demonstrable injury to [the organization's] activities" – which suffices for standing purposes – and "a mere setback to its abstract social interests" – which does not. Equal Rights Ctr. v. Post Properties, Inc., 633 F.3d 1136, 1138 (D.C. Cir. 2011) (citations and quotation marks omitted); accord PETA, 797 F.3d at 1100-01 (Millett, J., *dubitante*) (criticizing the D.C. Circuit's "organizational standing precedents" for holding "that the required Article III injury need not be what the defendant has done to the plaintiff; it can also be what the defendant has not done to a third party").

Adding to this haziness, there seems to be an emerging disagreement about the precise contours of the test used by this circuit to establish organizational injury. In the recently decided Food & Water Watch, Inc. v. Vilsack, 808 F.3d 905 (D.C. Cir. 2015), the majority set forth "a two-part test to determine whether an organization has alleged a cognizable injury" when asserting a claim against the government. Id. at 924. First is "whether the agency's action or omission to act 'injured the [organization's] interest and, second, whether the [organization] used

its resources to counteract that harm.'" Id. (quoting Equal Rights Ctr., 633 F.3d at 1140). On the first prong – which was the only one at issue in that case – the court explained that "an organization must allege that the defendant's conduct perceptibly impaired the organization's ability to provide services," which occurs "when the defendant's conduct causes an inhibition of [its] daily operations." Id. at 919 (citations and internal quotation marks omitted). Yet the court then looked to past cases in which the various plaintiffs' claimed injury was some diversion of operational resources to decide when and under what circumstances such a diversion impeded the organization's daily operations. Id. at 919-20. As the concurrence pointed out, this analytical move appeared to conflate the "first" prong with the "second." See Food & Water Watch, 808 F.3d at 924 n.5 (Henderson, J., concurring) ("My colleagues, I believe, have erroneously injected a prong-two consideration—*i.e.*, what FWW has spent its money to combat—into the prong-one inquiry whether the [agency action at issue] 'directly conflicts' with FWW's mission.").

Regardless of the particular formulation of the organizational-injury test, the circuit has, by and large, reasoned by induction in determining whether an organization has set forth a sufficient Article III injury – an approach that guides the Court's decisionmaking here.

Certain harms do not rise to the level of an "injury in fact." For instance, D.C. Circuit "precedent makes clear that an organization's use of resources for litigation, investigation in anticipation of litigation, or advocacy is not sufficient to give rise to an Article III injury." Food & Water Watch, 808 F.3d at 919; see Nat'l Ass'n of Home Builders v. EPA, 667 F.3d 6, 12 (D.C. Cir. 2011) (time and money spent "submitting comments to the EPA" and "testifying before the . . . Senate" does not establish Article III injury). Similarly, "an organization does not suffer an injury in fact where it 'expend[s] resources to educate its members and others' unless

doing so subjects the organization to 'operational costs beyond those normally expended.'" Food & Water Watch, 808 F.3d at 920 (quoting Nat'l Taxpayers Union, Inc. v. United States, 68 F.3d 1428, 1434 (D.C. Cir. 1995)).

Looking at those precedents, the Court of Appeals in Food & Water Watch concluded that the plaintiff FWW, a consumer-advocacy group worried that new (and looser) USDA regulations would result in a greater incidence of foodborne illness from contaminated poultry, had failed to establish organizational injury. Id. at 916, 919. FWW produced affidavits indicating that it would, as a result of new regulations, spend more "time and money on increasing its efforts to educate members of the public that just because a poultry product has a USDA inspection legend does not mean that it is not adulterated and is wholesome," and that it would "increase the amount of resources that it spends encouraging its members who wish to continue to eat chicken to avoid poultry" produced under the new rules and instead "purchase poultry at farmers' markets or direct from producers." Id. at 920 (quotations omitted). Those allegations of harm, the court concluded, made clear that

> FWW has alleged nothing more than an abstract injury to its interests . . . . FWW does not allege that the [challenged rule] limits its ability to seek redress for a violation of law. Nor does FWW allege that the USDA's action restricts the flow of information that FWW uses to educate its members. Although [FWW] alleges that [it] will spend resources educating its members and the public about [why the rule is ineffective in screening out contaminated poultry], nothing in [FWW's] declaration indicates that [its] organizational activities have been perceptibly impaired in any way.

Id. at 921.

In contrast, some operational injuries traceable to government action do suffice to establish "injury in fact." In PETA, for instance, the pro-animal advocacy group PETA challenged the USDA's decision not to enforce Animal Welfare Act (AWA) protections on

behalf of ill-treated birds, even though the agency had decided years earlier that the AWA's statutory protections extended to the winged. See 797 F.3d at 1090-91. PETA successfully argued that by refusing to take action when birds were alleged to have been harmed, USDA caused two types of injuries to the organization. First, in failing to undertake bird-related investigations and inspections as it was empowered to do by statute, USDA deprived PETA of information that it would otherwise have received from those investigations, requiring PETA to spend time and money independently gathering the information that it needed to educate the public about bird abuse. Id. at 1094-95. Second, USDA's failure to enforce the AWA against alleged perpetrators also required PETA to spend its own resources in trying to "seek redress for bird abuse" without the aid of USDA inspectors. Id. at 1095-96. This diversion of resources came "'in response to, and to counteract, the effects of the defendants' alleged [unlawful conduct],'" id. at 1097 (quoting Equal Rights Ctr., 633 F.3d at 1140), and thus sufficed as an injury in fact traceable to the USDA's allegedly unlawful actions. Id.; but see PETA, 797 F.3d at 1102-06 (Millett, J., *dubitante*) (concluding that but for the D.C. Circuit's erroneous but binding precedent, neither injury should suffice to establish Article III standing).

Similarly, in another pharmaceutical case, the Court of Appeals concluded – albeit with cursory analysis – that an organization that advocated for terminally ill patients had standing to challenge an FDA policy barring the sale of experimental new drugs. See Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach, 469 F.3d 129, 133 (D.C. Cir. 2006). The court concluded that where the organization alleged that it had to spend significant time and money to assist its members and others in trying to figure out how to access such potentially life-saving drugs, as well as providing "counseling and referral services," it had met the threshold for organizational injury. Id.

While no bright-line test emerges from this array of precedent, the Court will focus on a few key factors as it moves through its analysis. One is whether the injury relates to the organization's mere advocacy objectives or if, instead, it undermines the organization's direct, non-advocacy services. See Food & Water Watch, 808 F.3d at 919-20. Another is whether the organization truly "diverted" any resources at all; in other words, did the challenged agency action cause it to incur "operational costs beyond those normally expended" to carry out its day-to-day mission of educating the public or advancing its advocacy mission? See id.; Nat'l Taxpayers Union, 68 F.3d at 1434. With these front and center, the Court will do its best to apply the D.C. Circuit's organizational-standing principles as it turns to the injuries alleged here.

2. *IAOMT*

IAOMT is a "non-profit organization of dentists, dental students, physicians and science research professionals devoted to the examination, compilation, and dissemination of scientific research relating to the biological compatibility of oral/dental materials." Opp., Exh. 1 (Affidavit of David Kennedy, Former President of IAOMT), ¶ 1. Plaintiffs identify two harms IAOMT has suffered as a result of the FDA's actions. First, the 2009 Final Rule "directly conflicts with IAOMT's mission to promote the health of the public, including the reduction of the devastating effects of mercury exposure on patients, dentists, and staff." Opp. at 16. Second, the organization has "been forced to divert significant time and resources from [its] normal organizational activities to help [its] membership[] and the public address the FDA's legally insufficient and harmful Final Rule." Id. at 16-17.

The first "injury" requires little more than a passing glance. While Plaintiffs plead a plausible mission conflict in that IAOMT desires to "eliminate[e]" the "health risks from amalgam mercury" in the practice of dentistry, see Opp., Exh. 16 (IAOMT "Who We Are") at 2,

that alone does not confer standing. See Nat'l Treasury Employees Union v. United States, 101 F.3d 1423, 1430 (D.C. Cir. 1996) ("[T]he presence of a direct conflict between the defendant's conduct and the organization's mission is necessary—though not alone sufficient—to establish standing" for organizational plaintiffs.). The Court will, accordingly, focus on the ways IAOMT's resources are purportedly diverted as the relevant organizational injury claimed here.

a. Money Spent on Studies and Advocacy

The first claimed diversion-of-resources injury is that, "[a]s a direct result of the [2009 Final Rule], the IAOMT was forced to deviate a substantial portion of its resources to identify and dispute the FDA's errors [in that Rule.]" Opp. at 17. This injury does not suffice to confer standing for two main reasons: (1) the only service alleged to be impaired is pure issue advocacy, and (2) the FDA's conduct did not lead IAOMT to "divert" its resources in any meaningful way.

Beginning with the first, "a mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself to render the organization 'adversely affected' or 'aggrieved' within the meaning of the APA." Sierra Club v. Morton, 405 U.S. 727, 739 (1972). Here, IAOMT claims to have channeled its funds for the sole purpose of convincing the FDA that its decision to keep amalgam as a Class II device was error. In the wake of the Rule, it allegedly spent around $116,000 on two studies designed to address the FDA's findings and contracted with three individuals to identify and draft a Petition to address the FDA's mistakes, and to participate in a scientific-advisory-panel meeting scheduled by the FDA in December 2010. See Opp. at 17-18 & n.6; Opp., Exh. 4 (Affidavit of Kymberly Smith, IAOMT Executive Director), ¶¶ 3-5; ECF No. 39 (Errata, Affidavit of G. Mark Richardson, Consultant to IAOMT), ¶¶ 16-20. In sum: the FDA's 2009 Final Rule caused IAOMT to spend money trying to convince the FDA to modify that very same Rule.

There can be no doubt that these expenditures pertain directly and exclusively to IAOMT's issue-advocacy services – in particular, its desire to alter government regulatory policy. But a diversion-of-resources injury does not count for Article III purposes where "the only 'service' impaired is pure issue-advocacy." Ctr. for Law & Educ. v. Dep't of Educ., 396 F.3d 1152, 1162 (D.C. Cir. 2005); see also id. n.4 ("[T]o hold that a lobbyist/advocacy group had standing to challenge government policy with no injury other than injury to its advocacy would eviscerate standing doctrine's actual injury requirement."). "In essence, [IAOMT] seeks to sound an alarm regarding the dangers of [dental amalgam]. This is 'pure issue-advocacy.'" Food & Water Watch, 808 F.3d at 925 (Henderson, J., concurring); accord Abigail Alliance, 469 F.3d at 133 ("[A]n organization is not injured by expending resources to challenge the regulation itself; we do not recognize such self-inflicted harm.").

The conclusion that these expenditures are properly considered to be "issue advocacy" – and thus do not qualify as an organizational injury – is reinforced by the fact that IAOMT "ha[s] not identified any specific projects that [it] had to put on hold or otherwise curtail in order to respond to the [2009 Final Rule]." NAACP v. City of Kyle, Tex., 626 F.3d 233, 238 (5th Cir. 2010) (no organizational standing where plaintiff claimed that city zoning ordinances caused it to spend money "examining and communicating about developments in local zoning and subdivision ordinances," which did not differ in any way from its "routine lobbying activities"). For this reason, IAOMT's situation is quite unlike others in which organizations engaged in both advocacy and direct service provision, as the latter may provide the basis for standing while the former does not. See, e.g., Scenic Am., Inc. v. United States Dep't of Transp., 983 F. Supp. 2d 170, 178-79 (D.D.C. 2013) (even though some of organization's activities were "pure issue-advocacy" and thus could not support standing, plaintiff did suffer injury sufficient to challenge

federal agency guidance where it would have required organization to spend more resources on direct services organization provided to its members), appeal docketed, No. 14-5195 (D.C. Cir., Aug. 7, 2014).

Nor, for that matter, has IAOMT claimed that the Rule in any way "injure[d] the organization's advocacy activities" themselves, see Am. Soc. for Prevention of Cruelty to Animals v. Feld Entm't, Inc., 659 F.3d 13, 27 (D.C. Cir. 2011) – a difficult argument to make since the Rule has no impact whatsoever on IAOMT's ability to gather information, collect and present data, communicate its belief that dental amalgam is unsafe, or otherwise convince pertinent actors that amalgam should be more strictly regulated. See Fair Emp't Council of Greater Washington, Inc. v. BMC Mktg. Corp., 28 F.3d 1268, 1276 (D.C. Cir. 1994) (organization had standing to sue employer where its "alleged pattern of discrimination . . . has made the [plaintiff's] overall task [of reducing discrimination through counseling and outreach] more difficult"); Nat'l Treasury Employees Union, 101 F.3d at 1430 (explaining that an organization may have standing where it "alleges that a defendant's conduct has made the organization's activities more difficult"). Quite the contrary; IAOMT simply disagrees with the substantive decision made by the FDA and will no doubt continue to lobby for the reduction of mercury in dentistry – a position that long predates the Final Rule. See Kennedy Aff., ¶¶ 2-4. Its spending of money to further this advocacy mission – even where that spending is tailored to a very specific rule – does not by itself constitute an injury to the organization sufficient to create standing. See Americans for Safe Access v. DEA, 706 F.3d 438, 458 (D.C. Cir. 2013) ("ASA's asserted injury—that it must spend money to 'educate the public about the true benefits of marijuana' and to 'lobby[] local, state and federal governments,'—is essentially an argument that

ASA cannot allocate issue advocacy expenses in the way it would prefer, which is insufficient to establish standing.") (citation to plaintiff's affidavit omitted).

Moving to the second point, even if IAOMT's alleged injury were consanguineous with those that do support standing, it is not clear how the Final Rule led IAOMT to any true "diversion" of expenditures at all; on the contrary, its recent spending pattern falls neatly within the core set of activities it has long performed. According to IAOMT, which has existed since before dental amalgam was subject to *de facto* regulation in 1987, see Kennedy Aff., ¶ 2, it undertakes

> a plethora of activities relating to the practice of dentistry, [including, *inter alia*]: . . . educating its members on all issues in dentistry, but particularly issues relating to the potential adverse health effects posed by mercury fillings; funding scientific research; publishing scientific literature; promoting public education on dentistry and dental health issues; promoting mercury-free dentistry; [and] promoting and funding research on the environmental effects posed by the discharge of mercury.

Opp. at 17; see also Kennedy Aff., ¶¶ 3-5. That is all fine and well. But IAOMT has not explained how the Final Rule has forced it to divert or modify its activities in any meaningful way from its standard programmatic efforts that existed before the Rule was promulgated. The post-Final Rule activities, therefore, are not a "diversion" from, but rather a continuation of, IAOMT's "ordinary educational, advocacy, and training activities." Opp. at 21; Nat'l Ass'n of Home Builders, 667 F.3d at 12 (spending must be for "operational costs beyond those normally expended to carry out its advocacy mission") (citation omitted) (emphasis added).

Nor can Plaintiffs argue that the expenditures were a necessary part of challenging the regulation – with the ultimate possibility that the Rule might end up facing judicial review in court. The key flaw in this argument is that the D.C. Circuit has squarely rejected the notion that money spent in anticipation of litigation counts as a standing-conferring injury. See, e.g., Food

& Water Watch, 808 F.3d at 919 ("[A]n organization's use of resources for litigation, investigation in anticipation of litigation, or advocacy is not sufficient to give rise to an Article III injury.").

IAOMT offers no other affirmative argument for why its itemized list of advocacy-related expenditures constitutes a "concrete and demonstrable injury to [its] activities" and is not merely a "setback to its abstract social interests." Equal Rights Ctr., 633 F.3d at 1138 (citation and quotation marks omitted); accord Food & Water Watch, 808 F.3d at 919 (Mere "frustration of an organization's objectives is the type of abstract concern that does not impart standing.") (citation omitted). Nor have Plaintiffs cited any authority in support of IAOMT's position – a failing that suggests the injury here falls beyond the boundary of what has previously been considered sufficient to confer standing. In sum, these harms – to the extent they are even properly deemed "harms" at all – do not carry Plaintiffs across the line.

b. Advocating Against Professional Sanctions

The second injury – also a diversion-of-resources injury – fares no better than the first. IAOMT claims that the Final Rule forced it to spend $10,000 on a pamphlet designed to educate its members on how to "communicat[e] about mercury fillings with the public, with their patients, and with the various state dental boards." Opp. at 21; see Kennedy Aff., ¶ 15. To make sense of why it spent this money, and why it believes the FDA is responsible, some groundwork is in order.

According to IAOMT, since at least the 1990s, a third-party non-governmental entity, the American Dental Association, has "attack[ed] . . . IAOMT dentists who communicated to their patients or to the public that mercury fillings were toxic . . . ." Opp. at 19. Those "attacks" refer to formal complaints that the ADA would file on "offending IAOMT dentists." Id. The ADA would apparently offer the dentist a choice: either promise to "discontinue [such]

communications" or face a possible referral to "the relevant state dental board for prosecution." Id. (emphasis added); see id. at 20. If the dentist did not agree, and the ADA referred her to the state dental board, she would face a possibility of sanctions by the state, since "[t]he state dental boards were willing to prosecute these charges on the basis that these dentists had engaged in fraudulent and/or misleading conduct." Id. at 19. Apparently "[s]ome IAOMT dentists lost their licenses and/or incurred other professional sanctions" for such violations. Id.

Well before the FDA actions at issue here, IAOMT "expend[ed] significant resources to protect [its] members" from the "legal and professional consequences" of the ADA's and state dental boards' actions. See Kennedy Aff., ¶ 11. For instance, in 1999 IAOMT spent $25,000 on "disseminat[ing] to state dental boards scientific facts about the documented health risks associated with mercury fillings." Id., ¶ 13. In 2006, it also sued the North Carolina Dental Board for promising, in a newsletter, "to discipline North Carolina dentists who made 'false' representations about the toxicity of dental amalgam." Id., ¶ 14. (That case was dismissed for lack of standing. Id.) But these past expenditures, of course, are not the injury claimed by IAOMT here, which pertains only to the 2009 Final Rule.

At long last, therefore, we come to the injury complained of here, which is that, as a result of the 2009 Final Rule, in which the FDA made its position official that dental amalgam was safe, IAOMT members would be "even more vulnerable to harassment from state dental boards." Opp. at 20. It thus decided to spend $10,000 on developing and publishing a "Position Statement" that its members could use to figure out how best to communicate "about mercury fillings with the public, with their patients, and with the various state dental boards." Opp. at 21; see Kennedy Aff., ¶ 15. The standing question, then, is whether that expenditure constitutes an organizational injury attributable to the FDA's 2009 Final Rule. It does not.

As a reminder, "[t]o allege an injury to its interest, an organization must allege that the defendant's conduct perceptibly impaired the organization's ability to provide services," – *i.e.*, that "the defendant's conduct cause[d] an inhibition of [the organization's] daily operations." Food & Water Watch, 808 F.3d at 919 (citation and quotation marks omitted). The organization's spending of money or other resources "to educate its members and others" does not count as such an inhibition or impairment "unless doing so subjects [it] to 'operational costs beyond those normally expended.'" Id. at 920 (quoting Nat'l Taxpayers Union, Inc., 68 F.3d at 1434).

With this framework in mind, it is difficult to understand how IAOMT's spending $10,000 on an educational pamphlet represents an expenditure that falls outside the ambit of its normal activities. Quite the opposite, in fact, appears true. As noted, IAOMT has long supported efforts to educate state dental boards in the hopes of reducing potential penalties its dentists might suffer for espousing anti-mercury views. See Kennedy Aff., ¶¶ 11-14. Nothing about the 2009 Final Rule changed the game. As it has for almost 30 years, the FDA in 2009 merely reiterated its conclusion that dental amalgam is sufficiently safe to be regulated as a Class II device. Various third parties, including the ADA and state dental boards, allegedly agree. IAOMT's allocation of resources to combat this view is thus wholly unrelated to the FDA's 2009 decision to maintain the *status quo*; it thus cannot constitute "operational costs beyond those normally expended to review, challenge, and educate the public about" the harms of mercury-based dental products. See Nat'l Taxpayers Union, 68 F.3d at 1434; accord Nat'l Ass'n of Home Builders, 667 F.3d at 12 (no organizational standing where plaintiff's expenditures on efforts to "clarify" the scope of EPA's jurisdiction under Clean Water Act were

not alleged or shown to be "operational costs beyond those normally expended to carry out its advocacy mission") (citation and quotation marks omitted).

Nor for that matter does IAOMT's theory of causation bear the weight of any scrutiny. See Grocery Mfrs. Ass'n v. EPA, 693 F.3d 169, 175 (D.C. Cir. 2012) ("It must . . . be 'substantially probable' that the challenged agency action caused [plaintiff's] injury.") (quoting Fla. Audubon Soc. v. Bentsen, 94 F.3d 658, 663 (D.C. Cir. 1996)). The chain of events resulting in IOMTA's claimed resource diversion, for instance, requires first an independent – and at this point hypothetical – decision by a dentist. See Opp. at 21 n.7 (arguing that North Carolina Dental Board may penalize "any dentist who advises a patient or the public" that he practices "Mercury-free Dentistry" or who "make[s] any reference that mercury fillings are harmful") (citation and quotation marks omitted). Even assuming IAOMT dentists are hell-bent on disregarding a given state's rules of practice – and this does not even take into account the tenuousness of the link between the FDA's rule and these prosecutions – Plaintiffs offer no information regarding how likely it is that a dentist's decision to speak ill of amalgam will result in an ADA complaint, how likely such a complaint will result in a referral to a state dental board, how likely such referral will lead to a prosecution, and how likely such prosecution will yield a sanction. "This hypothetical chain of events fails as a showing of Article III standing." Grocery Mfrs. Ass'n, 693 F.3d at 175; accord Nat'l Taxpayers Union, 68 F.3d at 1433 (organization challenging federal estate- and gift-tax rates lacked standing even though it asserted that one of its donors alleged "that the new . . . rates will 'absolutely' affect his future donations," as such a claimed injury is "neither sufficiently concrete nor imminent to confer standing").

3. *Coalition of Mercury-Free Drugs (CoMeD)*

Unlike IAOMT, which has long advocated against mercury in dentistry, CoMeD's mission, as might be anticipated from its name, "is to reduce the level of mercury in all drugs, and end the knowing addition of mercury, in any form, to vaccines and other drugs." Opp., Exh. 3 (Aff. of Lisa Sykes, CoMeD President), ¶ 3. "The vast majority of the papers that CoMeD publishes," therefore, "relate to mercury in drugs, and particularly, in vaccines." Id. Only recently has CoMeD taken up the mantle of battling mercury in dental devices, and it is precisely the timing of this late-breaking interest that deprives CoMeD of standing here.

To remind the reader: a "conflict between a defendant's conduct and an organization's mission" is a "necessary[,] though not alone sufficient" condition for organizational standing. Nat'l Treasury Employees Union, 101 F.3d at 1429. Plaintiffs' pleadings, however, do not reveal any such conflict. As they explain, "Prior to the issuance of the Final Rule, CoMeD was primarily focused on the elimination of thimerosal in injectable drugs." Opp. at 29 (emphasis added). But because the FDA's position on mercury "was certainly within [CoMeD's] collective expertise to address, and [because] the Final Rule infringed on [its] organizational view that continuous mercury exposure presents an unreasonable risk of harm," Sykes Aff., ¶ 3, "CoMeD diverted significant resources in response to and to counteract the FDA's erroneous findings in the Final Rule." Opp. at 29.

An organization cannot, however, simply rewrite its mission statement in such a way as to create a predicate conflict for Article III standing. Cf. Nat'l Treasury Employees Union, 101 F.3d at 1429 ("[Plaintiffs] cannot obtain judicial review of otherwise non-justiciable claims simply by incorporating, drafting a mission statement, and then suing on behalf of the newly formed and extremely interested organization."). CoMeD simply does not claim that prior to

2009 its mission was any broader than eliminating mercury in drugs (particularly vaccines), and thus it is "entirely speculative whether the challenged practice" – *i.e.*, the Final Rule – "will actually impair the organization's activities." PETA, 797 F.3d at 1095 (citation and quotation marks omitted).

In any event, the only injury it claims is that the Rule caused it to "divert[] . . . resources to author and publish . . . four studies" that "critique" the Final Rule and its underlying scientific sources. See Sykes Aff., ¶¶ 6, 8; see also Opp. at 29 ("CoMeD diverted significant resources in response to and to counteract the FDA's erroneous findings in the Final Rule."). As was the case with IAOMT, such expenditures fall within the core of "issue advocacy" services that do not give rise to an Article III injury. See section III.A.2.a, *supra*; Abigail Alliance, 469 F.3d at 133-34 ("expending resources to challenge [a] regulation" constitutes "self-inflicted harm" that does not constitute "injury in fact"). CoMeD, like IAOMT, has not established standing to sue on its own behalf.

B. Individual Standing: Waller

Although numerous individuals joined in the filing of the Complaint, Plaintiffs exclusively focus in their Opposition on establishing the standing of just one, Roger Waller. See Opp. at 32. What we know about Waller comes not from his own hand via declaration or affidavit, but mostly from an affidavit (and appended exhibits) drafted by Leo Cashman, the Executive Director of an organization of which Waller is a member: Dental Amalgam Mercury Solutions (DAMS). See Opp., Exh. 2 (Affidavit of Leo Cashman, Executive Director of DAMS). In Cashman's telling, Waller is allegedly "a mercury poisoned individual currently incarcerated in the Ohio prison system." Id., ¶ 6. Waller believes his "mercury poison[ing]" derives from his mercury fillings; he would like those fillings removed, but "his confinement in

prison has rendered him unable to make his own dental treatment choices." Id., ¶¶ 6-7. The Ohio Department of Rehabilitation and Corrections (ODRC) refused Waller's "repeated requests to have his mercury fillings removed" and similarly rejected a grievance that he filed with ODRC's Office of the Inspector. See id., ¶¶ 7-8, see also Opp., Exh. 2A (ODRC Sept. 23, 2009, Disposition of Aug. 17, 2009, Grievance) (Grievance Decision) at 1. In Plaintiffs' view, "ODRC's refusal to replace Mr. Waller's amalgam fillings is directly traceable to the FDA's Final Rule," since the "ODRC cited to the [Rule] as the principal basis for the refusal to grant Mr. Waller's request." Opp. at 30-31.

To begin, Waller's position – that the 2009 Final Rule was the "principal basis" for ODRC's decision – is incorrect. Plaintiffs attach to their Opposition various ODRC filings that explain in some detail why it actually declined to remove his fillings: the medical justification Waller provided was wholly unsupported by facts. Specifically, Waller claimed to be suffering "chronic/accumulative mercury poisoning" or "Heavy Metal Poisoning." Grievance Decision at 1. As the ODRC decision explains, Waller's medical examination could not confirm any of the symptoms Waller claimed to be suffering, which were themselves dubious and hardly indicative of heavy-metal poisoning. See id. ("It is medically impossible to have all the problems [you complained of] and still walk around."); id. ("[V]isual observation and physical examination were inconsistent with the [claimed] symptoms and didn't reveal anything abnormal."). To err on the side of caution, however, the ODRC ordered "a screening for Heavy Metals," which revealed that "[a]ll metal levels, Mercury, Lead and Arsenic, were within normal ranges," and that "[t]here was no evidence of mercury poisoning." Id. Thus, even though ODRC did note that the FDA in 2009 "reaffirm[ed] that amalgams are absolutely safe," the principal basis for its

decision was that "[t]here [was] no need to remove your fillings" based on his actual symptoms and physical condition. Id. at 2.

Waller's pleadings, moreover, offer no sound basis for concluding that the FDA's actions "caused" his alleged injury – that is, his inability to have his mercury fillings removed. "[I]t does not suffice if the injury complained of is the result of the independent action of some third party not before the court." Bennett v. Spear, 520 U.S. 154, 169 (1997) (citations and alterations omitted). That the ODRC, who is not a party to the case, mentioned the FDA's "reaffirm[ation]" of the safety of dental amalgam, see Grievance Decision at 2, is a far cry from alleging a plausible causal relationship. Nor have Plaintiffs alleged any facts to support the conclusion that the FDA's action has a "determinative or coercive effect" on ODRC's decisions regarding its prisoners' health, see Bennet, 520 U.S. at 169, or that it was "at least a substantial factor" in the ODRC's decision here. Tozzi v. U.S. Dep't of Health & Human Servs., 271 F.3d 301, 308 (D.C. Cir. 2001)

Even more fundamentally, Waller offers little reason to think that a decision granting Plaintiffs all the relief they seek would redress his injury. See Defenders of Wildlife, 504 U.S. at 560-61 ("[I]t must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'") (quoting Simon v. E. Ky. Welfare Rights Org., 426 U.S. 26, 38, 43 (1976)). A prospective ban on the use of dental amalgam represents the outer limits of what Plaintiffs seek as a remedy. See Compl. at 26-27. But a ban on future sales and installation of amalgam says nothing about what the FDA would recommend, if anything, regarding individuals who presently have amalgam fillings. Plaintiffs have not even requested that the FDA, in addition to banning amalgam or classifying it as a Class III device, recommend removal of all currently existing amalgam fillings. Nor, for that matter, have Plaintiffs offered any

information regarding whether or how the FDA's safety and efficacy decisions are considered by ODRC in administering healthcare. It is thus pure speculation whether such a ban, without more, would cause the ODRC to reconsider its denial of Waller's request. For these reasons, Waller has failed to establish a redressable Article III injury, and he therefore has no standing to sue the FDA here.

C. Representational Standing: IAOMT and DAMS

Plaintiffs' final theory of standing for challenging the merits of the Final Rule is based on the idea that IAOMT and DAMS each has standing to bring suit "as the representative of its members." Hunt v. Washington State Apple Advert. Comm'n, 432 U.S. 333, 342 (1977) (quoting Warth v. Seldin, 422 U.S. 490, 511 (1975)). Organizations "have representational standing if: (1) at least one of their members has standing to sue in her or his own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of an individual member in the lawsuit." Am. Library Ass'n v. FCC, 401 F.3d 489, 492 (D.C. Cir. 2005) (reciting what are known as the Hunt factors). Defendants only dispute the first element. The Court will therefore address the two groups of members (IAOMT and DAMS) that Plaintiffs believe satisfy that element here, concluding that neither does.

1. *IAOMT*

IAOMT asserts standing on behalf of: (a) "[e]very IAOMT general dentist and dental student," all of whom allegedly face "unavoidable future exposure to dental amalgams," which they believe will cause them physical harm, see Opp. at 22; (b) member dentists who have faced or will face "disciplinary charges" from the ADA and state dental boards for "communicating the truth about mercury fillings," id. at 28; and (c) a Pennsylvania dentist named Michael Taras,

whose pending disciplinary case Plaintiffs believe is attributable to the FDA's Final Rule. Id. at 28-29. The court examines each separately.

a. Physical Harm to Dentists and Students

IAOMT claims that all of its member dentists and students will face unavoidable exposure to dental amalgam on account of the 2009 Final Rule, which in turn will cause them physical harm. The government's main argument as to both groups is that IAOMT fails to identify even one individual who has standing in his or her own right, which is necessary under the representational-standing test established in Hunt. The Court will first address the dentists, then the students.

i. IAOMT Dentists

IAOMT dentists aim to be free of mercury exposure in their dental practice but believe that the Final Rule is standing in their way. The difficulty with this argument – at least as it pertains to installing fillings – is that there is a readily available market alternative to mercury fillings: composite resin. See Opp. at 3; Mot., Exh. 1 (July 25, 2009, Citizen Petition) at 45 (explaining that "[t]he actual material cost of an amalgam filling is $1-2.00, while a composite costs $2-4.00," that the fee for composite installation is "approximately $30 higher" than for amalgam, and noting that some "independent-minded, fee-for-service dentists" have made "the switch to mercury-free, composite-based practice[s]"). The availability of such alternatives, in turn, makes it difficult to pin a prospective injury from mercury exposure on the FDA. See Coal. for Mercury-Free Drugs v. Sebelius, 671 F.3d 1275, 1282-83 (D.C. Cir. 2012) (consumers alleging physical harm from vaccines containing mercury-based preservative thimerosal lacked standing to challenge FDA rule deeming such vaccines safe, as "thimerosal-free vaccines are

readily available" and plaintiffs did not allege that such vaccines were "unreasonably priced as a result of FDA's decision to allow thimerosal-preserved vaccines").

Plaintiffs acknowledge this problem, stating candidly that "all, or nearly all, of IAOMT members have discontinued the placement of mercury fillings." Opp. at 23. They parry, however, by claiming that such dentists must nevertheless "continue to remove mercury fillings from their patients" if they want to stay in business. See Opp. at 23 (emphasis added); see also id. ("It is generally not financially possible to maintain a general dentistry practice while referring patients with mercury fillings to other dentists."). It is this removal-related exposure, then, that IAOMT claims is unavoidable and will cause future physical harm to its dentists.

As a preliminary matter, it is difficult to square this claim with the representation (cited above) that IAOMT made to the FDA in its July 25, 2009, Citizen Petition regarding dentists switching to mercury-free practices. See July 25, 2009, Citizen Petition at 45. A fair reading of this assertion would suggest that at least some dentists find it economically feasible to practice without handling mercury at all. But even if a "mercury-free" practice in fact means only a mercury-free-installation practice – and such dentists must still remove silver fillings – IAOMT's standing falters on other grounds.

As the government points out, IAOMT has failed to name a single member dentist who claims she will suffer future exposure to dental amalgam via filling removal because she simply cannot maintain a mercury-free practice without going under. This deficiency falls short of what is required by the first Hunt factor, which demands "specific allegations establishing that at least one identified member had suffered or would suffer harm." Summers v. Earth Island Inst., 555 U.S. 488, 498 (2009) (emphasis added).

As a proxy, Plaintiffs again point to the affidavit of David Kennedy, retired dentist and former IAOMT president, who asserts that dentists who insist on a pure, mercury-free practice and refuse to remove amalgam fillings would suffer "a substantial and detrimental reduction of the number of current and potential patients," resulting in "the financial failure of the practice." Kennedy Aff., ¶ 27. But this over-general, unexplained, and unsubstantiated speculation about the economics of mercury-free dentistry does not demonstrate the requisite injury in fact to at least one IAOMT member that is necessary for representational standing. See U.S. Chamber of Commerce v. EPA, 642 F.3d 192, 199-200 (D.C. Cir. 2011) ("[I]t is not enough to aver that unidentified members have been injured. Rather, the [plaintiff] must specifically identify members who have suffered the requisite harm.") (citation and quotation marks omitted). Similarly insufficient is a probabilistic prediction that at least one or some IAOMT members will face such harms in the future. See Summers, 555 U.S. at 497-98 (rejecting the "hitherto unheard-of test for [representational] standing: whether, accepting the organization's self-description of the activities of its members, there is a statistical probability that some of those members are threatened with concrete injury"); Coal. for Mercury-Free Drugs v. Sebelius, 725 F. Supp. 2d 1, 9 n.7 (D.D.C. 2010), aff'd, 671 F.3d at 1275 ("[T]he plaintiffs are mistaken that standing can be based on the argument that an unnamed member of its organization is likely to be harmed.").

ii. IAOMT Dental Students

Along these same lines, Plaintiffs argue that dental students will, on account of the FDA's failure to properly regulate amalgam, face unavoidable exposure to mercury. The theory of injury is that because the FDA concluded that amalgam is safe for human use, the American Dental Association has set dental-school accreditation requirements that require all dental students to be trained in the installation and removal of amalgam fillings. See Kennedy Aff., ¶

30. Given these requirements, IAOMT believes its dental-student members will face an increased risk of harm via exposure to airborne mercury. See id.; Opp. at 25.

As with its dentists, however, IAOMT identifies not a single member student who will unavoidably face mercury exposure. This is enough to deny it standing. See W. Wood Preservers Inst. v. McHugh, 292 F.R.D. 145, 148 (D.D.C. 2013) (denying reconsideration of dismissal for lack of standing where plaintiff failed to "identify specific member firms to support associational standing" and citing cases); Health Research Grp. v. Kennedy, 82 F.R.D. 21, 27 (D.D.C. 1979) ("[U]nless an organization truly Represents an Injured party its position will not be meaningfully different from that of the environmental organization in Sierra Club v. Morton, [405 U.S. at 736], which sought standing as a 'representative of the public.'").

Plaintiffs try to paper over this defect by filing a contested sur-reply (and accompanying affidavits), which the Court will consider because it does not alter the outcome. In that sur-reply, IAOMT identifies the name of a single dental student, Scott Kim. See Sur-Reply (ECF No. 45) at 2; id. Exh. 18 (Affidavit of Jack C. Kall, IAOMT Chairman), ¶ 2. Kim, apparently, "is currently a dental student" and "would be susceptible to the risk of future personal injuries described in the Plaintiffs' opposition papers." Sur-Reply at 2. Beyond providing a name and this cursory sentence, however, Plaintiffs offer no more specificity. The Court does not know, for instance, whether he attends an ADA-accredited dental program or whether that program, as Kennedy claims is true of all ADA-accredited schools, requires Kim to install amalgam fillings. See Kennedy Aff., ¶ 30. Similarly, it may be that Kim has already finished his amalgam-installation-and-removal coursework, or that his dentistry program would willingly exempt him from certain requirements. Without such specificity, the Court cannot police the critical boundary of its own Article III powers, and it is thus unwilling to find standing on the basis of a

lonely name, unadorned by any factual allegations that might otherwise establish his standing to sue.

Even if IOAMT had resolved this defect, however, it faces a larger problem, which is that its risk-of-harm-from-physical-exposure-to-mercury claim is unsubstantiated and logically unsound. To support its asserted injury, IAOMT relies on the affidavit of "risk assessment specialist" Mark Richardson, who claims that the "plac[ing] and remov[ing of] mercury fillings" will "likely expose a dental student . . . to dangerous levels of mercury vapor and amalgam particulate." Richardson Aff., ¶¶ 1, 13. But Richardson offers neither support (based on personal knowledge or literature he has digested) nor explanation for this bald assertion. He does not claim to have any basis for estimating actual airborne-mercury levels in dental schools. He similarly does not purport to have any familiarity with the basics of dental schools' curricular requirements, such as a minimum number of successful amalgam-filling installations and removals, a minimum number of hours of practice, or the frequency with which students must perform these actions. See id., ¶ 13.

In fact, Richardson recognizes that certain levels of mercury exposure are acceptable. In particular, "[o]ccupational safety limits for mercury established by [the U.S. Occupational Safety and Health Administration]" for dentists provide "a maximum safe dose of 832 μgs/day" given certain assumptions like an 8-hour workday, a 40-hour workweek, and an estimated rate of inhalation. See Opp. at 24; Richardson Aff., ¶ 12; 29 C.F.R. § 1910.1000(a)(2) ("[E]xposure . . . shall not exceed the 8-hour Time Weighted Average given for that substance in any 8-hour work shift of a 40-hour work week."). He does not quibble with that limit, and he does not allege that students will exceed that limit during dental school (even if they are not "employees" and are therefore not the parties intended to be protected by OSHA rules). Rather, he stumbles

through a contorted regulatory analysis of the various toxicity limits set by OSHA, the Environmental Protection Agency, and the Agency for Toxic Substances and Disease Registry – none of which makes any sense and, more importantly, has no bearing on dental students' actual exposure to mercury. In short, Richardson's affidavit offers nothing from which the Court can conclude that a dental student would "face a 'certainly impending,' or even likely, risk of future physical injury from" airborne mercury. Coal. for Mercury-Free Drugs, 671 F.3d at 1280.

Finally, IAOMT once again fails to show how the FDA caused any such injury or explain how a favorable decision would plausibly allow its students to avoid existing curricular requirements. That failure also serves as an independent basis for denying standing here. See Defenders of Wildlife, 504 U.S. at 560-61.

b. IAOMT Dentists Facing Disciplinary Charges

Similar flaws underlie Plaintiffs' claim that IAOMT has standing on behalf of member dentists who have faced or will face disciplinary charges "as a direct result of the FDA's refusal to properly classify mercury fillings." Opp. at 28. Even assuming these injuries are traceable to the conduct challenged here, IAOMT cannot simply aver that some indistinguishable segment of its members might face just such a risk in the future. See Summers, 555 U.S. at 497; Chamber of Commerce, 642 F.3d at 199-200. Certainly, Plaintiffs try to get more specific by claiming awareness of at least eleven named members "who were charged" according to the pattern described in Section III.A.2.b, *supra*. See Opp. at 19; Kennedy Aff., ¶ 12. But with the exception of dentist Michael Taras, whose specific circumstances the Court will address below, Plaintiffs provide nothing more than the individuals' names. At the risk of beating the same drum, the Court once again reiterates that merely naming an individual member, without illustrating why such individual has "standing to present, in his or her own right, the claim (or

the type of claim) pleaded by the association," falls short of what is required for representational standing. See UFCW Local 751, 517 U.S. at 555.

c. Michael Taras

IAOMT makes one last-ditch argument for representational standing, pointing to one of its members, dentist Michael Taras, who is currently the subject of a formal disciplinary complaint by the Pennsylvania State Board of Dentistry. See Opp. at 19; id., Exh. 8 (Board Order to Show Cause). It believes that the FDA's failure to more strictly regulate dental amalgam in its 2009 Final Rule is at least a contributing factor in the charges brought against him.

A closer look at the State's five-count complaint, however, makes clear that the Board's conduct is not sufficiently traceable to the FDA's Final Rule. The document includes a rash of disquieting, Little Shop of Horrors-esque allegations – including his unnecessarily filling or repairing of 15 teeth on a single patient who had no documented or observable tooth decay, accusing one of his patient's mothers of child abuse, screaming obscenities at another child when she complained of pain, and physically assaulting another patient's mother. See Board Order to Show Cause, ¶¶ 15-17, 26-29, 42-53.

What interests Plaintiffs, however, is that count five "involve[s] factual allegations concerning Dr. Taras' publication of anti-mercury views on his website." Opp. at 28. That is indeed so. But Plaintiffs fail to mention that Taras's personal views on dental mercury play at best a marginal role in what is a much more serious count of alleged wrongdoing. See Board Order to Show Cause, ¶¶ 58-64. According to Count Five, Taras convinced one of his patients to let him remove her mercury fillings on the ground that such fillings were "dangerous" and "cause many life-threatening health issues." Id., ¶¶ 57-58. Taras then botched the procedure, causing his patient to experience emergency-level pain in her teeth and gums, which then

required immediate care by an endodontist (read: root canals). Id., ¶¶ 69-70. To make matters worse, even though the injury occurred in a late-in-the-day appointment, Taras refused to help her track down an endodontist, "telling the patient to make the appointment herself." Id., ¶¶ 70-71. Once she finally found one, Taras then refused to forward an x-ray he had made of her teeth "without an upfront payment of $50." Id., ¶¶ 72.

Taken together, the Board concluded that these actions violated Pennsylvania rules of dental practice "by departing from, or failing to conform to, standards of acceptable and prevailing dental practice with regard to treatment provided to patient C.E.G." Id., ¶ 73 (emphasis added) (citing 63 Pa. Stat. § 123.1(a)(8)). His liability, in other words, hinges not on the information he conveyed to his patient but rather the inadequate treatment he provided. In any event, nothing in the Board Order suggests that had the FDA only more strictly regulated dental amalgam, Taras would be off the hook.

2. *DAMS*

DAMS claims representational standing on behalf of only one of its members, Roger Waller. See Opp. at 30-32. Because the Court has already concluded that Waller lacks individual standing to bring a claim, DAMS *a fortiori* cannot satisfy the first Hunt factor – *i.e.*, that "at least one of [the organization's] members has standing to sue in her or his own right." Am. Library Ass'n, 401 F.3d at 492. DAMS thus lacks standing as well.

D. Environmental Standing: IAOMT

Switching gears, the Court now moves to Plaintiffs' sixth count – that the FDA violated the Administrative Procedure Act when it failed to complete an Environmental Impact Statement or Environmental Assessment before issuing its 2009 Final Rule, which they believe was required by the National Environmental Protection Act (NEPA). As they see it, "The amalgam

in wastewater from dental offices is the largest direct contributor of mercury to water in the United States," Supp. Compl., ¶ 56, and they thus assert that the FDA was wrong not to analyze the environmental impact of amalgam in promulgating its Final Rule. See id., ¶ 58. In for a penny, in for a pound, the government again rejoins that Plaintiffs lack standing to assert this claim, having failed to identify a cognizable injury in fact traceable to the FDA's decision not to prepare an EA or EIS.

Before delving into this issue, the Court notes that the only Plaintiff claiming standing for this environmental injury is IAOMT, which Plaintiffs assert may proceed in both an organizational and representational capacity. The Court will first provide a brief overview of NEPA and then assess whether standing exists here.

1. *Legal Framework*

"[NEPA] is our basic national charter for protection of the environment." 40 C.F.R. § 1500.1(a). Broadly applicable across all walks of the federal government, it requires agencies proposing "major Federal actions significantly affecting the quality of the human environment" to prepare "a detailed statement . . . on . . . (i) the environmental impact of the proposed action" – a document commonly known as an EIS. See 42 U.S.C. § 4332(C); 40 C.F.R. § 1502.3; Wyoming Outdoor Council v. U.S. Forest Serv., 165 F.3d 43, 49 (D.C. Cir. 1999) (EIS must "describe[e] the reasonably foreseeable environmental impact both of the proposed federal action and of any feasible alternative(s) to the proposed federal action, including nonaction.") (citation and quotation marks omitted). An EIS is not always necessary, however. An agency may also conduct a preliminary inquiry to decide whether the "major Federal action" at issue would, in fact, "significantly affect[]" the environment; where it answers that question in the negative, an Environmental Assessment, which is less detailed than an EIS, may suffice. See 40 C.F.R. §§

1501.3(b), 1501.4, 1508.9; see also Theodore Roosevelt Conservation P'ship v. Salazar, 616 F.3d 497, 503 (D.C. Cir. 2010) (describing difference between EIS and EA).

In addition, agencies may, under regulations promulgated by the Council on Environmental Quality, categorically exclude certain types of agency actions from the requirement of preparing an EIS or an EA, so long as such actions do not "have a significant effect on the human environment." 40 C.F.R. § 1508.4. Relevant here, the FDA and CEQ have determined that the "[c]lassification or reclassification of a device" is just such a categorically excluded action, provided that such action "will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes." 21 C.F.R. § 25.34.

In promulgating the 2009 Final Rule, the FDA concluded that "its action to classify dental amalgam . . . [falls] within the scope of the categorical exclusion in 21 CFR [§] 25.34(b)" because the "change in classification alone does not result in the introduction of any substance into the environment, does not increase the existing levels of use, and does not change the intended use of these devices or their substitutes." 74 Fed. Reg. at 38705. For this reason, the FDA elected not to prepare an EIS or an EA, which it concluded was not required by NEPA. See id. at 38706.

It is this conclusion that Plaintiffs challenge. They somehow maintain that "dental mercury fillings are not subject to this categorical exclusion" and, stranger still, that "even if the exclusion applies, the FDA is still required to produce an EIS or EA." Supp. Compl., ¶ 61. Fortunately for the Court, it need not spend time debunking these faulty assertions because it is clear from the pleadings that IAOMT lacks standing to sue.

2. *Standing Analysis*

NEPA's "mandate to [federal] agencies is essentially procedural," Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519, 558 (1978), meaning that the statute "itself does not mandate particular results," but rather "imposes only procedural requirements on federal agencies with a particular focus on requiring agencies to undertake analyses of the environmental impact of their proposals and actions." Dep't of Transp. v. Pub. Citizen, 541 U.S. 752, 756-57 (2004).

A procedural-rights plaintiff like IAOMT must "demonstrate[] all of the traditional components of standing" – namely, injury in fact, causation, and redressability. Florida Audubon Soc. v. Bentsen, 94 F.3d 658, 665 (D.C. Cir. 1996) (*en banc*). The dispute here centers on only the first of those requirements – injury in fact.

To that end, the D.C. Circuit has explained that plaintiffs challenging an agency's allegedly wrongful decision not to prepare an EIS or an EA must show "a particularized environmental interest of theirs that will suffer demonstrably increased risk," which must be "fairly traceable to the agency act allegedly implicating the EIS." Florida Audubon, 94 F.3d at 665-66 (emphasis added); accord Florida Audubon, 94 F.3d at 674 (Rogers, J., dissenting) ("[T]he plaintiff in a NEPA case must . . . establish that her injury is fairly traceable to the underlying governmental action for which an EIS was not prepared."). That is, the injury must derive from the ultimate action requiring the EIS and not from the failure to prepare that document itself. Here, of course, that means IAOMT must allege an environmental interest that will be placed at risk by the FDA's failure to ban or more strictly regulate dental amalgam.

This proves quite challenging, as IAOMT claims the harm that it and its members suffer is exclusively an "informational injury" arising from the failure to prepare an EA or EIS. See

Opp. at 38. It believes that were the FDA to prepare such documents, IAOMT would then have access to information concerning the environmental effects of widespread use of dental amalgam. Or, as Plaintiffs explain it, "[T]he FDA's impermissible failure to conduct a required EIS or EA has crippled the IAOMT's ability to disseminate information about dental amalgams' detrimental impact on the environment." Opp. at 34; see id. at 37 ("IAOMT has been deprived of the information necessary to achieve its organizational mission."); id. at 38 ("IAOMT dentists . . . need information about the environmental impacts that are associated with the discharge of dental mercury . . . ."); Sur-Reply at 10 (IAOMT "has been adversely affected by the FDA's failure to comply with the provisions of NEPA in providing an honest assessment of mercury fillings' impact on the environment").

While IAOMT has also made passing reference to a few other environmental concerns, see Kennedy Aff., ¶ 28 (indicating that disposing of mercury "raise[s] significant concerns regarding the environmental impact associated therewith"), it has eschewed reliance on those "concerns" in favor of a narrow, laser-like focus on the "informational injury" that it believes "w[ould] be redressed if the FDA [were] required to comply with NEPA and produce an EIS or EA." Opp. at 38. But this informational injury – whether suffered by IAOMT or its members – is not traceable to the "agency act" that "implicate[s] the EIS," but rather the alleged procedural failing itself. Florida Audubon, 94 F.3d at 666. As pleaded, IAOMT lacks standing on its own behalf and on behalf of its members, all of whom apparently seek only "information about the environmental impacts that are associated with the discharge of dental mercury." Opp. at 38.

IAOMT leans heavily on Competitive Enterprise Institute v. National Highway Traffic Safety Administration, 901 F.2d 107 (D.C. Cir. 1990), which stated in *dicta* that "a right to specific information under NEPA has so far been recognized for standing purposes only when

the information sought relates to environmental interests that NEPA was intended to protect." Id. at 123. But the D.C. Circuit swiftly cabined that language a year later in Foundation on Economic Trends v. Lyng, 943 F.2d 79 (D.C. Cir. 1991), clarifying:

> Despite the general statements in our decisions, particularly National Wildlife Federation v. Hodel[, 839 F.2d 694, 712 (D.C. Cir. 1988)], and Competitive Enterprise [Institute], we have never sustained an organization's standing in a NEPA case solely on the basis of "informational injury," that is, damage to the organization's interest in disseminating the environmental data an impact statement could be expected to contain.

Id. at 84. In any event, the *en banc* court in Florida Audubon subsequently set forth a baseline requirement for traceability in NEPA standing that IAOMT fails to meet. For this reason, the Court will not address the government's argument in the alternative that Plaintiffs fail to state a claim under Federal Rule of Civil Procedure 12(b)(6).

IV. Conclusion

For these reasons, the Court will grant Defendants' Motion to Dismiss. A separate Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: July 1, 2016