[ORAL ARGUMENT SCHEDULED FOR MARCH 27, 2007]

No. 06-1147

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

MOMS AGAINST MERCURY; CONNECTICUT COALITION FOR ENVIRONMENTAL JUSTICE; OREGONIANS FOR LIFE; CALIFORNIA CITIZENS FOR HEALTH FREEDOM; KEVIN J. BIGGERS; KAREN JOHNSON, Arizona State Senator; LINDA BROCATO; R. ANDREW LANDERMAN, D.D.S.; ANITA VAZQUEZ TIBAU;

Petitioners,

v.

FOOD & DRUG ADMINISTRATION,

Respondent.

ON PETITION FOR REVIEW OF AGENCY ACTION OF THE
FOOD & DRUG ADMINISTRATION

BRIEF FOR RESPONDENT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Cir. Rule 28(a)(1), respondent submits the following certifications:

A. Parties and Amici.

Petitioners in this Court are four nonprofit corporations: Moms Against Mercury, Connecticut Coalition for Environmental Justice, Oregonians for Life, and California Citizens for Health Freedom; and five individuals: Kevin J. Biggers, Karen Johnson, R. Andrew Landerman, Linda Brocato, and Anita Vazquez Tibau.

Respondent in this Court is the Food & Drug Administration.

There are no amici before this Court.

B. Ruling Under Review.

This case is a petition for review brought directly in this Court to challenge the Food & Drug Administration's delay in classifying a type of medical device: encapsulated amalgam alloy and dental mercury. There is no district court ruling under review.

C. Related Cases.

This case was not previously before this Court or any other court, and counsel is not aware of any other related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

Catherine Y. Hancock
Counsel for Respondent

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GLOSSARY

EAADM . . . . . Encapsulated Amalgam Alloy and Dental Mercury

FDA . . . . . Food & Drug Administration

FDCA . . . . . Federal Food, Drug, and Cosmetic Act

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BRIEF FOR RESPONDENT

STATEMENT OF JURISDICTION

Petitioners invoke the jurisdiction of this Court pursuant to 21 U.S.C. § 360g and 5 U.S.C. § 703. See Br. at 1. As explained below, see infra pp. 31-38, neither of those provisions confer jurisdiction on this Court to review the agency action at issue. In its order of November 1, 2006, this Court directed petitioners to include a "'concise recitation of the basis upon which it claims standing.'" See Order of 11/1/2006 (quoting Sierra Club v. EPA, 292 F.3d 895, 900-01 (D.C. Cir. 2002)). Petitioners declined to do so, alleging that "their standing is self-evident," based on

affidavits "from eight of the nine Petitioners establishing the parties' injuries." Br. at 2. As discussed below, see infra pp. 20-31, those affidavits fail to provide any facts that establish concrete, personalized injuries that are traceable to the agency's action (or inaction) and redressable by petitioners' requested relief.

STATEMENT OF THE ISSUES

This case arises out of a petition for review, alleging that the Food & Drug Administration ("FDA") has failed to comply with its statutory obligation under the Federal Food, Drug, and Cosmetic Act to classify a type of medical device: encapsulated amalgam alloy and dental mercury. Petitioners seek an order compelling the agency to classify the device and to withdraw it from commerce until it is classified. The issues presented are as follows:

1. Whether petitioners lack constitutional standing to challenge the FDA's delay in classifying encapsulated amalgam alloy and dental mercury.

2. Whether this Court has subject matter jurisdiction over the petition for review.

STATUTES

The relevant statutes are contained in petitioners' statutory addendum.

STATEMENT OF THE CASE

On April 27, 2006, petitioners filed in this Court a "Petition (21 USC § 360g) To Order Mercury Amalgam Withdrawn from Interstate

Commerce." On June 1, 2006, petitioners filed a motion for emergency or interim relief.

Respondent, the FDA, moved to dismiss the petition for lack of subject matter jurisdiction on June 28, 2006. The FDA also opposed petitioners' motion for emergency relief.

On October 17, 2006, this Court denied petitioners' motion for emergency relief. See Order 10/17/06. The Court deferred action on the agency's motion to dismiss, ordering the case to be set for briefing and directing the parties to address the jurisdictional issues in their briefs. See id. In its briefing order, the Court "remind[ed]" petitioners to include arguments and evidence necessary to support their claim for standing in their opening brief. See Order 11/1/06.

STATEMENT OF THE FACTS

A. Classification of Medical Devices Under the Federal Food, Drug, and Cosmetic Act

In 1976, Congress amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399, extending the regulatory authority of the FDA to include premarket regulation of medical devices, thereby enabling the agency to "provide for the safety and effectiveness of medical device[s] intended for human use." See Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. §§ 360c-360k); see also Medtronic, Inc. v. Lohr, 518 U.S. 470, 475-76 (1996); Contact Lens Mfrs. Ass'n

v. FDA, 766 F.2d 592, 593 (D.C. Cir. 1985); 21 U.S.C. § 371(a) (granting FDA authority to issue regulations to implement the Act).

Under the FDCA, as amended, all medical devices are categorized in three classes, based upon the degree of regulation that the agency determines is necessary to reasonably assure their safety and effectiveness. See 21 U.S.C. § 360c(a). In making that determination, the agency, inter alia, must consider "the conditions of use prescribed, recommended, or suggested in the labeling of the device," and "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2).

Class I devices are subject to the least amount of regulation and are defined as those devices for which the "general controls" provided by the FDCA are sufficient to provide a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(A). The "general controls" include, inter alia, prohibitions on adulteration (21 U.S.C. § 351) and misbranding (which includes false or misleading labeling) (21 U.S.C. § 352), and requirements that manufacturers of devices register with the FDA (21 U.S.C. § 360) and maintain such records as the agency may require to assure a device's safety and effectiveness (21 U.S.C. § 360i).[1]

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[1] The general controls of the FDCA apply to all devices, regardless of the class in which they are placed. Moreover, the general controls apply to all devices whether or not they have already been classified. See H.R. Rep. No. 94-853, at 17 (1976) (noting that the "general controls" include the pre-existing

(continued...)

Class II covers those devices for which the general controls alone would be insufficient to reasonably assure the device's safety and effectiveness, but which may be marketed if "special controls," in addition to the general controls, would provide adequate assurance of the device's safety and effectiveness. See 21 U.S.C. § 360c(a)(1)(B). Special controls include performance standards, postmarket surveillance, patient registries, guidelines, or other actions the agency determines are necessary to reasonably assure a device's safety and effectiveness. Id.

Class III encompasses those devices that potentially pose the greatest risk. A device is placed in class III if the general controls alone, or general controls along with special controls, are insufficient to provide reasonable assurance of the device's safety and effectiveness. See 21 U.S.C. § 360c(a)(1)(C).

The FDA is required to classify all medical devices that were already in interstate commerce prior to the 1976 amendments (i.e., "pre-amendment devices"). See 21 U.S.C. § 360c(a), (b)(1). Post-amendment devices (i.e., those that entered commerce only after the 1976 amendments) are automatically classified by statute in class III, without any rulemaking, unless and until the FDA issues an order finding that the device is "substantially equivalent" to a

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(...continued)
adulteration and misbranding provisions of the FDCA and that "certain of the general controls," such as registration of device manufacturers, became applicable to all devices "immediately upon enactment of the . . . [Medical Device Amendments of 1976]").

device previously classified in class I or II, the agency reclassifies the device into class I or II, or the agency classifies the device into class I or II under the de novo classification provisions. See 21 U.S.C. § 360c(f)(1)-(3); see also H.R. Conf. Rep. No. 94-1090 at 56 (1976), as reprinted in 1976 U.S.C.C.A.N. 1103, 1108-09.

Because of the degree of risk to safety, class III devices, unlike class I and II devices, generally must be approved by the FDA before they are permitted to enter interstate commerce. See 21 U.S.C. §§ 360c(a)(1)(C), 360e; see also Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy, 67 Fed. Reg. 7,620, 7,621 (Feb. 20, 2002) (proposed rule). The notable exception to this general rule requiring premarket approval for class III devices is for pre-amendment devices. Pre-amendment devices that have been classified in class III are permitted to remain on the market at least until the FDA issues a final regulation requiring premarket approval. See 21 U.S.C. § 360e(b)(1)(A); see also Medtronic, Inc., 518 U.S. at 477-78; 67 Fed. Reg. at 7,621.

The FDA initiates the classification process for a pre-amendment device by referring the device to an expert panel, which evaluates the safety and effectiveness of the device and makes a recommendation to the FDA regarding the appropriate classification. See 21 U.S.C. § 360c(b), (c). The FDA then publishes in the

Federal Register the panel's recommendation and a proposed classification regulation for the device, and provides opportunity for public comment. See 21 U.S.C. § 360c(d)(1). After reviewing any comments regarding the proposed classification, FDA issues a final regulation classifying the device. See id.

B. FDA's Regulation of Encapsulated Amalgam Alloy and Dental Mercury

Encapsulated amalgam alloy and dental mercury ("EAADM") is a pre-amendment device that is used to create a filling material for dental cavities. See generally 67 Fed. Reg. 7,620 (2002) (proposed rule). The device is a "single-use capsule" that contains separately sealed portions of elemental mercury and amalgam alloy, which is composed of other metals such as silver, tin, copper, zinc, palladium, and/or indium. Id. at 7,621. The dental mercury and amalgam alloy in the capsule are mixed in a dentist's office to form "dental amalgam," which is used to fill cavities.[2] Id. at 7,621. EAADM is a prescription device, so its sale and use is limited to practitioners. See 21 C.F.R. § 801.109.

Although the FDA has not yet issued a regulation classifying EAADM pursuant to 21 U.S.C. § 360c, EAADM is effectively classified as a class II device, according to the most restrictive classification of its components, dental mercury and amalgam alloy,

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[2] As an alternative to using EAADM, a dentist may also prepare amalgam by separately measuring and combining the appropriate amounts of dental mercury and amalgam alloy. See 21 C.F.R. § 872.3050.

which have been classified in classes I and II, respectively.[3] See Dental Devices; General Provisions and Classifications of 110 Devices, 52 Fed. Reg. 30,082, 30,099, 30,102 (Aug. 12, 1987); 67 Fed. Reg. at 7,621; 21 C.F.R. § 872.3700 (dental mercury); 21 C.F.R. § 872.3050 (amalgam alloy). In addition, even though EAADM has not been formally classified, it is nevertheless subject to the general controls of the FDCA.

The FDA has also classified a number of individual, post-amendment dental amalgam devices in class II, pursuant to its authority to issue substantial equivalence orders for post-amendment devices (21 U.S.C. § 360c(f)(1)). See, e.g., App. 141-44. Those classifications are based on the FDA's determination that those post-amendment devices are "substantially equivalent" to the combination of amalgam alloy (class II) and dental mercury (class I). Therefore, those dental amalgam devices have been

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[3] The expert panel had recommended, and FDA had proposed, to place dental mercury in class II. But, in response to comments on the proposed rule, the FDA placed dental mercury in class I because it concluded that there was "no valid scientific evidence of systemic poisoning to patients exposed to amalgam containing mercury." 52 Fed. Reg. at 30,089. The FDA agreed that there was a risk to the few patients who are allergic to mercury, but determined that the labeling requirements under the general controls (21 U.S.C. § 352) would adequately ensure the safety of those patients. Id. Neither the petitioners nor any other party timely petitioned for judicial review, pursuant to 21 U.S.C. § 360g(a)(1), of the regulation classifying dental mercury in class I. Because a regulation classifying a device in class I is the only type of initial classification regulation subject to direct review in the courts of appeals, see 21 U.S.C. § 360g(a), petitioners could not have petitioned for review of the FDA's decision to classify amalgam alloy in class II.

classified in class II, according to the more restrictive classification of their components.[4]

In 1993, several citizen petitions were filed by individuals requesting that the FDA take certain actions with respect to dental amalgam and dental mercury, including banning dental mercury, reclassifying dental mercury in class III, and conducting environmental assessments on the effects of dental mercury. See 67 Fed. Reg. at 7,622. In response, the FDA convened a panel of experts to consider the petitions and the scientific studies submitted by petitioners. Id. The panel concluded that none of the studies supported claims that dental amalgam containing mercury is harmful. Id. Accordingly, the FDA declined to ban the use of dental mercury or reclassify it. Id. at 7,622-23.

At meetings in 1993 and 1994, the FDA asked the Dental Products Panel of the Medical Devices Advisory Committee to recommend a classification for EAADM. See 67 Fed. Reg. at 7,624. After considering expert testimony and reviewing published studies and a wide range of other literature, the panel concluded that there were "no major risks associated with encapsulated amalgam

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[4] Contrary to petitioners' suggestion (Br. at 25-26), the FDA has not determined that post-amendment dental amalgam devices are substantially equivalent to amalgam alloy. Rather, the FDA has determined that those devices are substantially equivalent to the combination of amalgam alloy and dental mercury. But because those two components have different classifications, the substantial equivalence orders must classify the device according to the more restrictive classification, in order to ensure that the device is appropriately regulated for safety and effectiveness.

alloy/mercury [EAADM] when used as directed," and unanimously recommended a class II classification. See id. at 7,625. The panel, however, recognized "that continued research in the area is prudent." Id. at 7,624.

Agreeing with the panel's recommendation, the FDA published a proposed rule to formally classify EAADM in class II. See 67 Fed. Reg. 7,620, 7,625 (Feb. 20, 2002). The rule also proposed to reclassify dental mercury from class I to class II, and to amend the classification of amalgam alloy to require certain special controls, such as labeling guidance. Id. The proposed rule describes the information regarding safety and effectiveness that the FDA reviewed, including a comprehensive risk assessment of dental amalgam issued in 1993 by the Public Health Service and reaffirmed in 1995; an updated literature review; the Dental Products Panel of the Medical Devices Advisory Committee's recommendation; reports by foreign governments and international health organizations; and numerous studies submitted to the FDA by citizen petitioners. Id. at 7,625-26. In weighing the benefits versus the risks of dental amalgam pursuant to 21 U.S.C. § 360c(a)(2)(C), the FDA concluded that:

> Given the known risks of untreated caries, the longstanding history of successful use of dental amalgam restorations, the benefits of products used in amalgam fillings over other alternative materials, and the overall lack of valid scientific evidence that persons whose carious teeth are treated with dental amalgam experience any adverse health effects, other than a very small number of people who are hypersensitive to mercury, FDA believes that the probable benefits of restorative

> dental products containing mercury outweigh the probable risks of using these products.

Id. at 7,627. Pursuant to 21 C.F.R. § 25.34(b) (exempting classification of devices from environmental assessments or impact statements), the FDA did not conduct an environmental assessment or issue an environmental impact statement in conjunction with its proposed rule. Id. at 7,628.

Since the issuance of its proposed rule to classify EAADM, the FDA has continued to monitor emerging scientific studies on dental amalgam. See Dental Amalgam; Request for Information, 68 Fed. Reg. 25,048 (May 9, 2003) (sponsoring review of scientific literature about the health effects of dental amalgam and offering the public an opportunity to participate); Life Sciences Research Office, Press Release, at http://www.lsro.org/amalgam/frames_amalgam_home.html (Dec. 9, 2004) (review concluded that there was "little evidence to link mercury fillings to human health problems"). The FDA has also received requests for further consideration of the potential risks of mercury in dental amalgam and for reconsideration of its 2002 proposed rule. For example, in November 2005, the FDA received citizen petitions from Consumers for Dental Choice, Inc., filed by the same counsel who represents petitioners in this case, requesting that the FDA set aside its proposed rule and "start over" the classification process, to include an independent study and consultation with experts outside of the field of dentistry. See Citizen Petitions, Docket Nos.

2005P-0462, 2005P-0465, available at http://www.fda.gov/ohrms/dockets/dockets/dockets2005.htm.

In response to those petitions and other comments to the proposed rule, the FDA announced on April 3, 2006, that two advisory committees would meet to discuss and review scientific literature on dental amalgam and its potential mercury toxicity. The FDA stated that the meeting would be open to the public and that "interested persons may present data, information, or views, orally or in writing." See Joint Meeting of the Dental Products Panel of the Medical Devices Advisory Committee of the Center for Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research; Notice of Meeting, 71 Fed. Reg. 16,582 (Apr. 3, 2006).

At that meeting, held on September 6 and 7, 2006, the panel generally agreed that there is no scientific evidence from which to conclude that dental amalgam creates a probable health risk to the general population. See Summary Minutes for Sept. 7 Meeting, at 21, 25, available at http://www.fda.gov/ohrms/dockets/ac/cdrh06.html#dental productspanel. The panel acknowledged concerns that mercury in dental amalgam may have adverse side effects on certain subsets of individuals, such as pregnant women or those with hypersensitivity to mercury, but concluded that, at this time, there is not sufficient scientific evidence to support a finding that the potential risks of dental amalgam outweigh the potential

benefits, even for those subgroups. Id. at 21, 24; see also 21 U.S.C. § 360c(a)(2)(C). In light of those concerns, however, the panel concluded that the FDA should continue to consider the safety of dental amalgam. See Summary Minutes for Sept. 7 Meeting, at 26.

To that effect, the FDA opened a public docket (2006N-0352) to accept additional comments about dental amalgam. See App. 152. That docket closed on November 9, 2006, and the FDA is currently reviewing the comments received, as well as studying the peer-reviewed literature and the findings and recommendations from the panel meeting. Id. Once the FDA completes this extensive review, the agency will take the appropriate next steps to classify EAADM. Id.

C. The Petition For Review

On April 27, 2006, petitioners, a group of four organizations and five individuals, filed a petition for review in this Court challenging the agency's delay in classifying EAADM. They generally allege that the mercury contained in dental amalgam poses a health risk, which, in their view, the FDA has effectively concealed by failing to classify EAADM, thereby endangering the public's health. Petitioners seek an order requiring the FDA to classify EAADM, as well as an order removing EAADM from commerce until the FDA completes the necessary steps to classify it and performs any necessary premarket approvals.[5]

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[5] Petitioners contend (Br. at 22-25) that these necessary (continued...)

The FDA moved to dismiss for lack of jurisdiction. This Court referred the motion to the merits panel. See Order 10/17/2006 ("The parties are directed to address in their briefs the issues presented in the motion to dismiss rather than incorporate those arguments by reference.").[6]

STANDARD OF REVIEW

Petitioners bear the burden of establishing standing as a prerequisite for the Court's exercise of jurisdiction. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 104 (1998); American Chemistry Council v. Department of Transp., 468 F.3d 810, 814 (D.C. Cir. 2006). Petitioners' burden of production in a petition for review is the same as in a motion for summary judgment, which requires petitioners to support each element of their claim to standing with specific facts set forth by affidavit

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(...continued)
steps of classification include, inter alia, an environmental assessment and a new panel recommendation. Those issues, however, are not yet ripe for this Court's review, since the FDA has not yet completed the classification process culminating in a final regulation.

[6] Petitioners incorrectly assert (Br. at 4) that the Court rejected the grounds for dismissal presented in the motion. In any event, a merits panel is free to reexamine denial of a motion based on lack of jurisdiction. See Hayes v. Government Printing Office, 684 F.2d 137, 138 n.1 (D.C. Cir. 1982) ("[I]n this court a merits panel is not bound by a motions panel's denial of a preliminary motion to dismiss for lack of jurisdiction."); Association of Inv. Brokers v. SEC, 676 F.2d 857, 863 (D.C. Cir. 1982) ("[W]e state, with the approval of the full court, that a motions panel order simply denying a motion to dismiss without saying more is without prejudice to reexamination upon full briefing and argument of the case.").

or other evidence. See International Bhd. of Teamsters v. Transportation Sec. Admin., 429 F.3d 1130, 1134 (D.C. Cir. 2005). Petitioners may not rely on mere allegations to establish standing. Sierra Club v. EPA, 292 F.3d 895, 898 (D.C. Cir. 2002).

Petitioners also bear the burden of establishing that a statute, upon which jurisdiction is invoked, confers the Court with subject matter jurisdiction to review petitioners' claim. See Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994); Commodity Futures Trading Comm'n v. Nahas, 738 F.2d 487, 492 & n.9 (D.C. Cir. 1984) ("A federal court presumptively lacks jurisdiction in a proceeding until a party demonstrates that jurisdiction exists. A party must therefore affirmatively allege in his pleadings the facts showing the existence of jurisdiction, and the court must scrupulously observe the precise jurisdictional limits prescribed by Congress."). If the Court determines that the FDCA confers jurisdiction to review the agency's delay in classification, then the Court's review is pursuant to the standards set forth in chapter 7 of the Administrative Procedure Act, 5 U.S.C. §§ 701-706. See 21 U.S.C. § 360g(c).

SUMMARY OF ARGUMENT

I. Petitioners fail to establish constitutional standing to challenge the FDA's delay in classifying a medical device under the Federal Food, Drug, and Cosmetic Act. Despite this Court's order and its rules requiring petitioners to provide argument and facts in their opening brief to support their claim to standing,

petitioners failed to do so. On that ground alone, dismissal of their petition is appropriate.

In any event, however, petitioners' claim to standing relies entirely on eight affidavits (filed on behalf of nine petitioners), which do not contain allegations, much less facts, sufficient to establish standing to bring their petition for review. Petitioners generally contend that encapsulated amalgam alloy and dental mercury ("EAADM") - a device used to make fillings for dental cavities - poses potential health risks due to its mercury content, and that the FDA's delay in classifying EAADM effectively concealed this health risk, resulting in adverse health effects for some individuals who received fillings made from EAADM. But only two of the five individual petitioners are even able to allege a personalized injury, as opposed to a general grievance. And those alleged injuries - past health problems caused by mercury fillings prior to removal of those fillings - are not cognizable for standing purposes because they are discrete, past injuries that are unlikely to recur and would not be remedied by the requested relief. Similarly, none of the organizational petitioners allege any injuries to themselves or to specific members.

Petitioners likewise fail to establish causation and redressability. Petitioners simply speculate that if the FDA had promptly classified EAADM, no adverse health effects would have resulted from the use of mercury fillings. But petitioners are unable to demonstrate that if FDA had classified EAADM, that would

have affected both the independent actions of dentists, as to whether to inform patients about the mercury content of fillings, and of patients, as to whether to refuse fillings that contain mercury. Moreover, petitioners fail to explain how their requested prospective relief - classification and a temporary ban on EAADM until it is classified - will redress any past, adverse health effects caused by mercury fillings. Accordingly, the petition for review should be dismissed.

II. Even if petitioners could establish standing, this Court lacks subject matter jurisdiction over the petition for review. Although this Court may hear a claim of unreasonable delay or agency inaction where necessary to protect its prospective jurisdiction under a governing statute to review the final agency action that is claimed to be withheld or delayed, petitioners have failed to identify a provision that confers jurisdiction on this Court to review directly a final regulation classifying EAADM. The Federal Food, Drug, and Cosmetic Act provides this Court with jurisdiction to review only certain, specified agency orders or regulations. The only initial classification regulation that is subject to direct review in this Court under that Act is a regulation classifying a device in class I. But the FDA has neither proposed, nor do petitioners seek, to classify EAADM in class I. Thus, if the FDA were to issue a final regulation classifying EAADM, petitioners could seek review of that regulation only in the district court, pursuant to the Administrative

Procedure Act. Accordingly, this Court lacks jurisdiction to review petitioners' claim that the FDA unreasonably delayed in classifying EAADM.

In any event, any delay in classifying EAADM has not been so egregious as to warrant the extraordinary relief that petitioners seek. Although the FDA has not issued a final regulation classifying EAADM, EAADM is already effectively regulated as a class II device, pursuant to the classification of its component parts. Thus, the delay in classification has had no practical consequences. In addition, the FDA is actively working towards classifying EAADM, including holding an advisory panel meeting in September 2006 to review the FDA's research, hear public comments, and discuss current scientific evidence. Moreover, because the FDA's classification determination depends, in part, upon current, available scientific knowledge, in which there is a lack of conclusive evidence regarding the health effects of mercury fillings, any delay in issuing a final rule should not be considered unreasonable.

ARGUMENT

I. PETITIONERS FAIL TO ESTABLISH STANDING TO CHALLENGE THE AGENCY'S DELAY IN CLASSIFYING ENCAPSULATED AMALGAM ALLOY AND DENTAL MERCURY.

Before the Court may exercise jurisdiction, it must assure itself that petitioners have established Article III standing. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992); Florida Audubon Soc'y v. Bentsen, 94 F.3d 658, 661 (D.C. Cir. 1996) (en

banc). To establish standing, petitioners must demonstrate at the outset of their case, through affidavits or other evidence, "a 'substantial probability' that [they] have been injured, that the defendant caused [their] injury, and that the court could redress that injury." Sierra Club v. EPA, 292 F.3d 895, 899 (D.C. Cir. 2002); accord International Bhd. of Teamsters v. Transportation Sec. Admin., 429 F.3d 1130, 1134 (D.C. Cir. 2005). In the context of a petition for review, mere allegations are insufficient to support standing. Sierra Club, 292 F.3d at 901.

Petitioners have failed to provide any argument in their opening brief to demonstrate that they have standing to challenge the FDA's delay in classifying EAADM. That failure is particularly anomalous in light of this Court's order specifically reminding petitioners of their obligation to address standing. See Order 11/1/06; see also D.C. Cir. R. 28(a)(7) (requiring petitioners to include a section on standing in their opening brief); D.C. Cir. R. 38 (Court may dismiss for failure to prosecute); International Bhd. of Teamsters, 429 F.3d at 1134 (noting that, in the future, failure to comply with Rule 28's requirement to address standing in opening brief may result in dismissal pursuant to Rule 38); see also Sierra Club, 292 F.3d at 900-01 (cautioning petitioners that standing must be argued in opening brief, and absent good cause, no other opportunity will be provided). Indeed, as the Court has explained, when a petitioner fails to address standing in its opening brief, because "some of the relevant facts are known only to the

petitioner," "the respondent is therefore left to flail at the unknown in an attempt to prove the negative." Sierra Club, 292 F.3d at 901.

Petitioners' deliberate failure to comply with fundamental requirements of this Court's rules and their decision to ignore this Court's prior order make it appropriate that this Court dismiss their petition on that basis alone.

In any event, had they chosen to address the issue of their standing, petitioners would have had nothing to say. Their claim to standing rests entirely on eight affidavits (see App. 155-62) submitted with their brief. See Br. at 1 (declining to address standing in their brief because petitioners believe that it is "self-evident"). Those affidavits are plainly deficient and fail to satisfy petitioners' burden as to each element of standing.

A. Individual Petitioners

Three of the five individual petitioners fail to even allege any personal, cognizable injury that, if supported by evidence, would support standing to bring their petition. See Lujan, 504 U.S. at 560-61 & n.1 (standing requires "concrete and particularized" injury that "affect[s] the plaintiff in a personal and individual way"); see also Sierra Club, 292 F.3d at 898 (petitioners must present specific facts and cannot rely on mere allegations).

Petitioner Kevin J. Biggers seeks review of the agency's delay in classifying EAADM in his official capacity as a member of the

Dental Board of California, a state agency which licenses and regulates dental practitioners. See App. 158. Petitioner Biggers states that because state law "mandates disclosure to each patient of the risks of mercury fillings," FDA's failure to classify "make[s] compliance with law unduly burdensome." Id. But such a conclusory allegation of a general burden does not constitute a particularized injury sufficient for standing. See Alaska Legislative Council v. Babbitt, 181 F.3d 1333, 1337-38 (D.C. Cir. 1999) (rejecting state legislators' standing to challenge a federal statute based on claim that statute generally interfered with their legislative duties to regulate the same subject matter). Petitioner Biggers does not explain how that alleged burden would affect or injure his individual efforts to regulate dental practitioners. Biggers' affidavit, in fact, undermines any conclusion that he is impaired by the FDA's delay. His affidavit suggests that because state law imposes an obligation on dentists to disclose the risks of mercury fillings to patients, dentists, not legislators, would bear any alleged extra burden of complying with state law. See App. 158.

Similarly, petitioner Karen Johnson, a state senator from Arizona and chair of the state senate's Children and Families Committee, also joins the petition in her official capacity, alleging that the FDA's failure to classify "puts [her] under substantial impairment to carry out [her] responsibilities" to regulate the dental profession and "to protect children and

families from dangerous toxins." App. 159. Such general allegations of injury, however, which would inhere to all the state senators, or, at a minimum, to all the members of the Children and Families Committee, fail to establish an individualized injury to petitioner, as is required for standing. See Alaska Legislative Council, 181 F.3d at 1337-38 (rejecting state senators' standing to challenge federal conservation statute based on theory that statute interfered with their general duty to legislate on state wildlife matters).

Petitioner R. Andrew Landerman, D.D.S., is a practicing dentist. App. 161. He states that he does not use mercury fillings, but contends that "many dentists" who do, fail to convey the risks of mercury fillings to their patients. He states that he "hoped that FDA would intervene, at the least with strong warnings, but better with a ban on mercury in dentistry," because the FDA's failure to do so "harms the people and the environment of my county, my state, and my nation". App. 161. Petitioner's affidavit is fatally insufficient, however, in that he does not even allege an injury to himself (or to his patients). See Warth v. Seldin, 422 U.S. 490, 499 (1975) ("A federal court's jurisdiction therefore can be invoked only when the plaintiff himself has suffered 'some threatened or actual injury resulting from the putatively illegal action' . . . . [and not] when the asserted harm is a 'generalized grievance' shared in substantially equal measure by all or a large class of citizens[.]") (footnotes

and citations omitted). Nor has he explained how "he personally would benefit in a tangible way from the court's intervention" compelling the FDA to classify EAADM. Warth, 422 U.S. at 508.

The two remaining individual petitioners, Linda Brocato and Anita Vazquez Tibau, are the only petitioners who even allege an individualized injury. Petitioners Brocato and Tibau, both advocates for the abolishment of mercury fillings, state that they received dental fillings containing mercury, which caused personal injury. See App. 160 (statement of petitioner Brocato) (alleging neurological damage); App. 162 (statement of petitioner Tibau) (alleging "substantial and life-threatening symptoms of asthma"). They both aver that at the time they received their fillings, they were unaware that the fillings contained mercury. App. 160, 162. Petitioners contend that if FDA "had done its job," they would have known of the potential health risk caused by mercury fillings, and "would have demanded alternative materials." App. 162.

Although these allegations may establish individualized injuries to petitioners Brocato and Tibau, those injuries are not cognizable for standing purposes because petitioners further explain that their health problems were remedied prior to the filing of the petition for review through removal of their mercury fillings. See App. 160, 162 (explaining that they recovered from the health problems allegedly caused by the fillings when the fillings were removed). Thus, petitioners themselves can identify only a "discrete, past injury," which is insufficient for standing.

KERM, Inc. v. FCC, 353 F.3d 57, 60 (D.C. Cir. 2004). And because petitioners are now aware of the potential health risks from mercury fillings, there is no likelihood that their alleged injury can reoccur in the future, regardless of whether the FDA classifies EAADM. Accordingly, petitioners have failed to establish an injury sufficient for purposes of standing. See Cruz v. American Airlines, Inc., 356 F.3d 320, 328-29 (D.C. Cir. 2004) (past injury will not support standing where requested remedy is prospective and past injury is unlikely to recur); Worth v. Jackson, 451 F.3d 854, 858 (D.C. Cir. 2006) (same).

In any event, even if the affidavits of petitioners Brocato and Tibau are sufficient to establish an injury for standing purposes, they present no evidence to show that the FDA's delay in classifying EAADM was the cause of their injuries, or that their requested relief - an order requiring the FDA to classify EAADM and a temporary ban on EAADM until the agency does so - would in any way redress their injuries.

To establish causation, petitioners must demonstrate that "it is substantially probable . . . that the challenged acts of the defendant, not of some absent third party, will cause [their] particularized injury." Florida Audubon Soc'y v. Bentsen, 94 F.3d 658, 663 (D.C. Cir. 1996) (en banc). Petitioners provide no facts, nor could they, from which the Court could conclude that the FDA's delay in classifying EAADM caused petitioners' past injuries. Indeed, even if the FDA had classified EAADM, neither the FDA nor

the device manufacturer would have been required to notify patients about the mercury content of EAADM and potential health hazards. The general controls of the FDCA, which include provisions on labeling (21 U.S.C. § 352), apply regardless of whether a device has been classified. And because EAADM is a prescription device, the only legally required labeling is directed toward the dentist or other practitioner, and not the patient. See 21 C.F.R. § 801.109. Thus, even if EAADM had been classified when petitioners received their fillings, the petitioners would not necessarily have been informed about the mercury content of the fillings or potential health risks. The fact that petitioners were not informed about the mercury content of the fillings (and any attendant risks) and/or offered alternative types of fillings, therefore, was the result of their dentists' independent action. See Lujan, 504 U.S. at 562 (explaining that where a plaintiff's asserted injury relies on government's failure to regulate someone else, causation and redressability may depend on the response of a third party).

In other words, at a minimum, petitioners would need to demonstrate that their fillings were produced from EAADM, that they received their fillings after Congress imposed the duty to classify EAADM, that if the FDA had classified EAADM then their dentists would have informed them of the mercury content and its potential risks, and that petitioners would have refused to have the mercury fillings implanted based on that information. This chain of

causation is too attenuated. Nor have petitioners provided any of the necessary facts to support such a theory of causation. Thus, petitioners' suggestion that FDA's delay in classifying EAADM (rather than their dentists' failure to obtain their informed consent) caused their particular injuries is entirely speculative.

Finally, "redressability examines whether the relief sought, assuming that the court chooses to grant it, will likely alleviate the particularized injury alleged by the plaintiff." Florida Audubon, 94 F.3d at 663-64 (footnote omitted). Petitioners cannot establish that classification of EAADM and a temporary ban on EAADM until it is classified, will redress the alleged past, adverse health effects that were caused by mercury fillings. See Cruz, 356 F.3d at 328 (plaintiffs lacked standing because requested relief - declaratory and injunctive relief - was prospective and therefore would not redress alleged past injury). And petitioners have not demonstrated any individualized, prospective injury which their requested remedy would redress. See Worth v. Jackson, 451 F.3d at 858 (when plaintiff seeks prospective relief he must establish prospective injury-in-fact for standing). Indeed, because petitioners are now aware of the mercury content of EAADM and the potential health risks of mercury, they would be unlikely to consent to receive mercury fillings in the future. Thus, petitioners cannot identify any prospective injury that their requested relief would redress.

To the extent petitioners suggest that the FDA's classification of EAADM would redress the prospective risk of injury to other individuals from mercury fillings, who may not be aware of mercury content in EAADM, see App. 160 ("countless numbers of people unaware of the mercury"); App. 162 (alleging health risks would have been disclosed "if FDA had done its job"), that alleged harm is also insufficient to establish petitioners' standing. See Warth v. Seldin, 422 U.S. at 499 ("The Art. III judicial power exists only to redress or otherwise to protect against injury to the complaining party, even though the court's judgment may benefit others collaterally."); id. (plaintiff "cannot rest his claim to relief on the legal rights or interests of third parties").

In any event, petitioners' requested relief, classification of EAADM, would not preclude the continued use of mercury fillings or ensure notice to patients of the potential risks of mercury. As explained above, even if EAADM were to be classified in class III, because it is a pre-amendment device, it could remain on the market at least until the FDA issues a final regulation requiring premarket approval. See 21 U.S.C. § 360e(b)(1)(A). Thus, individuals would continue to be able to choose mercury fillings. Moreover, as explained above, classification of EAADM (in any class) would ordinarily not require notification to the public (either by the manufacturer, the dentist, or the FDA) that EAADM contains mercury. See 21 C.F.R. § 801.109 (prescription devices only require labels directed at practitioners, not the public).

Accordingly, it is entirely speculative that the requested relief would result in patients having greater knowledge about mercury content in fillings or any potential risks therefrom. Petitioners, therefore, have no support for their claim that classification of EAADM would necessarily result in notice of mercury content to patients and would thereby prevent any risk of injury.

B. Organizational Petitioners

Petitioners also include four organizations. An organization may seek review either on its own behalf or on behalf of its members. See National Taxpayers Union, Inc. v. United States, 68 F.3d 1428, 1432-33 (D.C. Cir. 1995). Organizational standing requires an injury to the organization itself, as well as causation and redressability. To demonstrate a cognizable injury to the organization, it is not sufficient to allege that the organization's objectives have been frustrated or impaired. Id. at 1433. Rather, the organization must demonstrate a "'concrete and demonstrable injury to the organization's activities--with [a] consequent drain on the organization's resources--constitut[ing] . . . more than simply a setback to the organization's abstract social interests.'" Id. (quoting Havens Realty Corp. v. Coleman, 455 U.S. 363, 379 (1982)). The "organization must allege that discrete programmatic concerns are being directly and adversely affected by the challenged action." Id. (internal quotation marks omitted).

Petitioners fail to even allege that any of their activities have been impaired by the FDA's delay in classifying EAADM, much less provide any facts, as required at this stage, see Sierra Club, 292 F.3d at 898, to support such a conclusion. Petitioner Moms Against Mercury, a North Carolina nonprofit corporation that represents children allegedly suffering from neurological damage from mercury exposure, merely contends that "[a] central part of [its] mission" is to inform the public about sources of mercury that are "kept hidden by [the] FDA," which includes mercury in fillings. See App. 155. Similarly, petitioner Connecticut Coalition for Environmental Justice, a "state-based group representing the needs of lower-income and minority residents," merely alleges that "the burden of exposure to mercury via amalgam falls heavily on lower-income Americans," and that FDA's failure to warn patients about mercury content affects its members. See App. 156. Petitioner Oregonians for Life seeks "to protect unborn children from exposure to mercury via the mother's dental fillings," both through informing the public of the risks and advocating the abolition of mercury fillings. See App. 157. Finally, petitioner California Citizens for Health Freedom failed to even submit an affidavit.

Each of these petitioners, therefore, failed to allege any injury to discrete activities or programs. At most, these petitioners assert that if the FDA had classified EAADM, they might not have needed to advocate their policy preferences as vigorously.

See National Taxpayers, 68 F.3d at 1433 (allegation that organization's objectives are "frustrated" is not sufficient for standing). A drain on an organization's resources to advocate its policy preferences, however, does not constitute an injury in fact. See National Treasury Employees Union v. United States, 101 F.3d 1423, 1429 (D.C. Cir. 1996) ("[C]onflict between a defendant's conduct and an organization's mission is alone insufficient to establish Article III standing."); National Taxpayers, 68 F.3d at 1433-34. Otherwise, every advocacy group would be able to claim standing to challenge any policy or regulation it opposed. See National Taxpayers, 68 F.3d at 1434; Fair Employment Council of Greater Wash., Inc. v. BMC Mktg. Corp., 28 F.3d 1268, 1277 (D.C. Cir. 1994).

If an organization cannot demonstrate any injury to itself, it may nevertheless be able to establish representational standing by showing that the organization's members would have standing to sue, that the interests it seeks to protect are germane to the organization's purpose, and that participation of individual members in the lawsuit is not necessary. See National Taxpayers, 68 F.3d at 1435. The affidavits submitted by the organizational petitioners here, however, do not even indicate who their members are, much less provide any facts supporting a conclusion that those members have suffered cognizable injuries. See App. 155-57. At most, the affidavits suggest that some unidentified members have "unknowingly receive[d] mercury," but without any actual resulting

injury. See, e.g., App. 156. Thus, because the affidavits fail to establish any concrete, imminent injury (as opposed to speculation that an injury might occur at some indefinite time in the future) to the organizations' members, they are legally insufficient to establish representational standing. See Lujan, 504 U.S. at 564 & n.2.

In any event, the organizational petitioners face the same hurdle as the individual petitioners to establish causation and redressability. None of the organizations' affidavits provide facts to establish the necessary causal link (i.e., that the FDA's delay in classification concealed the fact that EAADM contains mercury, which may pose health risks, and thereby caused or risks injury to the organizations and/or their members) or redressability.

Accordingly, none of the individual or organizational petitioners have established Article III standing to support this Court's jurisdiction over the petition for review.

II. THIS COURT LACKS SUBJECT MATTER JURISDICTION TO REVIEW PETITIONERS' CLAIM THAT THE AGENCY UNREASONABLY DELAYED IN CLASSIFYING EAADM.

It is a well-settled principle of constitutional law that federal courts are courts of limited jurisdiction. See Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994). They may exercise only as much jurisdiction as is granted to them under the Constitution and by Congress. See id. The plaintiff bears the

burden of establishing the federal jurisdiction upon which its suit relies. See id. Petitioners have failed to satisfy that burden.

A. This Court recognized in Telecommunications Research & Action Ctr. v. FCC, 750 F.2d 70 (D.C. Cir. 1984) ("TRAC"), that the court of appeals, under the All Writs Act, 28 U.S.C. § 1651, may hear a claim of unreasonable delay or agency inaction where necessary to protect its prospective jurisdiction over the agency's final decision. The premise of TRAC is that the governing statute vests jurisdiction in the court of appeals to review the final agency action that is claimed to be withheld or delayed. The order compelling action is thus in aid of the court of appeals' future jurisdiction which would otherwise be frustrated by agency inaction. Id. at 75-76.

Petitioners fail to locate a relevant grant of rulemaking authority that is subject to ultimate review in this Court. Their extensive reliance on 21 U.S.C. § 360g is misplaced. Section 360g grants the United States Courts of Appeals original jurisdiction to review final agency action only in certain circumstances. That original jurisdiction is limited to petitions seeking review of certain, specified agency orders and regulations concerning medical devices, and provided that the petition is brought by "any person adversely affected by such regulation or order" within thirty days of the order or regulation. See 21 U.S.C. § 360g(a).

Petitioners invoke three subsections - (a)(4), (a)(8), and (a)(9) - of section 360g as establishing this Court's jurisdiction

over the petition for review. See Br. at 1. None of the types of orders or regulations which this Court is authorized to review under those subsections, however, is implicated here.

Subsection (a)(4) provides review only over (1) final regulations that require premarket approval for a device, and (2) orders granting or denying premarket approval. See 21 U.S.C. § 360g(a)(4). The FDA has issued no such regulation or order in regard to EAADM. Indeed, the FDA has not issued any final regulation or order regarding EAADM. Thus, there is no basis for this Court to exercise jurisdiction under subsection (a)(4). Moreover, because EAADM has yet to be formally classified, the FDA would have no basis to issue a regulation requiring premarket approval or an order granting or denying premarket approval, because such regulation or order could be issued only after a device has already been classified in class III. See 21 U.S.C. § 360e (only class III devices require premarket approval).

Petitioners also invoke subsection (a)(9). That subsection confers jurisdiction on this Court to review a regulation issued under section 360e(i)(2) or 360j(l)(5)(B), both of which provide for promulgation of a regulation reclassifying a device previously classified in class III. See 21 U.S.C. § 360g(a)(9). Since petitioners concede that the FDA has not yet classified EAADM, it is entirely unclear why they think the FDA has issued (or could issue) a regulation reclassifying EAADM. Indeed, petitioners fail to identify any such regulation.

Petitioners also rely on section 360g(a)(8), which confers jurisdiction on the Court to review orders under section 360c(i), determining that a post-amendment device is "substantially equivalent," for purposes of safety and effectiveness, to a predicate device which has already been classified. See 21 U.S.C. § 360g(a)(8). They allege that FDA is effectively issuing orders finding that EAADM is "substantially equivalent" to amalgam alloy in order to keep EAADM on the market without premarket approval and without classifying it. See, e.g., Br. at 18, 25-26.

That section, however, does not help petitioners. Any "substantial equivalence" determinations that the FDA has made for individual, post-amendment dental amalgams do not affect the marketing status of pre-amendment EAADM devices, which are allowed to remain on the market until the FDA classifies EAADM and issues a final rule requiring premarket approval. See 21 U.S.C. § 360e(b)(1)(A); see also Medtronic, Inc., 518 U.S. at 477-78; 67 Fed. Reg. at 7,621. Only post-amendment devices are automatically classified by statute in class III, and therefore require premarket approval prior to being introduced into commerce, unless or until, inter alia, the FDA issues an order determining that the post-amendment device is substantially equivalent to a pre-existing device or a device previously classified in class I or II. See 21 U.S.C. §§ 360c(a)(1)(C), (f)(1), 360e; 67 Fed. Reg. 7,620, 7,621 (2002); see also H.R. Conf. Rep. No. 94-1090 at 56 (1976), as reprinted in 1976 U.S.C.C.A.N. 1103, 1108-09. And, while the FDA

has issued orders finding individual, post-amendment dental amalgams substantially equivalent to the combination of amalgam alloy and dental mercury (see supra pp. 8-9), those orders are not at issue here. Petitioners have not challenged any of those individual orders and, in any event, the time to do so has expired. See 21 U.S.C. § 360g(a) (petition must be filed within 30 days of order).[7]

B. Petitioners urge that the Court has general authority to address alleged delays in classification without regard to the specific provisions conferring judicial review in this Court. No basis exists for this assertion. See Cutler v. Hayes, 818 F.2d 879, 888 n.61 (D.C. Cir. 1987) (FDCA "contains no single, overarching provision governing judicial review. Instead, discrete agency actions are subject to specialized review provisions."). If the FDA were to classify EAADM, review of that decision would lie only in the district court pursuant to the Administrative Procedure Act. See Wellife Prods. v. Shalala, 52 F.3d 357, 358 (D.C. Cir. 1995) (per curiam) (where FDCA does not provide for judicial review of specific type of regulation challenged, then review is in district court).

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[7] To the extent petitioners suggest that the FDA has issued a substantial equivalence order governing pre-amendment EAADM, they are incorrect. The FDA could not issue any order finding pre-amendment EAADM "substantially equivalent" to amalgam alloy or any other pre-existing device because section 360g(a)(8) applies only to orders determining that a post-amendment device is "substantially equivalent" to a pre-existing device. 21 U.S.C. § 360c(f)(1).

The only type of initial classification regulation designated for direct review in the court of appeals is a regulation classifying a device in class I. See 21 U.S.C. § 360g(a)(1). A class I classification, however, is not implicated in this matter: FDA's proposed rule seeks to classify EAADM as a class II device. See 67 Fed. Reg. 7,620, 7,625 (Feb. 20, 2002) (proposed rule). Moreover, petitioners have not asked the FDA to classify the device as class I, which is fatal to any claim of jurisdiction under TRAC. See In re Tennant, 359 F.3d 523, 529 (D.C. Cir. 2004) (explaining that there must be more than a theoretical possibility that an issue will be heard in a court before that court can reasonably be said to be protecting its future jurisdiction). To the contrary, petitioners seek to have EAADM classified as a class III device, see Pet. at 19,[8] a regulation which would not be subject to direct review in this Court. See 21 U.S.C. § 360g(a). As Congress has not provided for direct review in the courts of appeals of regulations initially classifying devices in class II or class III, any claim of jurisdiction under TRAC must fail. See Sierra Club v. Thomas, 828 F.2d 783, 790 (D.C. Cir. 1987).

Petitioners' suggestion that the FDA could classify EAADM in class III, and then issue a regulation requiring premarket approval

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[8] By seeking a ban on the product until the manufacturers obtain premarket approval, see Pet. at 26, petitioners are de facto asking this Court to order FDA to classify EAADM as a class III device, for that is the only classification for which premarket approval is required. 21 U.S.C. § 360c(a)(1)(C).

or an order granting or denying premarket approval of EAADM, either of which would be reviewable under section 360g(a)(4), is pure speculation and insufficient to invoke jurisdiction under TRAC. See In re Tennant, 359 F.3d at 529 (holding that there must be more than a theoretical possibility that an issue will be heard in a court before that court can reasonably be said to be protecting its future jurisdiction). And it is even more speculative to invoke TRAC jurisdiction on the theory that the FDA might classify EAADM in class III, and then at some later date might issue a regulation reclassifying EAADM in class I or II, pursuant to section 360e(i)(2) or 360j(l)(5)(B), which this Court would then have jurisdiction to review pursuant to 21 U.S.C. § 360g(a)(9).

C. In the alternative, petitioners contend that they seek review of FDA's notice of April 3, 2006, announcing the September 2006 meeting to discuss amalgam and review the scientific literature. See Br. at 1. Notice of a meeting, however, does not constitute an "order" within the meaning of 21 U.S.C. § 360g that is directly reviewable by this Court.

Although section 360g does not define "order," it does direct that review pursuant to the statute shall be done in accordance with the judicial review provisions of the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706. See 21 U.S.C. § 360g(c). The APA defines an "order" as "the whole or part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including

licensing." 5 U.S.C. § 551(6). An order is the result of adjudication, see 5 U.S.C. § 551(7), and is "directed to the determination of the legal status of particular persons or practices through the application of preexisting legal standards," Fed. Trade Comm'n v. Brigadier Indus. Corp., 613 F.2d 1110, 1117 (D.C. Cir. 1979). There is nothing in the April 2006 notice that suggests that it is the "final disposition" of a proceeding or the result of any adjudication. Indeed, the notice suggests the contrary by indicating that the FDA is still monitoring the scientific literature regarding dental amalgam devices. See 71 Fed. Reg. 16,682. In any event, the April 2006 notice is not of the limited type of orders or regulations that this Court is authorized to review directly under 21 U.S.C. § 360g(a).

Finally, petitioners wrongly invoke 5 U.S.C. § 703, Br. at 1, as a basis for jurisdiction. That provision does not confer subject matter jurisdiction on this Court over an action in which it otherwise could not exercise jurisdiction. See Trudeau v. Federal Trade Comm'n, 456 F.3d 178, 185 (D.C. Cir. 2006) ("APA does not confer jurisdiction" but provides a limited cause of action); TRAC, 750 F.2d at 76-77, 78 (section 703 "provides for district court review when statutory review is inadequate") (emphasis added).

D. Even if this Court had jurisdiction under TRAC and the FDCA to review the agency's delay in classifying EAADM, at a minimum, the Court must find that the agency's delay has been

"egregious" to warrant judicial intervention. See TRAC, 750 F.2d at 79. In determining whether an agency's delay rises to that standard, the Court considers four factors: (1) the length of the delay; (2) the reasonableness of the delay in the context of the statute; (3) the consequences of the delay; and (4) any reasons or justifications for the delay. Id. at 80. Given the lack of consequences of the delay, and the agency's ongoing efforts to classify in light of constantly changing scientific evidence, the agency's delay has not been so "egregious" as to warrant any action by this Court.

As explained above, although the FDA has not formally classified EAADM, it has separately classified its component parts: amalgam alloy (class II) and dental mercury (class I). Accordingly, EAADM is effectively classified in class II, pursuant to the highest classification of its components. As a result, EAADM is already regulated by the general controls, as well as by the special controls that are applicable to amalgam alloy. Moreover, the FDA has proposed to place EAADM in class II. See 67 Fed. Reg. 7,620 (Feb. 20, 2002) (proposed rule). Therefore, because the FDA has effectively regulated EAADM through regulation of its component parts as a class II device, petitioners cannot identify any consequences of the agency's delay.

Indeed, petitioners' brief underscores the lack of harm caused by any agency delay. Dental amalgams containing mercury have been used for decades, yet there is no conclusive scientific evidence

that they are so harmful so as to prompt decisive agency action, much less so as to warrant judicial intervention. Petitioners explain that dental amalgams containing mercury, which would include EAADM, are being phased out of dentistry, and that substitute filling materials are becoming more common. Br. at 6. Moreover, because there are alternatives to EAADM and other mercury-containing amalgams, patients may choose mercury-free fillings. Id.

Although petitioners complain that the public is ill-informed about mercury content in many fillings, Br. at 6-7, that is not a result of the agency's delay in classification, since classification of a prescription device ordinarily would not require a practitioner to inform his patients about mercury content and/or the potential risks of mercury. And, contrary to petitioners' accusations, Br. at 7, the FDA has not undertaken a campaign to conceal mercury content in dental devices. Indeed, the general labeling requirements that apply to EAADM, see 21 U.S.C. § 352; 21 C.F.R. § 801.109, do not control the content of the manufacturers' labels. As petitioners explain, a number of manufacturers do, in fact, warn about mercury content and potential health risks. Br. at 5-6. Accordingly, any delay in classification has in no way affected either the information provided to dentists or to the general public.

Given the complex issues and intense disagreement about the scientific evidence regarding mercury and its potential health

effects, the agency's delay is not unreasonable. As petitioners recognize, the FDA has been actively working towards classifying EAADM. In 2002, the FDA issued a proposed rule. But in response to public comments, the FDA determined that further research was necessary. In September 2006, an FDA advisory panel reviewed the FDA's research and heard public comments. See App. at 150. Although the panel agreed that there was no conclusive evidence that dental amalgams have adverse health effects, the panel concluded that the FDA needed to further evaluate the potential health effects of mercury, particularly with regard to certain subsets of individuals, such as pregnant women, children, and those with potential hyper-sensitivity to mercury. Id. at 150-51. Thus, given the complexity of the issue and the lack of conclusive scientific evidence on the health effects of dental amalgams, the agency has proceeded appropriately in its efforts to classify EAADM.

This is not a case where the agency has been neglecting its duty to classify; rather, the agency has been steadily working towards classification, but has been slowed, in part, by the lack of literature and definitive scientific evidence on which its decision will be based.

CONCLUSION

For the foregoing reasons, this Court should dismiss the petition for review.

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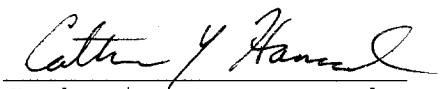
CERTIFICATE OF COMPLIANCE

Counsel for respondent hereby certifies that the foregoing Brief for Respondent satisfies the requirements of Federal Rule of Appellate Procedure 32(a)(7)(B) and D.C. Circuit Rule 32(a). The brief was prepared in Courier New monospaced font, has 10.5 or fewer characters per inch (twelve-point font), and, excluding parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and D.C. Circuit Rule 32(a)(2), contains 9,775 words, according to the count of Corel Wordperfect 12.



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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of February, 2007, I filed and served the foregoing Brief for Respondent by causing the original and fourteen copies to be sent to this Court by hand delivery, and by causing two copies to be served upon the following counsel as specified below:

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