United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 27, 2007 Decided April 13, 2007

No. 06-1147

MOMS AGAINST MERCURY, ET AL.,
PETITIONERS

v.

FOOD & DRUG ADMINISTRATION,
RESPONDENT

On Petition for Review of Agency Action of the
Food and Drug Administration

Charles G. Brown argued the cause for petitioners. With him on the briefs was *Robert E. Reeves*.

Catherine Y. Hancock, Attorney, U.S. Department of Justice, argued the cause for respondent. With her on the brief were *Peter D. Keisler*, Assistant Attorney General, *Jeffrey A. Taylor*, U.S. Attorney, *Mark B. Stern*, Attorney, *Daniel Meron*, General Counsel, U.S. Department of Health & Human Services, and *Eric M. Blumberg*, Deputy Chief Counsel.

Before: SENTELLE, HENDERSON and TATEL, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* SENTELLE.

SENTELLE, *Circuit Judge*: A number of advocacy organizations and individuals seek review of regulatory inaction by the Food and Drug Administration ("FDA"). They assert that the FDA should classify, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 ("FDCA" or the "Act"), a material commonly used for dental fillings. The material, they contend, must be regulated by the FDA in order to protect consumers against its deleterious health effects. We hold that we lack jurisdiction over the subject matter, and thus dismiss the petition.

I.

The dental fillings at issue in this case are comprised of approximately equal parts (1) dental mercury and (2) amalgam alloy comprised of silver and other metals. Dentists typically receive these fillings in encapsulated form. The two components are separately sealed in one capsule, and are combined to create the "silver" material used to fill dental cavities. In encapsulated form, the device is called "encapsulated amalgam alloy and dental mercury," or "EAADM."

The FDCA, as amended by the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976), authorizes the FDA to regulate "medical devices," a broad category of instruments and implants that includes items such as syringes, surgeon's gloves, and dental fillings. The FDA regulates a device by placing it into one of three classes, depending on the extent of regulatory control necessary to ensure its safety and effectiveness. Class I devices are safe enough to be regulated only by "general controls," the lowest level of regulation. 21 U.S.C. § 360c(a)(1)(A). Class II devices present a higher risk and thus require stricter "special controls." *Id.* § 360c(a)(1)(B). Devices placed in class III are subject to the

highest level of controls, including pre-market approval, because their risks cannot be addressed by general or special controls. *Id.* § 360c(a)(1)(C).

When it enacted the classification system, Congress provided that all devices not yet on the market would be automatically classified as class III devices. *Id.* These "post-amendment devices" are thus subject to strict pre-market approval requirements unless FDA determines that they are "substantially equivalent" to class I or II devices that are already on the market. *Id.* § 360c(i). Devices that predated the amendments ("pre-amendment devices") were not automatically classified, but were left for FDA to classify under specified procedures. *Id.* § 360c(b)(1). If, after classification by either method, the FDA determines that a device has been placed into the wrong class, the agency can reclassify it on its own initiative or in response to a petition. *Id.* § 360c(e).

FDA has classified a number of pre-amendment dental devices, including dental mercury in class I and amalgam alloy in class II. 21 C.F.R. §§ 872.3700, 872.3050 (1987). FDA acknowledged that dental mercury presents some risks to patients and dentists, but concluded that those risks were adequately addressed by labeling requirements and other general controls. *Dental Devices; General Provisions and Classifications of 110 Devices*, 52 Fed. Reg. 30,082, 30,089 (Aug. 12, 1987). Although FDA has not yet classified the encapsulated form of these two devices, the agency notes that it is in the process of reaching a classification decision. A proposed rule issued in 2002 would classify EAADM as a class II device, and would amend or revise the classifications of amalgam alloy and dental mercury. *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. 7620

(Feb. 20, 2002). In 2006, in light of emerging research and requests for reconsideration of its proposed rule, FDA convened a panel meeting of two advisory committees. *Notice of Meeting*, 71 Fed. Reg. 16,582 (Apr. 3, 2006). FDA's efforts to classify EAADM continue: currently the agency is conducting an extensive review of scientific literature, the panel recommendations, and the comments to its proposed rule. Until it is classified, FDA states that EAADM is effectively regulated as a class II device because that is the highest classification attaching to one of its component parts.

Petitioners are four organizations, representing the economic, health and environmental interests of their members and the public generally; and five individuals, representing their personal economic, medical and professional interests. They believe that mercury in dental fillings causes physical harm to dental office employees who must handle the material when they implant and remove fillings, and to dental patients (and their unborn children) who inhale mercury vapors emanating from the fillings in their mouths. Petitioners contend that, if FDA were to classify EAADM, the public would be better informed of its dangers in choosing whether to accept it or demand other, safer filling materials. They argue that FDA's decision not to classify EAADM, knowing the risks it poses to individuals and the environment, constitutes a violation of the FDCA. Petitioners ask this Court to order FDA to classify EAADM, and to remove the device from commerce until it has done so.

II.

FDA argues that this Court should dismiss the instant petition because this Court lacks subject matter jurisdiction and because petitioners lack standing. In every case, the jurisdictional requirements of Article III must be present before

a court may proceed to the merits. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998). Where both standing and subject matter jurisdiction are at issue, however, a court may inquire into either and, finding it lacking, dismiss the matter without reaching the other. *See Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 584 (1999) (holding that, because *Steel Co.* "does not dictate a sequencing of jurisdictional issues," a court may "choose among threshold grounds for denying audience to a case on the merits"). In this case, we hold that we lack jurisdiction over the subject matter of petitioners' claim. We thus dismiss the petition without reaching the question of standing.

As to subject matter jurisdiction, FDA's failure to classify a device does not directly give rise to judicial review in this Court under the FDCA. Under section 360g, persons who are adversely affected by specified FDA regulations or orders may file, in the courts of appeals, a petition for judicial review within thirty days of the relevant FDA action. 21 U.S.C. § 360g(a). Specifically, petitioners invoke provisions authorizing this Court's review of three FDA decisions: (1) subjecting a device to pre-market approval under subsection (a)(4); (2) determining that a post-amendment device is substantially equivalent to a pre-amendment device under subsection (a)(8); and (3) reclassifying a device from one class to another under subsection (a)(9). As petitioners concede, however, the FDA has engaged in none of these actions with regard to EAADM. These provisions thus cannot support jurisdiction in this Court.

Section 360g(a)(4) authorizes judicial review of "the promulgation of a regulation under paragraph (3) of section 360e(b) of this title requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 360e(g)(1) or 360e(g)(2)(C) of

this title." All of the referenced subsections address procedures for requiring a device to obtain pre-market approval. In this case, the FDA has not promulgated any regulations relating to pre-market approval of EAADM, nor has it issued any order relating to such application. Subsection (a)(4), therefore, cannot be the basis of our jurisdiction.

Section 360g(a)(8) brings under the judicial review provision "an order pursuant to section 360c(i) of this title." The cross-referenced section describes procedural requirements for the FDA to determine that a post-amendment device is substantially equivalent to a pre-amendment device. In this case, EAADM has not been – and indeed, as a pre-amendment device, could not be – the subject of any order deeming it substantially equivalent to a pre-amendment device. The final subsection petitioners cite as a source of subject matter jurisdiction is similarly inapposite. Section 360g(a)(9) applies to "a regulation under section 360e(i)(2) or 360j(*l*)(5)(B)." The cited provisions, in turn, relate to orders revising the classification of a device. Since the FDA has issued no order classifying EAADM, provisions relating to the revision of its classification are not applicable. These three subsections cited by petitioners, then, apply only to certain agency actions, none of which has occurred here.

Nor can this Court assert jurisdiction under a theory that agency actions can be challenged in this Court as long as the FDCA does not provide for exclusive jurisdiction elsewhere. If judicial review of an FDA action or inaction is not provided for in the Act, challenges to such actions may be brought only in the district court. *See Cutler v. Hayes*, 818 F.2d 879, 887 n.61 (D.C. Cir. 1987) ("Agency action taken under sections silent" as to judicial review "are directly reviewable only in a district court under some appropriate head of its jurisdiction, for courts of appeals have only such jurisdiction as Congress has chosen to

confer upon them."). We have, however, previously recognized a limited exception to this rule. When the agency's final action is exclusively reviewable in this Court, we have exercised jurisdiction over a claim that the agency has unreasonably delayed that action. In *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70, 75 (D.C. Cir. 1984) ("*TRAC*"), this Court held that a claim of unreasonable delay was reviewable directly and exclusively in this Court because any final FCC order could be reviewed in this Court. On those facts, the Court asserted jurisdiction over the intermediate issue in order to "protect its future jurisdiction." *Id.* at 76.

It is this Court's interest in protecting its future jurisdiction that gives rise to jurisdiction under a *TRAC* theory. The interest does not arise if the final agency action is not reviewable in this Court. *See Cutler*, 818 F.2d at 887 n.61 (noting that "[e]ssential to our holding" in *TRAC* "were statutory provisions enabling us to review *any* final FCC order") (emphasis added). In the instant case, the FDA final action with regard to EAADM may or may not be reviewable in this Court. For example, if the FDA were to deem it a class I device, that regulation would be directly reviewable in this Court. 21 U.S.C. § 360g(a)(1). Classifications of devices into classes II or III, on the other hand, are directly reviewable only in district court because the FDCA does not provide for their review in the courts of appeals. *Cf. Cutler*, 818 F.2d at 887 n.61. Any number of other scenarios can be imagined as well. After the FDA classifies EAADM, it might subsequently take some action that is directly reviewable in this Court, such as reclassifying it or requiring manufacturers to obtain pre-market approval. But we do not assert jurisdiction on the basis of hypothetical scenarios. *TRAC* is not properly extended to cases where the basis of prospective jurisdiction is a speculative chain of events. *Cf. In re Tennant*, 359 F.3d 523, 529 (D.C. Cir. 2004) (holding that unless "there has been a proceeding of *some* kind instituted before an agency or court

that might lead to an appeal," speculative claims of future appeals court jurisdiction are not sufficient to confer prospective jurisdiction). We have no reason to suppose that agency action, reviewable in this Court, is imminent.

III.

Petitioners have failed to carry their burden of demonstrating that this Court has subject matter jurisdiction over their claim. *See Georgiades v. Martin-Trigona*, 729 F.2d 831, 833 n.4 (D.C. Cir. 1984) (citing *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936)). We are thus compelled to dismiss their petition without considering the merits of petitioners' claim.

So ordered.