United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 08-5458 **September Term, 2009**

Filed On: November 27, 2009

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC., ET AL.,

APPELLANTS

v.

FOOD & DRUG ADMINISTRATION, ET AL.,

APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:07-cv-00668)

Before: SENTELLE, *Chief Judge*, BROWN, *Circuit Judge*, and EDWARDS, *Senior Circuit Judge*.

JUDGMENT

This cause was considered on the record from the United States District Court for the District of Columbia, and was briefed and argued by counsel. It is

ORDERED AND ADJUDGED that the judgment of the District Court be affirmed.

In 2006, in an adjudication involving Duramed Research, Inc. (Duramed), the Food and Drug Administration ("FDA") approved a supplemental new drug application ("SNDA") filed by Duramed for Plan B, an emergency contraceptive previously available by prescription only. NDA 21-045/S-011, Letter from Steven Galson, M.D., M.P.H., Director, Center for Drug Evaluation and Research, United States Food and Drug Administration, to Joseph A. Carrado, M.Sc., R.Ph., Vice President, Clinical Regulatory Affairs, Duramed Research, Inc. (Aug. 24, 2006), *reprinted in* Joint Appendix 77-80. The SNDA allowed Plan B to be sold over the counter to all consumers age 18 and over, while maintaining the prescription requirement for younger consumers. Appellants, Association of American Physicians & Surgeons, Inc., Concerned Women for America, Family Research Council, and Safe Drugs for Women, who were not parties to the Duramed SNDA

adjudication, filed a complaint in District Court in April 2007 seeking to vacate FDA's approval of the SNDA. Appellants claimed that the FDA's action violated the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. The District Court dismissed the case for lack of standing and, in the alternative, for appellants' failure to exhaust mandatory administrative remedies. *See Ass'n of Am. Physicians & Surgeons, Inc. v. Food & Drug Admin.*, 539 F. Supp. 2d 4 (D.D.C. 2008) ("*AAPS*"). We affirm largely for the reasons stated by the District Court.

"A party invoking federal jurisdiction bears the burden of establishing standing." HARRY T. EDWARDS & LINDA A. ELLIOTT, FEDERAL STANDARDS OF REVIEW: REVIEW OF DISTRICT COURT DECISIONS AND AGENCY ACTIONS 110 (2007). In *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), the Court explained:

> [T]he irreducible constitutional minimum of [Article III] standing contains three elements. First, the plaintiff 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. Second, there must be a causal connection between the injury and the conduct complained of – the injury has to be fairly . . . traceable to the challenged action of the defendant, and not . . . the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Id. at 560-61 (internal quotation marks and citations omitted). "In addition to determining whether a petitioner has Article III standing, a court presented with a challenge to agency action must also determine 'whether the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.' *Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 153 (1970); *see also Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 394-97 (1987). The zone-of-interest inquiry, which is 'basically one of interpreting congressional intent,' *Clarke*, 479 U.S. at 394, is a prudential requirement of general application that applies unless expressly negated by Congress. *See Bennett v. Spear*, 520 U.S. [154, 163 (1997)]." EDWARDS & ELLIOTT, *supra*, at 112-13. Appellants advanced numerous theories in an attempt to support their standing, but the District Court correctly found that they failed to meet their burden. *See AAPS*, 539 F. Supp. 2d at 4, 13-21. The District Court's decision needs no amplification.

Moreover, even if appellants were able to demonstrate standing, the District Court properly found that they failed to exhaust their administrative remedies. Exhaustion applies to actions under the APA "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." *Darby v. Cisneros*, 509 U.S. 137, 147 (1993). FDA rules allow for citizen petitions through which "[a]n interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). However, agency regulations explicitly require that "[a] request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing . . . before any legal action is filed in a court." *Id.* § 10.45(b). Appellants filed no such citizen petition with FDA contesting the SNDA approval of Plan B and they proffered no legally viable excuse for this failure.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or rehearing *en banc*. *See* FED. R. APP. P. 41(b); D.C. CIR. R. 41.

Per Curiam
FOR THE COURT:
Mark J. Langer, Clerk

By: /s/
Michael C. McGrail
Deputy Clerk