United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20-5346 **September Term, 2021**

FILED ON: APRIL 8, 2022

COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS, INC., A DELAWARE CORPORATION,
APPELLANT

v.

XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:18-cv-00633)

Before: SRINIVASAN, *Chief Judge*, MILLETT and PILLARD, *Circuit Judges*

JUDGMENT

This appeal was considered on the record from the United States District Court for the District of Columbia, and was briefed and argued by counsel. The Court has accorded the issues full consideration and has determined that they do not warrant a published opinion. *See* D.C. CIR. R. 36(d). For the reasons stated below, it is

ORDERED and **ADJUDGED** that the judgment of the District Court for the District of Columbia be **AFFIRMED**.

I

Plaintiff Council on Radionuclides and Radiopharmaceuticals, Inc. ("Council") is a trade association with member companies in the United States and Canada. Those members "manufacture and distribute radiopharmaceuticals, sealed sources, radionuclides, and contrast agents primarily used in medicine and life science research." J.A. 10. The Council's "mission and activities include advocacy for regulations and legislation that facilitate the growth and viability of its member companies[.]" J.A. 10.

The Council filed a complaint in federal district court challenging the Centers for Medicare & Medicaid Services' ("Centers") February 1, 2016, final rule addressing Medicaid reimbursement for covered outpatient drugs. *See* Medicaid Program: Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016) ("Final Rule"). The complaint was filed against the United States Department of Health and Human Services and its Secretary in his official capacity (collectively, "Department").

The Council contends that the Final Rule's inclusion of radiopharmaceuticals as "covered outpatient drug[s,]" 42 U.S.C. § 1396r-8(k)(2)–(3), for purposes of the Medicaid Drug Rebate Program was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). In the Final Rule, the Centers addressed a comment suggesting that, "due to distinct features of radiopharmaceuticals, such products do not meet the statutory definition of [covered outpatient drugs]." Final Rule, 81 Fed. Reg. at 5187.[1] The Centers disagreed, reasoning that "[r]adiopharmaceuticals meet the definition of a [covered outpatient drug] if they are approved under section 505 of the [Federal Food, Drug, and Cosmetic Act] unless the limiting definition in [42 U.S.C. § 1396r-8(k)(3)] applies." *Id*.

In its answer to the Council's complaint, the Department challenged the Council's standing. The parties then filed cross-motions for summary judgment. The Council sought to establish its standing with two declarations, as well as relevant evidence in the administrative record. One of the declarations was from member company Curium US LLC, and the other from member company Advanced Accelerator Applications, a Novartis Company.

The district court denied the Council's motion for summary judgment and granted the Department's cross-motion on standing grounds. The court held that the Council failed to establish standing because neither the Curium nor the Advanced Accelerator declaration "establishes that either member has been harmed or will be harmed by the Final Rule." *Council on Radionuclides & Radiopharmaceuticals, Inc. v. Azar*, No. 18-633, 2019 WL 5960142, at *5 (D.D.C. Nov. 13, 2019).

II

We review the district court's grant of summary judgment *de novo*. In doing so, we accept the Council's evidence as true and draw "all justifiable inferences" in its favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

We agree with the district court that the Council has failed to establish its standing to bring this suit on behalf of its members. By suing in its representational capacity, the Council had to show that "at least one of its members would have standing to sue in [its] own right[.]" *American Trucking Ass'ns v. Federal Motor Carrier Safety Admin.*, 724 F.3d 243, 247 (D.C. Cir. 2013)

[1] The Federal Register mistakenly labels the page that occurs between pages 5186 and 5188 as "5185" instead of "5187." *See* Final Rule, 81 Fed. Reg. at 5185–5188.

(citation omitted). And because this case is at the summary-judgment stage, the Council had to "set forth by affidavit or other evidence specific facts" documenting that a member "suffered an injury in fact" that is "fairly traceable to the challenged action of the defendant" and that is redressable by a favorable court decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–561 (1992) (internal quotation marks and citations omitted).

The Council has failed that task. It did not show that at least one of its members has suffered an injury in fact caused by the Final Rule.

The Council is correct that the Final Rule is "aimed directly at plaintiffs" in that it directly regulates the radiopharmaceutical products that they produce. *Virginia v. American Booksellers Ass'n*, 484 U.S. 383, 392 (1988). But that alone does not establish an injury in fact caused by the new regulation for purposes of standing. The Council must also show either that (i) the operation of the Final Rule has caused one of its members an "actual" injury, such as "significant and costly compliance measures," *id.*, or (ii) there is a credible threat of enforcement given its members' current and intended behavior, *id.* at 392–393; *see also Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (injury in fact requirement met where there exists a "credible threat of prosecution" of plaintiffs for their intended course of conduct); *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) ("A plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement.").

On the record before us, the Council has not shown that the Final Rule has caused any actual harm to its members. The Advanced Accelerator declaration states only that the company "currently participates in the Medicaid Drug Rebate Program and has entered into a Medicaid Drug Rebate Program Agreement[,]" and that "the Medicaid Drug Rebate Program requires manufacturers to report product identifying information * * * in addition to pricing information[.]" J.A. 50. The Council concedes that the record is silent as to whether the Council's members have paid or will have to pay rebates as a result of the Final Rule. *See* Oral Arg. Tr. 6.

The record does indicate that Advanced Accelerator has filed product reports after the Final Rule issued for one of its radiopharmaceutical drugs. And to be sure, the filing of such reports generates administrative and other resource costs that could constitute an injury in fact. *See Association of American R.Rs. v. Department of Transp.*, 38 F.3d 582, 585 (D.C. Cir. 1994). The problem here, though, is that the declaration does not connect the filing of reports, or any other action by Advanced Accelerator, to the Final Rule. Nothing in the declaration explains whether Advanced Accelerator has taken or will take any action that it would not have taken but for the Final Rule's new regulatory reach. For example, Advanced Accelerator's reports may have been filed as a result of the statute, rather than the Final Rule. *See* Oral Arg. Tr. 47–50. As the Council conceded at oral argument, Oral Arg. Tr. 47–51, the record contains no evidence from which the inference could be drawn that any Council member is now filing reports or intends to file reports that it would not have filed anyhow even in the absence of the Final Rule. We therefore cannot conclude that Advanced Accelerator's conduct changed in any way because of the Final Rule. Without showing that the Final Rule caused a relevant change in conduct, the Council has not met its burden to show standing based on this theory of harm. *See California Ass'n of Physically*

Handicapped, Inc. v. FCC, 778 F.2d 823, 827 (D.C. Cir. 1985) (injury not traceable to agency action where "alleged injury occurred before, existed at the time of, and continued unchanged after the challenged" action).

The Council argues instead that the injury inflicted by the Final Rule is an increased likelihood of penalties for its members' potentially inaccurate reporting. But, for three reasons, the Council has not demonstrated a "credible threat" of enforcement penalties faced by its members. *Susan B. Anthony List*, 573 U.S. at 159; *Babbitt*, 442 U.S. at 298.

First, the Advanced Accelerator declaration states only that the lack of clarity from the Medicaid Drug Rebate statute, and that the Final Rule necessitates that radiopharmaceutical manufacturers "make good-faith, reasonable assumptions about how to satisfy reporting requirements." J.A. 51. This assertion does not support a credible threat of enforcement because the statute requires the knowing provision of false information to trigger the penalty provisions. *See* 42 U.S.C. § 1396r-8(b)(3)(C)(ii) ("Any manufacturer with an agreement under this section that knowingly provides false information * * * is subject to a civil money penalty[.]"); 42 C.F.R. § 1003.110 ("*Knowingly* means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required.") (emphasis in original). In this litigation, the Centers have represented that "manufacturers can in fact successfully report by making reasonable assumptions." Defendants' Reply to Pls.' Opp'n to Defs.' Cross-Mot. for Summ. J. at 6, *Council on Radionuclides*, 2019 WL 5960142. Nothing in the record suggests that the Council's members intend to knowingly violate the Final Rule, undermining the Council's argument that they face any credible threat of enforcement.

Second, the Final Rule states that the Centers "have been working with the radiopharmaceutical manufacturers to address questions and concerns regarding the reporting of these drugs[,]" and that, "[i]f a manufacturer has a specific question regarding certain aspects of the reporting requirements specific to radiopharmaceuticals, they should contact [the Centers] for further discussion." Final Rule, 81 Fed. Reg. at 5187. The Final Rule adds that the Centers "will continue to be available to assist manufacturers with questions on these drugs." *Id*. Given the Centers' readiness to work with radiopharmaceutical manufacturers on the reporting requirements, the prospect of an enforcement action against a Council member operating in good faith approaches non-existence.

Third, the Council has pointed to no evidence of any enforcement actions by the Centers against radiopharmaceutical manufacturers to date.

In short, far from establishing a credible threat of enforcement, the record shows the opposite: As long as radiopharmaceutical manufacturers continue their present practice of "mak[ing] good-faith, reasonable assumptions about how to satisfy reporting requirements[,]" J.A. 51, supported if needed by the Centers' assistance, no plausible risk of an enforcement action against them has been shown.

For all of those reasons, the Council has failed to establish standing because it has not demonstrated that either the operation or enforcement of the Final Rule has caused one of its members an injury in fact traceable to that rule, or that there is a substantial risk that the Final Rule will cause an alleged harm. *See Susan B. Anthony List*, 573 U.S. at 158. The judgment of the District Court is affirmed.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate 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/
Daniel J. Reidy
Deputy Clerk