

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 12, 1999 Decided April 13, 1999

No. 98-5317

University Medical Center of Southern Nevada,
Appellant

v.

Donna E. Shalala, Secretary,
United States Department of Health & Human Services,
Appellee

Appeal from the United States District Court
for the District of Columbia
(No. 97cv00560)

Elliott B. Adler argued the cause and filed the briefs for appellant.

Robert D. Kamenshine, Attorney, United States Department of Justice, argued the cause for appellee. With him on the brief were Frank W. Hunger, Assistant Attorney General, Wilma A. Lewis, United States Attorney, and Anthony J. Steinmeyer, Attorney, United States Department of Justice.

Michael E. Anderson was on the brief for amicus curiae National Association of Public Hospitals and Health Systems.

Before: Silberman, Ginsburg, and Tatel, Circuit Judges.

Opinion for the Court filed by Circuit Judge Silberman.

Silberman, Circuit Judge: University Medical Center of Southern Nevada (UMC) appeals from the district court's dismissal, for lack of standing, of its challenge to the Department of Health and Human Service's administration of a drug discount program. We agree that appellant lacks standing, albeit on different grounds than those relied on by the district court, and affirm the dismissal.

I.

Congress, concerned that many federally funded hospital facilities serving low-income patients were incurring high prices for drugs, enacted section 340B of the Public Health Service Act. 42 U.S.C.A. s 256b (Supp. 1998). Section 340B requires a manufacturer of "covered outpatient drugs" to enter into a contract with the Secretary of HHS--a condition for eligibility for Medicaid matching funds--under which the manufacturer agrees to provide these drugs to certain "covered entities" at discounted prices.¹ A covered entity is one that meets certain statutory criteria; as relevant here, an eligible hospital is one that has a "disproportionate share adjustment" percentage (which is a measure of the number of low-income patients served by the hospital) greater than 11.75 for the most recent cost reporting period, and that does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.² HHS

¹ Covered outpatient drugs are those drugs defined under section 1927(k) of the Social Security Act, 42 U.S.C. s 1396r-8(k) (1994). See 42 U.S.C. s 256b(a)(3); see also id. at s 1396r-8(a), (c) (setting forth rebate requirements).

² The type of covered entity involved in this case is defined in 42 U.S.C. s 256b(a)(4)(L)(i)-(iii). The disproportionate share adjustment is calculated in accordance with 42 U.S.C. s 1395ww(d)(5)(F) and 42 C.F.R. s 412.106 (1998).

initially interpreted the latter eligibility criterion as barring only "double dipping"--that is, hospitals could participate in both the section 340B discount program and a group purchasing organization provided that the hospital did not receive 340B discounts on the same drugs purchased through the group purchasing organization. As the program matured, however, HHS subsequently changed its interpretation, concluding that participation in a group purchasing organization for the purchase of covered outpatient drugs would, after May 1994, render the hospital ineligible for 340B discounts.

HHS compiled an initial list of qualifying hospitals when the program went into effect on December 1, 1992, and updates the list quarterly based on information (including the hospital's disproportionate share adjustment) contained in cost reports provided to HHS by the hospital's fiscal intermediary. If cost data show that a hospital has become eligible, it is added to the list at the beginning of the next quarter; similarly, if the data show a hospital is no longer eligible, it is removed from the list at the beginning of the next quarter. In other words, the hospital's eligibility status is prospective only. At the start of the program, however, manufacturers did not yet have in place the mechanism to provide the discounts to covered entities at the point of sale. HHS therefore allowed retroactive discounts to allow manufacturers time to integrate the discounts into their drug distribution system while at the same time ensuring that covered entities

received the discounts to which they were entitled. If a hospital had been on the initial list, it would be able to get discounts from the manufacturer retroactive to December 1, 1992, and hospitals placed on the list subsequently would be eligible for discounts retroactive to their inclusion on the list, provided the hospitals requested such retroactive discounts from the manufacturers before June 13, 1994. After June 13, 1994, discounts could only be obtained at the time of purchase.

Appellant wished to participate in the 340B program, but it was not included on the initial eligibility list because the cost report submitted by its fiscal intermediary for the most recent cost reporting period reflected a disproportionate

share adjustment of less than the required 11.75 percent. When the intermediary completed an audit of UMC's 1991 cost report (in circa August 1993), it discovered that the correct disproportionate share adjustment percentage exceeded that required for eligibility. Both UMC and the intermediary then gave the Health Care Financing Administration and the Office of Drug Pricing, which oversees the 340B program, the corrected numbers, and told them that UMC had a qualifying disproportionate share adjustment percentage. UMC alleged that the government did not respond to any of this correspondence. When the administrative process was complete (following the influence of a congressional "intermediary") and HHS had satisfied itself that UMC did indeed qualify for the 340B program discounts, UMC was placed on the eligibility list on July 1, 1994. This meant UMC could only receive discounts on drugs purchased on or after that date. During the period from December 1992 to June 1994, UMC had continued to purchase certain covered outpatient drugs through its group purchasing arrangement.

UMC then filed a complaint in the district court, seeking a declaratory judgment that HHS was arbitrary and capricious in not putting UMC on the list earlier, and that UMC is entitled to retroactive discounts for covered drugs purchased between December 1, 1992 and June 13, 1994. HHS countered first that UMC lacked standing because the ultimate relief it seeks--retroactive discounts--cannot be gained by a judgment against the government. The district court agreed that UMC did not have standing, but not on the grounds argued by the government. Rather, the district court concluded that the plain language of the statute excludes from 340B eligibility hospitals that participate in group purchasing agreements. Since UMC continued to participate in such a program during the period for which it also claims it should receive retroactive discounts under section 340B, the district court thought UMC is statutorily barred from receiving such discounts. See *University Med. Ctr. v. Shalala*, 5 F. Supp.2d 4, 8-9 (D.D.C. 1998).

II.

UMC makes two arguments: the district court erred in interpreting the statute and therefore erroneously found that UMC lacked standing, and the district court erred procedurally in granting judgment on the pleadings to the government.³ The government agrees that the district court's interpretation of the group purchasing exclusion in the statute was erroneous and that UMC is not barred from eligibility by virtue of its previous participation in a group purchasing organization. During the time period for which UMC seeks retroactive discounts, participation in a group purchasing arrangement was not a per se bar to participation in the 340B program--only double-dipping was prohibited. It is conceded, therefore, that UMC does not want for standing on this basis. The government alternatively claims--as it did below--that UMC lacks standing because the asserted injury is not redressable. UMC's inability to obtain retroactive discounts from drug manufacturers, the government contends, will not be affected by any judgment against HHS.⁴

We start, of course, with the jurisdictional question. A party invoking federal jurisdiction must show injury-in-fact that is fairly traceable to the challenged conduct of the defendant and that is likely to be redressed by a favorable decision of the court. See *Lujan v. Defenders of Wildlife*, 504

3 Because we resolve this case on jurisdictional grounds, we do not reach the merits. We note, however, that UMC misunderstands the district court's role in reviewing agency action. The district court sits as an appellate tribunal in such a case, and the question whether HHS acted in an arbitrary and capricious manner is a legal one which the district court can resolve on the agency record--regardless of whether it is presented in the context of a motion for judgment on the pleadings or in a motion for summary judgment (or in any other Rule 12 motion under the Federal Rules of Civil Procedure). See *Marshall County Health Care Auth. v. Shalala*, 988 F.2d 1221, 1225-26 (D.C. Cir. 1993).

4 The government also argues that even if UMC has standing it has no valid claim because the Administrative Procedure Act (APA) provides no remedy for an agency's alleged "negligent" delay in processing an ultimately granted application.

U.S. 555, 560-61 (1992). The injury must be distinct and palpable and not merely hypothetical, abstract, or conjectural. See *Allen v. Wright*, 468 U.S. 737, 751 (1984); *Warth v. Seldin*, 422 U.S. 490, 501 (1975). And "[i]t must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Defenders of Wildlife*, 504 U.S. at 561 (quoting *Simon v. Eastern Ky. Welfare Rights Organization*, 426 U.S. 26, 41-42 (1976)).

UMC has categorized its injury in varying ways. In its motion for summary judgment before the district court, UMC argued that HHS acted unreasonably in failing to place UMC on the list earlier, thereby depriving UMC of the full benefit of the discounts available to it under the 340B program. Thus characterized, UMC appeared to be asserting a mone-

tary injury--the denial of discounts as a result of not being on the list. But in response to HHS's counter-argument that such an injury is not redressable because it depends on the actions of the drug manufacturers who were not parties to the suit, UMC contended before the district court and reiterates here that its requested relief--a judgment declaring that UMC was unlawfully excluded from the list--would fully redress its injury. This is so, appellant insists, because the "illegal exclusion from the eligibility list, and not the fact that UMC was forced to pay higher drug prices, is the wrong that UMC seeks to redress" in this lawsuit. Appellant's shifting formulation of its injury is understandable. If it were simply HHS's alleged illegal action--its failure to put UMC on the list during the now-closed "window" for retroactive discounts--then UMC lacks standing because alleged illegality without an injury-in-fact does not satisfy standing requirements. See *Allen v. Wright*, 468 U.S. at 754 (stating that "an asserted right to have the Government act in accordance with law is not sufficient, standing alone, to confer jurisdiction on a federal court"); *Steel Co. v. Citizens for a Better Environment*, 118 S. Ct. 1003, 1018-19 (1998).

If, on the other hand, the asserted injury is the loss of discounts during the retroactive period, then UMC's case

founders because it fails to meet the redressability requirement. Even assuming that appellant could establish "a causal nexus between the agency action" (not putting UMC on the list during the retroactive period) "and the asserted injury" (not getting retroactive discounts), *Freedom Republicans, Inc. v. Federal Election Comm'n*, 13 F.3d 412, 418 (D.C. Cir. 1994), it still does not show that its claimed injury " 'is likely to be redressed' " by a declaratory judgment. See *Humane Soc'y v. Babbitt*, 46 F.3d 93, 100 (D.C. Cir. 1995) (quoting *National Wildlife Fed'n v. Hodel*, 839 F.2d 694, 704 (D.C. Cir. 1998)). Whether UMC can get the retroactive discounts apparently depends on whether the manufacturers--who are not parties to this action--could be persuaded to pay them--presumably based on their contract with HHS to which UMC is not even a party. If it could be said that UMC was legally entitled to get the discounts as a result of being placed on the list effective December 1, 1992, then we might have a different situation. That would force us to ask how likely it was that appellant would succeed in the second suit. (We are not aware of a case that presents that situation; we are inclined to think that a plaintiff should bring in parties like the drug manufacturers as third-party defendants.) But we do not have to wrestle with this problem because UMC does not even claim that it has a contingent legal right against the drug manufacturers. Even if appellant had a declaratory judgment that the government unlawfully delayed in placing UMC on the list, it has never explained how, or under what legal theory, it would be entitled to recover against the manufacturers. UMC suggested that because its injury has two parts--being left off the list and losing the discounts--it should be allowed to seek redress in two steps, first getting a declaratory judgment and then suing the manufacturers. But that is essentially a concession that the redressability requirement cannot currently be met. Redressability must be satisfied now to establish jurisdiction.

* * * *

As UMC has not shown that HHS has caused it an injury that we can redress, we affirm the district court's dismissal of the case.