No. 20-1784

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Sep 24, 2020
DEBORAH S. HUNT, Clerk

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS,

Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINSITRATION, et al.,

Defendants-Appellees.

O R D E R

Before: COLE, BATCHELDER, and McKEAGUE, Circuit Judges.

Plaintiff Association of American Physicians & Surgeons ("AAPS") appeals the district court's judgment dismissing for lack of standing its civil suit seeking immediate access to strategic reserves of hydroxychloroquine ("HCQ"). It moves for emergency injunctive relief in the form of an order requiring Defendants to "expeditiously release the HCQ [stored in the strategic national stockpile] to pharmacies in the United States which promise to fill prescriptions for them without delay or restriction in protecting against COVID-19" and to "publicly post a list of those pharmacies, with their contact information." Defendants U.S. Food and Drug Administration ("FDA") and its commissioner, the U.S. Department of Health and Human Services ("HHS") and its secretary, and the Biomedical Advanced Research and Development Authority ("BARDA") and its acting director oppose the motion. AAPS replies.

"A preliminary injunction is an extraordinary remedy designed to preserve the relative positions of the parties until a trial on the merits can be held." *Tenn. Scrap Recyclers Ass'n v. Bredesen*, 556 F.3d 442, 447 (6th Cir. 2009). "Whether to grant a preliminary injunction is a matter within the discretion of the district court and is thus reviewed for abuse of discretion." *Id.* (citing *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 540 (6th Cir. 2007)). We consider four factors to determine whether injunctive relief is appropriate: (1) whether the movant has shown "a likelihood of success on the merits" of its underlying claim; (2) "whether the movant will suffer irreparable harm" in the absence of injunctive relief; (3) whether the requested injunctive relief will substantially injure other interested parties; and (4) where the public interest lies. *Id.* "Whether the plaintiff is likely to succeed on the merits is a determination of law that is reviewed de novo." *Id.* (citing *Certified Restoration*, 511 F.3d at 541).

The district court held that AAPS was unlikely to succeed on the merits of its substantive claims because it lacked Article III standing to bring them. "[N]o principle is more fundamental to the judiciary's proper role in our system of government than" standing. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quoting *Raines v. Byrd*, 521 U.S. 811, 818 (1997)). AAPS asserts that it has first-person standing, associational standing to bring suit on behalf of its members, and third-person standing to bring suit on behalf of its members' patients.

To establish first-person standing, AAPS must show that it "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Id.* at 1547 (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)). In support of first-person standing, AAPS asserts that it had to cancel a conference due to lack of interest because "many fear attending events without a prophylactic to protect against COVID-19." That alleged injury is too attenuated to support the causation element

of standing; there are nearly innumerable reasons why a person would decide not to attend an AAPS conference in the middle of a global pandemic. Thus, AAPS fails to show that cancelling the conference is fairly traceable to Defendants' refusal to distribute the strategic stockpile of HCQ.

AAPS also argues that it is unable to deal directly with state medical boards "without Defendant FDA's improper interference with HCQ." It is not entirely clear what AAPS means when it says "interference," but it apparently alleges that Defendants' restriction on access to the stockpiled HCQ is understood by state medical regulators as implicit disapproval of HCQ's prophylactic use and that state medical boards are so influenced by Defendants' disparagement of HCQ that they will censure physicians who prescribe it to patients not covered by the EUA.

This alleged injury is insufficient to support first-person standing for two reasons. First, AAPS makes clear that Defendants cannot regulate the practice of medicine and that prescribing medications for off-label use is a long-standing and broadly accepted practice. Accordingly, AAPS's claim that Defendants wield significant influence over AAPS members' medical practices is unpersuasive. Second, to the extent state medical regulators are relying on Defendants' decision not to allow unfettered access to the stockpile, it is not clear how an injunction would change that situation. Below, AAPS moved the district court to order Defendants "to retract their unsupported disparaging statements." Notably, it does not seek that relief in this court. And if, as AAPS implies, state medical boards have internalized Defendants' conclusions regarding the efficacy of HCQ in treating COVID-19, an injunction compelling Defendants to release the drug in spite of those conclusions is unlikely to change how a state's medical board regulates the drug.

An organization has associational standing to pursue relief on behalf of its members if it can show that "(1) the organization's 'members would otherwise have standing to sue in their own

right'; (2) 'the interests it seeks to protect are germane to the organization's purpose'; and (3) 'neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.'" *Friends of Tims Ford v. Tenn. Valley Auth.*, 585 F.3d 955, 967 (6th Cir. 2009) (quoting *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977)). But AAPS members do not have an injury fairly traceable to Defendants' actions or redressable by the injunction AAPS seeks.

AAPS refers to Dr. John Doe, a physician who has been unable to successfully prescribe a full regimen of HCQ and, along with other members, fears retaliation by state medical boards based on Defendants' restrictions on HCQ. However, AAPS members' alleged difficulty in accessing HCQ cannot be due to scarcity caused by the stockpile; as AAPS itself asserted, HCQ is in plentiful supply, and easy to make. As such, neither Defendants' "withholding" of the stockpiled HCQ nor the alleged expiration of the drug is interfering with physicians' ability to prescribe or use of the drug. Moreover, even if Defendants' refusal to release HCQ from the national stockpile was having a significant effect on commercial access to the drug, an injunction would not solve the problem because state medical boards—not Defendants—control how physicians can prescribe or use drugs. As noted above, AAPS fails to show that state medical boards are likely to change the way they regulate HCQ because of an injunction forcing Defendants to release doses from the stockpile against their better judgement.

Because Defendants have not interfered with AAPS members' ability to prescribe or obtain commercially available HCQ and cannot be held responsible for the allegedly threatening regulatory environment surrounding its use, AAPS has not shown that its members' alleged injuries are fairly traceable to Defendants or redressable by this suit. Accordingly, AAPS cannot maintain associational standing based on its members' alleged injuries.

That said, AAPS cites *N.Y. State Club Ass'n, Inc. v. City of New York*, 487 U.S. 1, 9 (1988), for the proposition that "an association has standing to sue on behalf of its members when those members would have standing to bring the same suit," and that "[i]t does not matter what specific analysis is necessary to determine that the members could bring the same suit." AAPS argues that, because its members have third-party standing to assert claims on behalf of their patients, it has third-party standing to assert those claims on behalf of its members.

Although AAPS cited it in support of third-party standing, the *N.Y. State Club Ass'n* Court was testing *associational* standing. *Id.* at 8–9. As such, it could be an avenue to establish *associational* standing, if AAPS can show that its members would have third-party standing to sue on behalf of their patients.

Third-party standing is "rare," but it "allows federal courts to hear cases in which a plaintiff can 'show that (1) it has suffered an injury in fact; (2) it has a close relationship to the third party; and (3) there is some hindrance to the third party's ability to protect his or her own interests.'" *Crawford v. United States Dep't of Treasury*, 868 F.3d 438, 455 (6th Cir. 2017) (quoting *Mount Elliott Cemetery Ass'n v. City of Troy*, 171 F.3d 398, 404 (6th Cir. 1999)). Importantly, the would-be litigant must have established standing in their own right before they can assert standing on behalf of a third-party. *See Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004) (holding that a party with standing must "make two additional showings" to assert third-party standing).

Still, as discussed above, AAPS members cannot establish first-person standing because they have not suffered an injury fairly traceable to Defendants and redressable through the relief AAPS seeks. Accordingly, they cannot maintain third-party standing on behalf of their patients. *Crawford*, 868 F.3d at 455. And, consequently, AAPS cannot establish associational standing

based on its members' third-party standing. *Friends of Tims Ford*, 585 F.3d at 96; *N.Y. State Club Ass'n, Inc.*, 487 U.S. at 8–9.

AAPS argues that, even in the absence of standing, judicial review is authorized under the Administrative Procedures Act ("APA"), 5 U.S.C. § 706(2). But emergency-use authorizations are exempt from review under the APA. 5 U.S.C. § 701(a)(2); 21 U.S.C. § 360bbb-3(i).

The remaining factors also cut against AAPS. Its motion is almost silent as to irreparable harm. Indeed, it merely asserts in its closing paragraph that the irreparable harm is obvious and mentions in passing a massive loss of life. Loss of life would constitute irreparable harm, but because that harm is not fairly traceable to Defendants' actions, there is no risk of irreparable harm redressable by the injunction AAPS seeks. *See Tenn. Scrap Recyclers Ass'n*, 556 F.3d at 447. On the other hand, intervening to force Defendants to distribute HCQ would substantially injure Defendants' ability to manage the national strategic stockpile—which Congress expressly authorized Defendants to do. The public interest lies with upholding that legislative intent, and with "provid[ing] for and optimiz[ing] the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency." 42 U.S.C. § 247d-6b(a)(1).

The motion for an injunction pending appeal is **DENIED**.

ENTERED BY ORDER OF THE COURT

Deborah S. Hunt, Clerk