United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 18-5364 **September Term, 2019**

FILED ON: APRIL 10, 2020

CENTER FOR RESPONSIBLE SCIENCE,
APPELLANT

v.

STEPHEN M. HAHN, IN HIS OFFICIAL CAPACITY AS THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:17-cv-02198)

Before: MILLETT, PILLARD, and WILKINS, *Circuit Judges*.

J U D G M E N T

This appeal was considered on the record from the United States District Court for the District of Columbia and 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). It is hereby

ORDERED AND ADJUDGED that the District Court's order filed October 22, 2018, be **AFFIRMED**.

Center for Responsible Science ("CRS") appeals the District Court's dismissal of its amended complaint against Scott Gottlieb,[1] in his official capacity as Commissioner of the Food and Drug Administration ("FDA"). We affirm the District Court's dismissal of this case for lack of standing, concluding that CRS's pled injuries suffer the same Article III deficiencies as the injuries alleged in *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905 (D.C. Cir. 2015).

CRS's citizen petition to the FDA asserted that the FDA's decades-old disclosure regulations

[1] In the course of this appeal, Stephen M. Hahn, in his official capacity as the Commissioner of the FDA, was substituted for Scott Gottlieb, pursuant to FED. R. APP. P. 43(c)(2).

fall short of fulfilling certain ethical obligations to inform potential clinical participants "that preclinical animal testing may not predict the degree of risk to which the trial participants will be subjected." JA 70 (Am. Compl. ¶ 99). To cure this deficiency, CRS proposed that the FDA amend its regulation, 21 C.F.R. § 50.25, to require clinical drug trials to include CRS's own drafted warning in informed consent documents. The FDA denied CRS's citizen petition, and CRS filed suit in the District Court alleging that such denial was arbitrary and capricious, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). For purposes of determining whether CRS has standing to bring this suit, we assume the merits in its favor. *Waterkeeper All. v. EPA*, 853 F.3d 527, 533 (D.C. Cir. 2017). When confronted with the dismissal of a complaint for lack of standing, we evaluate *de novo* whether the plaintiff has shown standing "under the standard applicable pursuant to Federal Rule of Civil Procedure 12(b)(1)." *Food & Water Watch*, 808 F.3d at 913. At this early stage, "general factual allegations of injury resulting from the defendant's conduct may suffice," *Bennett v. Spear,* 520 U.S. 154, 168 (1997) (internal quotation marks omitted), but "[w]e do not assume the truth of legal conclusions, nor do we accept inferences that are unsupported by the facts set out in the complaint," *Arpaio v. Obama,* 797 F.3d 11, 19 (D.C. Cir. 2015) (citation and internal quotation marks omitted).

An organization has standing to pursue claims on its own behalf so long as it meets the same standing requirements as an individual plaintiff: an "actual or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be redressed by a favorable court decision." *Food & Water Watch*, 808 F.3d at 919 (quoting *Equal Rights Ctr. v. Post Props., Inc.*, 633 F.3d 1136, 1138 (D.C. Cir. 2011)). When analyzing whether an organization has suffered an injury in fact, we conduct a two-part inquiry, "ask[ing], first, whether the agency's action or omission to act injured the organization's interest, and, second, whether the organization used its resources to counteract that harm." *Id.* (quoting *People for the Ethical Treatment of Animals v. U.S. Dep't of Agric.*, 797 F.3d 1087, 1094 (D.C. Cir. 2015) ("*PETA*")) (some brackets omitted). In *Food & Water Watch*, we concluded that the organization failed to satisfy the first prong because it failed to allege that the government's acts or omissions "perceptibly impaired the organization's ability to provide services." *Id.* at 919 (quoting *Turlock Irrigation Dist. v. FERC*, 786 F.3d 18, 24 (D.C. Cir. 2015)). We make the same conclusion here.

CRS's allegations are no different than those in *Food & Water Watch*, amounting to "no more than an abstract injury to its interests" and broadened issue advocacy. *Id.* at 921. Similar to Food & Water Watch ("F&WW"), CRS's stated mission is educating the public on specific issues – here, issues related to scientific research practices and the informed consent of clinical trial participants – and challenging governmental regulations that do not advance its goals. *See id.* at 920 (One of F&WW's "primary purposes is to educate the public about food systems that guarantee safe, wholesome food produced in a sustainable manner."). Just as F&WW alleged that the government's proposed regulations would require F&WW to "spend time and money on increasing its efforts to educate members of the public" about the limitations of the government's proposed regulation, *id.*, so, too, CRS merely alleges that the FDA's denial of CRS's petition to amend the existing regulations "would cost CRS a substantial sum of money and/or time to educate and protect the welfare of potential clinical trial participants nationwide about the issues with animal testing," JA 88 (Am. Compl. ¶ 193). Of course, we held in *Food & Water Watch* that such

allegations did not give rise to a cognizable injury that can support Article III standing. 808 F.3d at 921.

CRS has failed to offer any basis to materially distinguish its amended complaint from *Food & Water Watch*, which we also analyzed under the motion-to-dismiss standard prior to any discovery taking place. *Id.* at 913. CRS argues that, unlike F&WW, it is "stepping into the breach and doing what the agency should have done," notably by engaging in direct outreach to encourage principal investigators to provide the warnings that CRS believes are required. Appellant's Reply Br. 15. That alleged advocacy does not identify the kind of harm to an organization's "services," *Food & Water Watch*, 808 F.3d at 919 (quoting *Turlock Irrigation Dist.*, 786 F.3d at 24, "daily operations," *PETA*, 797 F.3d at 1094, or "activities," *Am. Anti-Vivisection Soc'y v. U.S. Dep't of Agric.*, 946 F.3d 615, 619 (D.C. Cir. 2020), that we have recognized as injury in fact. Indeed, as the District Court noted, CRS began those efforts in an apparent attempt to create a basis for standing only after that court dismissed CRS's initial complaint. CRS argued at oral argument that F&WW's injury was too speculative to support standing, but this position confuses our different standing analyses in that case. *See* Oral Arg. Rec. 27:00-27:56. Our analysis of the individual plaintiffs' standing centered around whether the individuals "plausibly allege[d] that the regulations *substantially* increase the risk of" harm. 808 F.3d at 916 (emphasis added). Our analysis of the organization's standing, however, did not turn on whether F&WW pled a speculative injury, especially since the Court accepted as true the factual allegation that F&WW "*will* spend time and money on increasing its efforts to educate members of the public[.]" *Id.* at 920 (emphasis added).

Our decisions in *PETA* and, most recently, *American Anti-Vivisection Society* do not direct a different result here. In both of those cases, there were allegations that the plaintiff organizations were denied access to an avenue for redress and denied information that "perceptibly impaired [the organization's] ability to both bring [ ] violations to the attention of the agency charged with preventing avian cruelty and continue to educate the public." *PETA*, 797 F.3d at 1095 (internal quotation marks omitted); *see Am. Anti-Vivisection Soc'y*, 946 F.3d at 619 (government inaction caused deprivation of key information needed to effectuate mission). Like F&WW, CRS does not allege that the FDA "limits its ability to seek redress for a violation of law. Nor does [CRS] allege that the [FDA's] action restricts the flow of information that [CRS] uses to educate[.]" *Food & Water Watch*, 808 F.3d at 921.

Thus, CRS's amended complaint fails for the same reasons that F&WW's complaint failed: "nothing in [CRS's pleadings] indicates that [CRS's] organizational activities have been perceptibly impaired in any way." *Id.* Because we conclude CRS's amended complaint fails to show how its activities were impaired by the FDA's denial of its citizen petition, we need not address the second prong, which asks whether CRS sufficiently pled that it used or diverted resources to counteract the harm.

CRS's alternative efforts to establish organizational standing also fail. CRS first points to 21 C.F.R. § 10.45(d)(1)(ii), which states that "[i]t is the position of [the] FDA" that "[a]n interested person is affected by, and thus has standing to obtain judicial review of final agency action[,]"

including the FDA Commissioner's final decision on a petition for rulemaking. 21 C.F.R. § 10.45(d)(1)(ii). According to CRS, that regulation demonstrates Congress's and the FDA's intention for organizations such as CRS to bring these types of suits into federal court. Of course, neither Congress nor the FDA can confer a right to judicial review that is not authorized by Article III of the Constitution. *Hydro Inv'rs Inc. v. FERC*, 351 F.3d 1192, 1197 (D.C. Cir. 2003). Lastly, CRS's plea that *someone* must have standing in a life-or-death case cannot carry CRS over the threshold. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 420 (2013) ("[T]he assumption that if [the plaintiffs] have no standing to sue, no one would have standing, is not a reason to find standing." (internal quotation marks omitted)).

We therefore affirm the District Court's dismissal of this case for lack of jurisdiction. 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 petition for 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