UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR RESPONSIBLE SCIENCE, *et al.*,

Plaintiffs,

v.

DR. SCOTT GOTTLIEB,

Defendant.

Civil Action Nos. 17-2198 (JEB)

MEMORANDUM OPINION

Plaintiffs — three individuals and the Center for Responsible Science — believe that everyone who participates in a clinical-drug trial should be aware of differences in the data between preclinical animal testing and clinical human-subject experimentation. To that end, in May 2014, they submitted a Citizen Petition to the Commissioner of the Food and Drug Administration requesting that three specific warnings be added to the standard informed-consent materials. When the FDA denied the Petition, Plaintiffs brought this one-count Administrative Procedure Act suit against the current Commissioner, Scott Gottlieb. Defendant now moves to dismiss, contending that none of the Plaintiffs has standing, thus robbing the Court of subject-matter jurisdiction. For the reasons discussed below, the Court agrees and will grant the Motion, but permit Plaintiffs an opportunity to amend.

I. Background

Few understand the long and arduous road a new drug takes to finally come to market. After the drug is developed, researchers often test its safety on laboratory animals in preclinical trials. See Compl., ¶¶ 91-92. If it can clear the preclinical stage, the drug sponsor submits an

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investigational new-drug application to the FDA, the agency responsible for regulating research on human subjects. Id., ¶¶ 88, 93. If approved, clinical research — *i.e.*, testing conducted on humans rather than animals — begins. As part of its duty to protect human subjects, the FDA requires the drug sponsor to obtain "legally effective informed consent" for each participant. See 21 C.F.R. § 50.20. Under current Agency regulations, informed-consent documents must contain eight elements, one of which describes "any reasonably foreseeable risks or discomforts to the subject." Id. § 50.25(a)(2).

It is on this last point that Plaintiffs believe the FDA is abdicating its duty. Two of the Plaintiffs, Hal Garcia-Smith and John Tessmer, have previously participated in clinical trials and believe that informed consent should include warnings about the differences between animal and human testing. See Compl., ¶¶ 11, 15-16, 20, 24. The third individual Plaintiff, Michael Vokhgelt, lost a son as a result of his participation in a clinical trial. Id., ¶¶ 25-28. Because Vokhgelt has other children who he fears may need experimental cancer treatments, he also would like the FDA to mandate that drug sponsors alert people of the risks of using data from preclinical animal testing before they decide to do a clinical trial. Id., ¶ 36. CRS is a non-profit, non-member organization that seeks to "promote advances in regulatory science" by "advocat[ing] for better results for patients" and "bringing policy up to date with existing science." Id., ¶¶ 1-4. As part of its mission and activities, CRS "monitors serious adverse events . . . in clinical trials." Id., ¶ 4.

On May 30, 2014, the organization and two of the individual Plaintiffs petitioned the FDA to amend its informed-consent regulation to include information about preclinical animal testing. Id., ¶¶ 65, 68. Specifically, the Petition requested that the FDA add three informed-consent elements to the eight extant ones:

> (9) The drug you will be given has been tested in animals and by other laboratory methods to determine whether it is likely to be safe and effective in humans. The decision to allow testing of this drug on humans relies heavily on the presumption that animal tests predict human response. Due to differences between animals and humans, animal tests may not predict whether a drug is safe and/or effective for use in humans.
>
> (10) Some participants in clinical trials in which other investigative drugs were tested have died or have been seriously injured by the drug that was tested.
>
> (11) The drug you will be given may later prove to be either unsafe for humans or ineffective in treating the condition for which it is being tested. You should not assume the drug will treat a medical condition you may have, because a determination of efficacy in an animal study does not necessarily predict efficacy in humans.

Compl., Exh A at 7. On April 12, 2017, the FDA denied the Petition, stating that the additional elements pertain to drug trials only, while the informed-consent regulations apply to all clinical trials. The Petition's warnings, therefore, "raise[d] broader concerns that make them inappropriate for inclusion in FDA's existing informed consent regulations." Compl., Exh. D at 3.

Six months later, Plaintiffs brought this suit for declaratory and injunctive relief, alleging that the FDA's denial was "arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(a)." Compl., ¶ 215. Defendant, contending that all Plaintiffs lack standing, now moves to dismiss for want of jurisdiction.

II. Legal Standard

In evaluating Defendant's Motion to Dismiss, the Court must "treat the complaint's factual allegations as true . . . and must grant plaintiff 'the benefit of all inferences that can be derived from the facts alleged.'" Sparrow v. United Air Lines, Inc., 216 F.3d 1111, 1113 (D.C. Cir. 2000) (quoting Schuler v. United States, 617 F.2d 605, 608 (D.C. Cir. 1979)) (internal

citation omitted); see also Jerome Stevens Pharms., Inc. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005). The Court need not accept as true, however, "a legal conclusion couched as a factual allegation," nor an inference unsupported by the facts set forth in the Complaint. Trudeau v. Fed. Trade Comm'n, 456 F.3d 178, 193 (D.C. Cir. 2006) (quoting Papasan v. Allain, 478 U.S. 265, 286 (1986) (internal quotation marks omitted)).

To survive a motion to dismiss under Rule 12(b)(1), Plaintiffs bear the burden of proving that the Court has subject-matter jurisdiction to hear their claims. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992); U.S. Ecology, Inc. v. U.S. Dep't of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000). A court has an "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority." Grand Lodge of the Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). For this reason, "'the [p]laintiff's factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion' than in resolving a 12(b)(6) motion for failure to state a claim." Id. at 13-14 (quoting 5A Charles A. Wright & Arthur R. Miller, Fed. Practice & Procedure § 1350 (2d ed. 1987)) (alteration in original). Additionally, unlike with a motion to dismiss under Rule 12(b)(6), the Court "may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction." Jerome Stevens, 402 F.3d at 1253; see also Herbert v. Nat'l Acad. of Sciences, 974 F.2d 192, 197 (D.C. Cir. 1992).

III. Analysis

Contrary to what laypersons might generally believe, not every aggrieved person gets to have her day in court. To properly invoke the jurisdiction of federal courts, a plaintiff must demonstrate that she has a "case" or "controversy" within the parameters of Article III, a doctrine known as standing. At a minimum, standing requires the plaintiff to establish (1) an

injury that is (2) traceable to the defendant's conduct and (3) likely redressable by the court. Lujan, 504 U.S. at 560-61. In a suit for injunctive relief, "past harm is not sufficient to establish an injury in fact." Nat'l Whistleblower Ctr. v. HHS, 839 F. Supp. 2d 40, 45-46 (D.D.C. 2012). The plaintiff, rather, must show "a real and immediate — as opposed to merely conjectural or hypothetical — threat of future injury." Nat'l Res. Def. Council v. Pena, 147 F.3d 1012, 1022 (D.C. Cir. 1998) (citation omitted). Defendant here argues that neither the individual Plaintiffs nor CRS meets the constitutional requirements for standing. The Court addresses each separately.

A. Individuals

The individual Plaintiffs allege that, because of the FDA's refusal to add their proposed informed-consent statements, they are either unable to participate in clinical trials or, in the case of Vokhgelt, fear that his children will need to participate in a trial without informed consent. See Compl., ¶¶ 15-16, 24, 207. Setting aside whether these are actually injuries in the Article III context, the individuals face a bigger standing obstacle: any future injury cannot be traceable to the FDA's action here.

As a preliminary matter, any past injury — *i.e.*, ill effects from previous trial participation — cannot be attributable to the FDA's denial of their Citizen Petition, which only occurred in April 2017. As to future injuries, what they claim harms them is a lack of information. Yet, they already have such information. As Defendant notes, because they "already possess the information they claim they need to make informed decisions[,] . . . any harm they might face in the future would result from their informed decision to participate in clinical drug trials and not FDA's denial of their citizen petition." Mot. at 13. Notably, the language Plaintiffs want added to the regulation is generic and would not change with each clinical trial. That is, there is no

difference between what they already know and what they would see in informed-consent materials if the FDA approved the Petition. As a result, it is difficult to imagine a scenario in which any individual would have standing here. The Court, consequently, finds that all of the individual Plaintiffs lack standing.

B. CRS

Plaintiffs next argue that CRS itself has standing to sue. Organizations can sue either on their own behalf ("organizational standing") or on behalf of their members ("representational standing"). See Scenic Am., Inc. v. U.S. Dep't of Transp., 983 F. Supp. 2d 170, 176 (D.D.C. 2013). Because CRS does not have any members, it may invoke only the former. To prevail, it must show the same three standing elements as any individual — (1) injury, (2) causation, and (3) redressability. The injury must be "'concrete and demonstrable . . . with [a] consequent drain on [its] resources,' rather than 'simply a setback to [its] abstract social interests.'" People for the Ethical Treatment of Animals, Inc. (PETA) v. U.S. Dep't of Agric., 7 F. Supp. 3d 1, 8 (D.D.C. 2013) (quoting Nat'l Ass'n of Home Builders v. EPA, 667 F.3d 6, 11 (D.C. Cir. 2012)) (alterations in original). It is here that CRS falters.

Caselaw for organizational standing is not a model of clarity, but this Circuit has made clear that, at a minimum, the organization must "allege 'that discrete programmatic concerns are being directly and adversely affected by' the [agency's] inaction," PETA, 7 F. Supp. 3d at 8 (quoting Nat'l Taxpayers Union, Inc., v. United States, 68 F.3d 1428, 1433 (D.C. Cir. 1995)), not merely that the organization has had to increase spending on "pure issue-advocacy" or litigation. See Nat'l Ass'n of Home Builders, 667 F.3d at 12 (quoting Ctr. for Law & Educ. v. Dep't of Educ., 396 F.3d 1152, 1162 (D.C. Cir. 2005)). To defeat a motion to dismiss, an organization must substantiate its injury "by affidavit or other specific evidence that a challenged statute or

policy frustrates the organization's goals and requires the organization to expend resources . . . [it] otherwise would spend in other ways." Comite de Jornaleros de Redondo Beach v. City of Redondo Beach, 657 F.3d 936, 943 (9th Cir. 2011) (internal quotation marks and citation omitted). In other words, although a plaintiff need not prove facts to defeat a motion to dismiss, it must allege some facts that, if true, would establish standing. See Lujan, 504 U.S. at 561; Arpaio v. Obama, 797 F.3d 11, 19 (D.C. Cir. 2015).

CRS alleges that it has standing here "because the interests at stake are germane to [its] purposes, and FDA's response will require further extensive advocacy work on [its] part . . . [,] placing a significant drain on its limited resources, causing a diversion of its resources, and the frustration of its mission." Compl., ¶ 209. Such broad allegations cannot suffice to allege standing, particularly where advocacy spending and detriment to its mission standing alone have been held not to constitute sufficient injury. See Food & Water Watch, Inc. v. Vilsack, 808 F.3d 905, 919-21 (D.C. Cir. 2015). The Court needs to know how resources are being drained and from and to where they are being diverted. CRS conclusorily states that "in the absence of the amended regulation, it would cost [it] a substantial sum of money to educate and protect the welfare of potential clinical trial participants nationwide about the issues with animal testing," Compl., ¶ 210, but the Court, without more specifics, is unable to discern whether those outlays would be "normally expended" to carry out the organization's advocacy mission and the ways in which resources would otherwise be spent if the regulation were amended. See Nat'l Ass'n of Home Builders, 667 F.3d at 12 (citation omitted).

The Court notes that this is not a strenuous burden at the motion-to-dismiss stage, but a necessary one nonetheless. See Scenic America, 983 F. Supp. 2d at 178 (finding organization had standing based on declarations detailing "[c]oncrete examples of the activities that [the

organization] undertakes to oppose" the challenged conduct); PETA, 7 F. Supp. 3d at 8-9 (finding organization had standing based on "two specific, programmatic harms" alleged). Two sentences of general assertions just does not cut it. Given that CRS may well be able to clear this hurdle, the Court will not dismiss the entire case. Instead, it will only dismiss the Complaint and give Plaintiffs thirty days to file an amended one if they so choose. See Ciralsky v. CIA, 355 F.3d 661, 666-67 (D.C. Cir. 2004) (distinguishing between dismissing case and dismissing complaint only).

IV. Conclusion

Because none of the Plaintiffs can satisfy the constitutional requirements for Article III standing, the Court will grant Defendant's Motion to Dismiss, while permitting leave to amend. An Order to that effect will issue this same day.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: April 27, 2018