UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR RESPONSIBLE SCIENCE, **Plaintiff,** **v.** **SCOTT GOTTLIEB,** **Defendant.**	**Civil Action No. 17-2198 (JEB)**

MEMORANDUM OPINION

Before a new pharmaceutical drug can come to market, testing must prove it to be both safe and effective. Plaintiff Center for Responsible Science believes that the Food and Drug Administration's informed-consent regulation governing these initial human tests does not sufficiently warn participants of the dangers they face. CRS thus proposed that the FDA amend its regulation to add three additional disclosures, but the Agency demurred. Plaintiff then turned to the courts. It filed a one-count Complaint under the Administrative Procedure Act against Scott Gottlieb, the FDA's current commissioner, asking the Court to require what CRS could not convince the Agency to adopt. The threshold question — and the one that ultimately trips Plaintiff up — is whether it can invoke this Court's jurisdiction. Once before, this Court found that CRS had failed to sufficiently demonstrate Article III standing, but sent it back to the drawing board instead of dismissing the case. CRS now returns with added detail. Its Amended Complaint, however, still falls short of establishing the organizational injury necessary for this suit to continue. As round two thus yields the same result, the Court will grant Defendant's Motion to Dismiss.

I. Background

Only a brief rehearsal of the facts is necessary to tee up the sole jurisdictional issue at play. For a deeper dive into the governing regulatory scheme and requested disclosures that color this case, the Court directs interested readers to its first Opinion on this issue. See Ctr. for Responsible Sci. v. Gottlieb, 311 F. Supp. 3d 5, 6–8 (D.D.C. 2018).

FDA regulations require that certain information "shall be provided to each subject" of a clinical trial within the Agency's jurisdiction. See 21 C.F.R. § 50.25. Simply put, CRS believes that these disclosures are not enough. It contends that participants should be warned that testing drugs on laboratory animals — which generally precedes clinical trials involving humans — can be a poor predictor of safety and efficacy in human subjects. See ECF No. 17 (Pl. Opp.) at 3–6.

So CRS took action. Armed with its criticism, Plaintiff submitted a Citizen Petition to the FDA in May of 2014 requesting that the Agency amend its disclosure requirements for human subjects in clinical trials to provide three additional warnings. See ECF No. 14 (Am. Compl.), ¶ 37. Paraphrased, these warnings would disclose that prior animal tests may not be predictive of safety in humans and that, in the past, participants died during clinical trials as a result of ingesting the tested drugs. Id., ¶ 40. The warning would also caution participants that the drug may not be effective in treating their condition even if that efficacy was shown in animal-based tests. Id.

Defendant denied the Petition. It reasoned that the requested modification was overbroad, since the disclosures were relevant only to drug trials, but the regulations cover all clinical trials. The FDA also decided that these additions would preclude needed flexibility in informed-consent disclosures. Id., ¶¶ 152, 154.

Unhappy with this response, CRS filed suit under the Administrative Procedure Act. It alleged that the Agency's rejection of its Petition was arbitrary and capricious as well as beyond the FDA's statutory authority. In the first round of this litigation, the Court dismissed Plaintiff's Complaint without reaching the merits of its contention, finding that CRS had not cleared the first hurdle of any suit in federal court: demonstrating Article III standing. Open to the possibility that Plaintiff's deficiency could lie in the inartfulness of its pleading rather than a lack of interest in the case, the Court granted CRS a second bite at the apple and permitted leave to amend. See Ctr. for Responsible Sci., 311 F. Supp. 3d at 10.

CRS now returns with a beefed-up Complaint. It provides the Court with additional detail concerning both its mission and the actions it has taken relevant to the challenged conduct. Established in 2012, Plaintiff is a "non-profit watchdog group" whose mission serves to "promote advances in regulatory science." Am. Compl., ¶ 1. Although its interests are broad ranging, CRS realizes this mission in part by promoting "safer, more effective outcomes during human trials." Id., ¶ 191. To perform this function, it monitors clinical trials for deaths and other serious adverse events and provides education to various stakeholders interested in human test methods. Id., ¶¶ 4, 192. CRS's staff consists of one full-time, salaried employee and one part-time volunteer. Id., ¶ 202.

CRS also provides more detail on the actions that it alleges its employee took in response to the FDA's denial of the Citizen Petition. These actions fall, roughly, into three buckets. First, this employee — Tamara Drake — has been compiling data of adverse events in clinical trials. Id., ¶ 198. Plaintiff does not hide, however, that Drake has long performed this task, dating back to before the denial of the Citizen Petition. See Pl. Opp. at 25–26.

Second, Drake began compiling a list of all clinical trials that were either in the process of recruiting human participants or planned to begin recruiting shortly. See Am. Compl., ¶ 198. Unlike the aggregation of adverse events, she did not begin this task until after the FDA's denial of CRS's Citizen Petition. Id.; Pl. Opp. at 26. Starting in May 2018, approximately one year after the denial of the Citizen Petition, but only two weeks after this Court first dismissed CRS's Complaint for lack of standing, Drake also began contacting the principal investigators of these trials. See Am. Compl., ¶ 198; Pl. Opp. at 27. She urged each investigator to voluntarily adopt the disclosures that the FDA had decided not to require. See Am. Compl., ¶ 198. Only a small percentage of investigators have responded to CRS's outreach efforts. See Pl. Opp. at 27.

Third, and finally, CRS points to public education. Through press releases and other mechanisms (which it has not specified), CRS has notified the public and other stakeholders of the FDA's denial of the Citizen Petition and the "limitations of animal testing." Am. Compl., ¶ 204.

Once again, Defendant has filed a Motion to Dismiss under Rule 12(b)(1) because, the Agency says, CRS's Amended Complaint still does not establish that it has Article III standing. So once more into the breach of organizational standing ventures the Court. This time, like King Henry V's final assault on Harfleur, proves the last. Despite its renewed efforts, CRS's alleged injury does not clear Article III's bar, which precludes it from maintaining this challenge.

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), Plaintiff bears the burden of proving that the Court has subject-matter jurisdiction to hear its claim. 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

The Court begins with an exposition of the nuanced legal test here, before turning to its application.

A. Organizational-Standing Requirements

Not every disagreement merits a lawsuit. Federal courts decide only "cases or controversies," a phrase given meaning by the doctrine of "standing." See Whitmore v. Arkansas, 495 U.S. 149, 154–55 (1990); U.S. Const. art. III. A party's standing "is an essential and unchanging part of the case-or-controversy requirement of Article III." Lujan, 504 U.S. at 560. To have standing, a party must, at a constitutional minimum, meet the following criteria. First, the plaintiff "must have suffered an 'injury in fact' — an invasion of a legally-protected interest which is (a) concrete and particularized . . . and (b) 'actual or imminent, not 'conjectural' or 'hypothetical.'" Id. (internal quotation marks and citations omitted). Second, "there must be a causal connection between the injury and the conduct complained of — the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'" Id. (alterations in original) (citation omitted). Third, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" Id. at 560-61 (citation omitted). A "deficiency on any one of the three prongs suffices to defeat standing." U.S. Ecology, Inc. v. U.S. Dep't of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000). 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).

Organizations can satisfy Article III standing in one of two ways. They can sue either on their own behalf ("organizational standing") or on behalf of their members ("representational standing"). See Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach, 469

F.3d 129, 132 (D.C. Cir. 2006). CRS invokes only the former here. To prevail, consequently, it must show that the organization itself, like any individual plaintiff, satisfies the three familiar elements of standing — (1) injury, (2) causation, and (3) redressability. See Equal Rights Ctr. v. Post Properties, 633 F.3d 1136, 1138 (D.C. Cir. 2011). The sole issue now before the Court is whether CRS has made that required showing.

As this Court noted on the last go round, organizational-standing doctrine in the D.C. Circuit is "not a model of clarity." Ctr. for Responsible Sci., 311 F. Supp. 3d at 9. That said, the Court will do its best to extract from the Circuit's caselaw a cohesive framework to guide its inquiry.

The injury-in-fact requirement garners the most ink because, although the broad contours of this prong are well established, the particulars are less well defined. To satisfy Article III, an organization must allege a "concrete and demonstrable injury to [its] activities." Food & Water Watch, Inc. v. Vilsack, 808 F.3d 905, 919 (D.C. Cir. 2015) (citation omitted). The meaning of this phrase is evident most clearly from its opposite: "a mere setback" to the organization's "abstract social interests is not sufficient." Equal Rights Ctr., 633 F.3d at 1138 (internal quotation marks omitted). Organizations cannot, therefore, establish standing when they seek only to "vindicate their own value preferences through the judicial process." Am. Soc. for Prevention of Cruelty to Animals v. Feld Ent't, Inc. (ASPCA), 659 F.3d 13, 25 (D.C. Cir. 2011) (quoting Sierra Club v. Morton, 405 U.S. 727, 750 (1972)).

In recent years, this Circuit has employed a two-step test to draw this distinction. The Court must ask first "whether the agency's action or omission to act injured the [organization's] interest," and then, if satisfied, whether "the organization used its resources to counteract that harm." People for the Ethical Treatment of Animals v. USDA (PETA), 797 F.3d 1087, 1094

(D.C. Cir. 2015); accord Elec. Privacy Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity, 878 F.3d 371 (D.C. Cir. 2017) (employing same test); Food & Water Watch, Inc. v. Vilsack, 808 F.3d 905, 919 (D.C. Cir. 2015) (same); see also Havens Realty Corp. v. Coleman, 455 U.S. 363, 379 (1982) (finding organizational injury based on an "injury to the organization's activities" followed by "the consequent drain on the organization's resources"). Although, at first blush, this articulation may seem to merely restate the general injury-in-fact requirement in more words, courts have since developed meaningful definitions for both prongs.

Start with the requirement of an injury to the organization's interest. To pass muster under this prong, the challenged conduct must "perceptibly impair[] the organization's ability to provide services." Food & Water Watch, 808 F.3d at 919 (quoting Turlock Irrigation Dist. v. FERC, 786 F.3d 18, 24 (D.C. Cir. 2015)). Said otherwise, it must "inhibit[]" the organization's "daily operations," PETA, 797 F.3d at 1094 — *i.e.*, "ma[k]e the organization's activities more difficult." Nat'l Treasury Emps. Union v. United States, 101 F.3d 1423, 1430 (D.C. Cir. 1996). Articulations of this rule abound, but they all focus on the same point: the organization's tasks must be impeded. See, e.g., Fair Emp't Council of Greater Washington, Inc. v. BMC Marketing Corp., 28 F.3d 1268, 1276 (D.C. Cir. 1994) (finding sufficient that conduct made plaintiff's "overall task more difficult"); Nat'l Veterans Legal Servs. Program v. U.S. Dep't of Def., No. 14-1915, 2016 WL 4435175, at *1 (D.D.C. Aug. 19, 2016) (requiring that challenged conduct "undermine the organization's ability to perform its fundamental programmatic services"). A necessary aspect of this requirement is that there be a "direct conflict between the defendant's conduct and the organization's mission." Abigail Alliance, 469 F.3d at 133. Alone, however, this conflict is insufficient. Id. In this vein, the Court's task is to differentiate between "organizations that allege that their activities have been impeded" — for whom the doors to the

federal courts are open — "from those that merely allege that their mission has been compromised" — against whom the doors swing shut. Id. (emphasis added).

Once this first prong is met, the Court moves on to the second and asks "whether the organization used its resources to counteract that harm." Food & Water Watch, 808 F.3d at 919. Not all uses of resources count, however. For one, resources spent educating the public or the organization's members cannot establish Article III injury "unless doing so subjects the organization to 'operational costs beyond those normally expended.'" Food & Water Watch, 808 F.3d at 920 (quoting Nat'l Taxpayers Union, Inc. v. United States, 68 F.3d 1428, 1434 (D.C. Cir. 1995)). Along a similar axis, the devotion of resources to advocacy for the organization's preferred policy — whether that advocacy is directed at Congress, the courts, or an administrative agency — falls short of the line. See Turlock Irrigation Dist., 786 F.3d at 24 (mentioning "litigation or administrative proceedings" as being insufficient); Nat'l Ass'n of Home Builders v. EPA, 667 F.3d 6, 12 (D.C. Cir. 2011) (mentioning "testifying before the United States Senate" and "submitting comments to the EPA" as being insufficient); Ctr. for Law & Educ. v. Dep't of Educ., 396 F.3d 1152, 1161 (D.C. Cir. 2005) (mentioning lobbying as being insufficient). Similarly, resources spent on, or in anticipation of, litigation cannot establish injury. See Food & Water Watch, 808 F.3d at 919; see also Spann v. Colonial Village, Inc., 899 F.2d 23, 27 (D.C. Cir. 1990) ("An organization cannot, of course, manufacture the injury necessary to maintain a suit from its expenditure of resources on that very suit.").

These injuries are "self-inflicted" and thus insufficient for Article III purposes. See, e.g., Abigail Alliance, 469 F.3d at 133. At times, courts have expanded the boundary encompassing such injuries (and thus precluding standing) beyond the three categories of costs already mentioned — namely, normal-course educational initiatives, certain advocacy costs, and

litigation expenses. See Elec. Privacy Info. Ctr., 878 F.3d at 378–79 (finding that plaintiff organization's use of resources "to focus public attention on emerging privacy and civil liberties issues" was a "self-inflicted budgetary choice" insufficient for Article III); BMC Marketing, 28 F.3d at 1276 (finding that "diversion of resources for testing" — *i.e.*, sending individuals to determine whether employer discriminated on basis of race — was "self-inflicted" result of plaintiff's "own budgetary choices" and did not confer standing). This category, however, has limits. The D.C. Circuit has made clear that an injury is not a "self-inflicted budgetary choice" merely by virtue of having been made willfully or voluntarily. See Equal Rights Ctr., 633 F.3d at 1140. Rather, as long as the organization expended resources "in response to, and to counteract, the effects of the defendant['s]" challenged conduct, that diversion can suffice for Article III purposes. Id.

To sum up then: an organization seeking to bring a case in its own right must first allege that the challenged conduct perceptibly impairs its activities, as opposed to merely frustrating its mission, and then must show that it expended resources — beyond those normally carried out to advance such mission — to address that impairment.

The discussion is not yet complete. The preceding saga lays out only the required showing under the injury-in-fact prong of Article III standing for an organizational plaintiff. But the flagging reader need not despair, for not much need be said about the two following prongs. The tests for causation and redressability mirror, with little added gloss, the requirements for a non-organizational plaintiff who attempts to invoke the jurisdiction of the federal courts. Just as outside the organizational-standing context, a plaintiff must show that its injury is "fairly traceable to the defendant's allegedly unlawful conduct." ASPCA, 659 F.3d at 24. It must also be "likely" that the injury would be "redressed by a favorable court decision." Id.; see also

Scenic Am., Inc. v. U.S. Dep't of Transp., 836 F.3d 42, 50–51 (D.C. Cir. 2016) (holding that organizational plaintiff failed redressability prong of standing).

B. Application to CRS

With the territory charted, the Court can now turn to the task of situating this case within that landscape. Although CRS primarily presses one argument — namely, that it is injured because it has turned its attention to urging principal investigators to provide the warnings that the FDA refused to require — two other allegations of injury still linger within the Amended Complaint. To get to the root of the issue, the Court thus first clears away this underbrush. CRS's focus, as it turns out, is prudent: neither of these two other allegations requires much more than a passing glance.

First up is Plaintiff's point in the Amended Complaint that, as a consequence of the FDA's denial of its Citizen Petition, CRS has been "forced to pay its one full-time employee to spend significant time identifying and aggregating data on clinical trials in which there have been deaths and serious adverse events." Am. Compl., ¶ 198. The Government posits that this activity cannot possibly serve as CRS's injury-in-fact. See ECF No. 16 (Def. MTD) at 15–16; ECF No. 18 (Def. Reply) at 4–6. Its ink, however, ultimately need not have been spilled: the parties are in agreement here. In its Opposition, CRS eschews any reliance on "compiling the chart of clinical treatment-related deaths" as the basis for its Article III injury. See Pl. Opp. at 42. This concession is logical. Nowhere in its Amended Complaint (or Opposition, for that matter) does CRS sufficiently draw out the connection between the FDA's conduct and CRS's action. Plaintiff does not allege, for instance, that there would be fewer adverse events in clinical trials if investigators provided warnings about the limitations of animal testing. Nor is it intuitively clear why that would be the case. With this gap in the logical chain, the Court is

unable to conclude that CRS's actions are "in response to, and to counteract the effects of" Defendant's challenged conduct. See Equal Rights Ctr., 633 F.3d at 1140. Indeed, Plaintiff's brief, with refreshing honesty, makes clear that its employee engaged in this activity well before the FDA denied its Citizen Petition. See Pl. Opp. at 25–26.

CRS's allegation of injury stemming from its public-education initiatives, although not conceded, fares no better. Plaintiff asserts that it has diverted resources "to notifying the public and other stakeholders, through press releases and other mechanisms, of the denial of the Petition and the limitations of animal testing." Am. Compl., ¶ 204. Such activity, however, can only constitute an injury-in-fact if it subjects the organization to "'operational costs beyond those normally expended' to carry out its advocacy mission." Nat'l Ass'n of Home Builders, 667 F.3d at 12 (quoting Nat'l Taxpayers Union, 68 F.2d at 1434). This is where the argument stumbles. CRS's self-described advocacy mission includes "provid[ing] education to various stakeholders regarding the availability of human-relevant tests methods." Am. Compl., ¶ 192. The educational campaign here appears part and parcel of that mission, and the record indicates that the current activity does not extend beyond what it does in the normal course.

For instance, the Government points out, and Plaintiff does not dispute, that CRS engaged in various public-education initiatives regarding the limitations of animal testing well before the denial of the Citizen Petition. See Def. MTD at 17–18; Def. Reply at 13–14. Of course, any notification about the denial of the Citizen Petition occurred after the actual denial. But the general rule is that such additional notifications, when consistent with the organization's advocacy mission, cannot alone confer standing. See Food & Water Watch, 808 F.3d at 920 (rejecting as insufficient plaintiff's assertion that it "would have to increase the resources that it spends on educating the general public and its members" regarding the effect of the challenged

agency action); Nat'l Taxpayers Union, 68 F.3d at 1434 (holding that organization's "self-serving observation that it has expended resources to educate its members and others regarding [the challenged law] does not present an injury in fact"). CRS's only response is to allege generally that it "divert[ed] its resources" to engage in this public-education campaign. See Am. Compl., ¶ 204. That is not enough. Such a conclusory statement cannot save the day when the record reveals the educational campaign at issue to be functionally similar to the organization's normal-course campaigns independent of the challenged conduct.

With those two asserted injuries out of the way, the Court can turn to the allegation with the most meat, and the one that CRS urges most actively. Plaintiff alleges that its sole full-time employee has turned her attention to finding clinical trials that are (or are soon to be) recruiting participants and urging the principal investigators of such trials to adopt the disclosures that the FDA refused to require by denying the Citizen Petition. See Am. Compl., ¶ 198; Pl. Opp. at 35. CRS says that this activity has precluded the employee from undertaking a variety of other initiatives — unrelated to animal-testing disclosures — that it would like her to pursue. See Am. Compl., ¶¶ 206–11.

Plaintiff's argument — *i.e.*, that it has diverted its organizational resources to picking up the slack left from the FDA's desertion of its duties — holds some intuitive appeal. Running this argument through the two-step test articulated by the D.C. Circuit, however, leaves no room for intuition. Simply put, it does not clear the first hurdle.

It is settled law in this Circuit that an organizational plaintiff must first show that the challenged conduct made its activities more difficult. See, e.g., PETA, 797 F.3d at 1094; Food & Water Watch, 808 F.3d at 919. As its Amended Complaint expounds, now in considerable detail, CRS engages in a number of educational and advocacy initiatives. See Am. Compl.,

¶¶ 186–92. Satisfying standing thus requires that Plaintiff show that its ability to engage in these tasks has been impaired. This CRS has not done. Nowhere does Plaintiff satisfactorily explain how, as a result of the FDA's denial of the Citizen Petition, it has become "more difficult" for CRS to perform any of these educational or advocacy operations. See BMC Marketing, 28 F.3d at 1276; see also PETA, 797 F.3d at 1094 (requiring that challenged conduct "inhibit[]" the organization's "daily operations").

CRS offers two responses. It first points out that Drake (Plaintiff's sole employee) must now urge principal investigators of clinical trials to adopt the disclosures. See Pl. Opp. at 35, 38; Am. Compl., ¶¶ 198–203. This activity has been made more difficult, CRS says, for had the FDA required the disclosures CRS wants, there would be no need for Drake's endeavors. See Am. Compl., ¶ 203. Second, CRS switches gears and contends that the challenged conduct instead inhibits Plaintiff's other advocacy initiatives — unrelated to disclosures about animal testing in drug trials — that it planned to pursue absent the FDA's action. See Pl. Opp. at 35, 38; Am. Compl., ¶¶ 206–12. The Court addresses each argument in turn.

Start with the timeline underlying Plaintiff's alleged injury. Driven by its mission, CRS filed a Citizen Petition seeking to codify certain disclosures within the FDA's informed-consent regulations. When the Agency refused, Plaintiff took up the mantle and began directly urging investigators to include these disclosures. Nowhere in this account does CRS allege any activity predating the denial of its Citizen Petition that is made more difficult by the denial of the Petition. At the time of the FDA's denial, the only item impaired was CRS's desire that human participants in clinical trials be given information about the limitations of animal testing. Without more, that is not enough because a "conflict between a defendant's conduct and an organization's mission is alone insufficient to establish Article III standing." Nat'l Treasury

Employees, 101 F.3d at 1429. To borrow applicable language from another district court analyzing this same body of law, "[i]t is clear from the Circuit's holdings . . . that having a concrete injury to an organization's interests means that the challenged activity must hamper the organization's ability to do what it does, and that complaining that the organization's ultimate goal has been made more difficult is not sufficient." New England Anti-Vivisection Soc'y v. United States Fish & Wildlife Serv., 208 F. Supp. 3d 142, 166 (D.D.C. 2016) (internal citations omitted).

Turning next to the post-denial conduct — *i.e.*, Drake's efforts at contacting clinical trials — it would seem anomalous for a party to be able to build a program in response to an agency's action, then achieve Article III standing by alleging that the agency's action impaired that program's operation. It is not at all clear, moreover, that the FDA's action does, in fact, inhibit Plaintiff's activity in the manner intended by the D.C. Circuit. CRS does not allege, for instance, that it is "deprived . . . of key information" necessary to urge investigators to adopt the desired disclosures. See PETA, 797 F.3d at 1091. Nor does it contend that the FDA's action cuts off a means of performing this task. Id. Defendant's conduct may create a need for CRS's program; it does not make the program more difficult. In sum, the Agency's denial of the Citizen Petition has no doubt frustrated CRS's goal that every clinical participant receive a warning about the limitations of animal testing, but it has not impeded Plaintiff's ability to engage in its advocacy and educational functions.

But wait, retorts CRS: its activities have been impeded because it has diverted resources away from other functions it would like to perform. These functions, it says — including, among other things, initiatives regarding skin sensitization and eye irritation and a new petition demanding FDA transparency — have thus been thwarted.

This second argument also lands wide of the mark. Plaintiff confuses the two prongs of the injury-in-fact inquiry. That CRS has diverted resources (in the form of Drake's time) is certainly relevant to step two — "whether the organization used its resources to counteract that harm," Food & Water Watch, 808 F.3d at 919 — but comes into play only after Plaintiff shows an initial impairment to its programs. Put otherwise, an organization can only divert resources to counteract "that harm" once there is a harm to counteract. The diversion itself cannot alone constitute the harm. Holding otherwise would be hopelessly circular. The law here, too, is clear: organizational standing is not based on "diversion of resources from one program to another, but rather on the alleged injury that the defendants' actions themselves had inflicted upon the organization's programs." BMC Marketing, 28 F.3d at 1277 (interpreting Havens Realty, 455 U.S. at 379); cf. Int'l Acad. of Oral Medicine & Toxocology v. U.S. FDA, 195 F. Supp. 3d 243, 257 (D.D.C. 2016) ("[A] diversion-of-resources injury does not count for Article III purposes where 'the only service impaired is pure issue advocacy.'") (quoting Ctr. for Law & Educ., 396 F.3d at 1162). Plaintiff must show, therefore, that something about the challenged action itself — rather than the organization's response to it — makes the organization's task more difficult. Cf. New England Anti-Vivisection Soc'y, 208 F. Supp. 3d at 163 (holding that "organizational standing requires more than a sincere and strong objection to the challenged government action and a stated intention to use the organization's resources to oppose it").

One factual point bears mentioning. In the controlling cases in which courts have found organizational standing satisfied, the activity impaired and the conduct challenged bore a close connection. For example, in Havens Realty, housing discrimination impaired the organization's counseling and referral services for homeseekers. See 455 U.S. at 379. In PETA, the USDA's refusal to apply an animal-welfare statute to birds impeded PETA's educational and advocacy

initiatives on behalf of birds. See 797 F.3d at 1094. That is not the case here. CRS's argument attempts to connect the FDA's refusal to amend informed-consent regulations regarding the limitations of animal testing to initiatives having nothing to do with these regulations. See Am. Compl., ¶ 211. Its thwarted initiatives include "a petition and guidance related to skin sensitization" and "an amendment to a skin and eye irritation petition to include a discussion of new technology." Id. In other words, Plaintiff presents a pure diversion case. This, too, separates CRS from the territory controlling law has deemed sufficient for organizational standing.

Placing this case within the factual contexts charted by past cases further confirms the Court's conclusion. In PETA, for example, the Court of Appeals hinged its standing decision on two harms directly attributable to the challenged conduct. The court concluded that USDA's refusal to apply an animal-welfare statute to birds — the action challenged by PETA — "deprived PETA of key information that it relies on to educate the public" and thus directly impeded PETA's ability to perform its public-education services. See 797 F.3d at 1094. Similarly, USDA's refusal precluded PETA from "filing complaints with the USDA," which cut off a means by which PETA advanced its mission. Id. at 1097. CRS makes no such allegation here: as mentioned above, the FDA's refusal does not limit any flow of information or means of redress.

Along the same line, in the bulk of cases satisfying organizational standing, the plaintiff organization engaged in direct services to individuals that were made more difficult by the challenged action. See, e.g., Havens Realty, 455 U.S. at 379; Abigail Alliance, 469 F.3d at 132–33; BMC Marketing, 28 F.3d a 1276. Here, however, CRS provides no such direct services and thus cannot claim that the FDA's denial of the Citizen Petition impaired its daily operations in

the same manner as this line of cases. If CRS had alleged, for example, that it provided direct services to clinical participants — perhaps, for example, by providing some independent review of each trial to these members or clients — this might be a different case.

Instead, the cases in which courts have failed to find standing more closely track the circumstances here. In Food & Water Watch, for example, the D.C. Circuit rejected as insufficient the plaintiff's claim that, following the FDA's refusal to provide particular poultry-inspection services, it would "increase the amount of resources that it spends encouraging its members . . . to avoid poultry" that had been subject to an insufficient inspection. See 808 F.3d at 920. In that case, like this one, the organization directed its resources to mitigating a risk that it thought the government should have exercised more diligence in preventing. District courts in this Circuit have similarly and repeatedly concluded that a mere diversion of resources to advance the advocacy mission of an organization is insufficient to confer standing. See, e.g., Cigar Ass'n of Am. v. U.S. Food & Drug Admin., 323 F.R.D. 54 (D.D.C. 2017); New England Anti-Vivisection Soc'y, 208 F. Supp. 3d at 165–66; Nat'l Veterans Legal Servs. Program, 2016 WL 4435175, at *1. Given this law, the Court sees its conclusion as inescapable: CRS does not allege a constitutionally sufficient injury-in-fact to invoke jurisdiction. Its claim cannot proceed.

Adding a belt to these suspenders, the Court also has reservations about Plaintiff's assertion of causation. After losing the first round, CRS apparently went back to the drawing board not only to add detail to its Complaint, but also to review the actions it could take to allege standing. Plaintiff, again with appreciated candor, admits that it did not start contacting principal investigators until May 2018 — over a year after the denial of the Citizen Petition, yet a mere two weeks after this Court dismissed its Complaint but granted leave to add further detail about the actions CRS took in response to the Agency's challenged conduct. See Ctr. for Responsible

Sci., 311 F. Supp. 3d at 10; Pl. Opp. at 27. This timing casts a dark shadow over CRS's allegation that its conduct is "fairly traceable" to the challenged action of Defendant — *i.e.*, the denial of the Citizen Petition, as opposed to the Court's granting of the FDA's initial motion to dismiss.

With that, this challenge comes to an end. In its first Opinion, the Court noted that "at a minimum, the organization must allege that discrete programmatic concerns are being directly and adversely affected by the agency's inaction." Ctr. for Responsible Sci., 311 F. Supp. 3d at 9 (internal quotation marks and alterations omitted). Even on this second round, such deficiency still lingers.

IV. Conclusion

For these reasons, the Court will grant Defendant's Motion to Dismiss. A separate Order so stating will issue this day.

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

Date: October 22, 2018