

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND**

PEOPLE FOR THE ETHICAL  
TREATMENT OF ANIMALS, INC.,

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Plaintiff,

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v.

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Civil Action No. 8:21-cv-02413-PX

LAWRENCE TABAK, *et al.*,

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Defendants.

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**MEMORANDUM OPINION**

Pending before the Court is the motion to dismiss filed by Defendants Lawrence Tabak, in his official capacity as Director of the National Institutes of Health; the National Institutes of Health (“NIH”); Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and the United States Department of Health and Human Services (“HHS”). ECF No. 36.<sup>1</sup> The motion is fully briefed, and no hearing is necessary. *See* D. Md. Loc. R. 105.6. For the following reasons, the Court GRANTS in part and DENIES in part Defendants’ motion.

**I. Background<sup>2</sup>**

Plaintiff People for the Ethical Treatment of Animals, Inc. (“PETA”) is a non-profit organization “dedicated to protecting animals from abuse, neglect, and cruelty.” ECF No. 1 ¶ 12. PETA’s mission includes reducing the number of animals harmed in clinical research. *Id.* ¶ 13.

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<sup>1</sup> The docket erroneously names Attorney General Merrick Garland and former Acting United States Attorney Jonathan Lenzner as defendants. The Court directs the Clerk to remove these individuals from the docket. Additionally, Defendants’ corrected memorandum in support of the motion appears to be filed on behalf of Tabak, Becerra, and the NIH, although the motion refers generically to “Defendants.” ECF Nos. 36 & 39-1 at 3. The Court construes the motion as pursued on behalf of all Defendants, including HHS.

<sup>2</sup> The Court construes the averred facts in the light most favorable to Plaintiffs. *Ibarra v. United States*, 120 F.3d 472, 474 (4th Cir. 1997).

PETA carries out this mission through public education, investigations, protest campaigns, and direct advocacy to government agencies and private researchers. *Id.* ¶¶ 12–13, 19–24.

Pertinent to this lawsuit, PETA has devoted resources to challenging NIH’s funding of animal-involved research. *Id.* ¶¶ 23–26. NIH, an agency falling under HHS, is authorized under the Public Health Service Act (“PHSA”) to award grants for research into the treatment and prevention of “physical and mental diseases and impairments of man.” *Id.* ¶¶ 34–36; 42 U.S.C. § 241(a). The Act requires that research funded by NIH be subject to “appropriate technical and scientific peer review,” as defined by the PHSA’s implementing regulations. ECF No. 1 ¶ 37; 42 U.S.C. § 289a(a)(1). Under these regulations, NIH must consider several “pertinent factors” during the peer review process. These include “the adequacy of the approach and methodology proposed to carry out the research,” the “innovativeness and originality of the proposed research,” and the “adequacy of the proposed protection for . . . animals.” ECF No. 1 ¶ 42; 42 C.F.R. § 52h.8.

For several decades, NIH has funded animal-involved research designed to study the disease pathway of human sepsis, a bacterial infection that kills roughly 270,000 Americans each year. ECF No. 1 ¶¶ 48, 53. Many research studies involve injecting live mice with toxins by puncturing their abdomens, causing the animals great pain and suffering. *Id.* ¶¶ 55–57. The efficacy of these sepsis studies, however, has been seriously called into question. Over the last 18 years, at least fifteen peer-reviewed studies have taught that mice are a poor substitute for human pathophysiology of sepsis. *Id.* ¶ 67. One study, published in 2013, concluded that sepsis treatments developed for mice universally failed when administered to humans. *Id.* ¶ 60. In 2019, an NIH working group tasked with considering the broader applicability of mice studies determined that such studies raised “substantial doubt in the broader scientific community”

because the human disease progression for sepsis differs fundamentally from other animals, rendering animal-based studies of limited applicability. *Id.* ¶¶ 67–68. Despite this, NIH continues to fund sepsis research using mice. *Id.* ¶¶ 71, 77–95.

Prior to this lawsuit, PETA challenged NIH’s funding of animal-based sepsis studies in several ways. For example, PETA has created and disseminated public education materials designed to explain how NIH’s experiments harm the animal subjects with no utility to humans. *Id.* ¶¶ 23, 25. PETA has also engaged in direct advocacy, pressing NIH to discontinue funding sepsis studies that harm mice. *Id.* ¶ 23. In one letter, authored on October 23, 2019, PETA laid out recent research that called into question the efficacy of these experiments. *Id.* ¶ 72. Three weeks later, on November 14, 2019, NIH responded that it would take PETA’s position under “further advisement,” but, at present, it viewed the mice-involved experiments as valuable for what the studies might “teach us.” *Id.* ¶ 73. Since that exchange, NIH has funded at least five specific mice-involved sepsis studies. *Id.* ¶¶ 77–94.

On September 20, 2021, PETA filed suit challenging NIH’s decisions to continue funding animal-involved sepsis studies as arbitrary and capricious final agency actions, in violation of the Administrative Procedure Act (“APA”), 5 U.S.C. § 706(2)(A). *Id.* ¶ 76. The Complaint specifically avers that grants issued since PETA’s October 23, 2019 letter, including five specific grants identified in the Complaint, constitute arbitrary and capricious final agency actions because the approval process failed to follow the pertinent regulatory criteria. *Id.* ¶ 96. More broadly, the Complaint avers that NIH’s response to PETA’s letter, in which NIH suggested some unspecified utility in animal-based studies, constitutes an “ongoing policy, pattern and practice” of unlawful APA action. *Id.* ¶ 98.

On April 21, 2022, Defendants moved to dismiss the action pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of standing, and in the alternative, for failure to state a claim under Rule 12(b)(6). *Id.* The motion is fully briefed and so the Court first turns, as it must, to the question of standing.

## **II. Standing**

### **A. Standard of Review**

A motion to dismiss for lack of standing implicates this Court's subject matter jurisdiction. *Beyond Sys., Inc. v. Kraft Foods, Inc.*, 777 F.3d 712, 715 (4th Cir. 2015). The plaintiff bears the burden of establishing subject matter jurisdiction. *Lovern v. Edwards*, 190 F.3d 648, 654 (4th Cir. 1999). If "a claim fails to allege facts upon which the court may base jurisdiction," the court must dismiss the action. *Davis v. Thompson*, 367 F. Supp. 2d 792, 799 (D. Md. 2005).

In determining whether jurisdiction exists, "the court may look beyond the pleadings and the jurisdictional allegations of the complaint and view whatever evidence has been submitted on the issue . . . ." *Khoury v. Meserve*, 268 F. Supp. 2d 600, 606 (D. Md. 2003) (quoting *Capitol Leasing Co. v. FDIC*, 999 F.2d 188, 191 (7th Cir. 1993)) (internal quotation marks omitted). Where the defendant contends that the complaint "simply fails to allege facts upon which subject matter jurisdiction can be based," the Court construes the complaint facts as true and most favorably to the plaintiff. *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982). Whether the Court retains subject matter jurisdiction must be decided before reaching the merits of the case. *Jones v. Am. Postal Workers Union*, 192 F.3d 417, 422 (4th Cir. 1999).

## B. Analysis

Defendants first contend that the Complaint must be dismissed because PETA has not suffered a concrete and particularized injury sufficient to confer standing to sue in this Court. ECF No. 39-1 at 17.<sup>3</sup> Pursuant to Article III of the United States Constitution, federal courts have limited jurisdiction, hearing only live “Cases” and “Controversies.” U.S. Const. art. III, § 2. A party’s standing to maintain an action “is an essential and unchanging part of the case-or-controversy requirement of Article III.” *Davis v. FEC*, 554 U.S. 724, 733 (2008) (citations omitted). Where, as here, standing is challenged at the motion to dismiss stage, the Court must “accept as true all material allegations of the complaint and construe the complaint in favor of the complaining party.” *David v. Alphin*, 704 F.3d 327, 333 (4th Cir. 2013). To establish standing, the plaintiff must demonstrate that “(1) it has suffered an ‘injury in fact’ that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000).

When an organization sues on its own behalf, as PETA does here, it may establish an injury in fact by showing that defendants’ actions caused “concrete and demonstrable injury to the organization’s activities,” with a “consequent drain on the organization’s resources.” *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). An organization cannot meet the injury-in-fact requirement simply because it *chose* to divert resources to educate its members or challenge

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<sup>3</sup> PETA has requested permission to file a motion to strike several exhibits that Defendants attached to their motion and reply brief. ECF No. 60. Defendants contend that these exhibits should be considered in resolving whether PETA maintains organizational standing. ECF No. 62. But the exhibits seem to challenge the scientific validity of the studies described in the Complaint that question the utility of mice-involved sepsis research. Accordingly, the exhibits speak to the merits of PETA’s claims, not whether PETA has averred plausibly a sufficient injury in fact to confer standing. For this reason, the exhibits do not aid the Court in its standing analysis, but the Court does not need the parties to formally brief whether the exhibits should be stricken from the record.

an unlawful action in litigation, as such efforts result “not from any actions taken by the defendant, but rather from the organization’s own budgetary choices.” *Lane v. Holder*, 703 F.3d 668, 675 (4th Cir. 2012) (internal quotations and alterations omitted); *see also Nat’l Fed’n of the Blind, Inc. v. Wal-Mart Assocs., Inc.*, 566 F. Supp. 3d 383, 395 (D. Md. 2021) (Plaintiffs’ injury was insufficient because it stemmed “exclusively from the costs associated with the instant lawsuit.”). However, where “defendant’s actions impede [an organization’s] efforts to carry out its mission” and the organization must divert resources to counteract that harm, the organization has standing to sue. *Lane*, 703 F.3d at 675; *see also Havens Realty*, 455 U.S. at 379.

Applying well established precedent in *Havens Realty* and *Lane*, the Fourth Circuit recently held that PETA satisfied the injury-in-fact requirement necessary to sue a roadside zoo for violations of the Endangered Species Act. *See PETA v. Tri-State Zoological Park of W. Md., Inc.*, 843 F. App’x 493, 496 (4th Cir. 2021). In *Tri-State*, PETA alleged that the defendant zoo had so mistreated the protected species as to constitute a “take” under the statute, and that such unlawful mistreatment frustrated PETA’s mission to protect animals from abuse. *Id.* PETA averred in the complaint, and demonstrated at trial, that it had to divert its resources to combat the public misperception that the zoo had taken appropriate care of the animals. *Id.* PETA also used its resources to complain to the relevant government agencies regarding the zoo’s poor practices, and to investigate and monitor the zoo’s misconduct. *Id.* Collectively these efforts frustrated PETA’s “ability to engage in mission-related campaigns against other zoos.” *Id.*

This Court concluded in *Tri-State* that PETA had established sufficient injury in fact to confer organizational standing, *PETA v. Tri-State Zoological Park of W. Md., Inc.*, 424 F. Supp. 3d 404, 430 (D. Md. 2019), and the Fourth Circuit agreed, *Tri-State*, 843 F. App’x at 496. Critically, the Fourth Circuit reasoned that PETA’s claimed injury did not stem solely from

litigation costs. *Id.* at 497 (citing *Lane*, 703 F.3d at 675). Rather, PETA sued to redress the ongoing injury caused by Defendants’ frustration of its mission and the consequent diversion of resources that it had suffered apart from litigation. *Id.*

The Complaint plausibly avers a similar injury here. Contrary to Defendants’ assertions, PETA has made plausible that Defendants’ funding of animal-involved sepsis research without regard to the applicable PHSA regulations frustrates PETA’s overall mission by subjecting more animals to needless pain and suffering. PETA has necessarily expended resources in an effort to convince the agency to cease funding such studies and adhere to the applicable regulatory criteria. ECF No. 1 ¶¶ 23–26. PETA specifically has organized public pressure campaigns against NIH, written letters to NIH officials trying to convince them to deny funding, and published literature to rectify the misperception that NIH’s grants do not fund research that harms animals. *Id.* Accordingly, PETA has been forced to “divert resources away from other animal-protection projects in order to devote these resources to educating the public about and advocating for the cessation of” animal-involved sepsis experiments. *Id.* ¶ 26. This is precisely the sort of mission-driven diversion of resources that the Fourth Circuit found sufficient to establish an organizational injury in *Tri-State*. See *Tri-State*, 843 F. App’x at 496 (citing *Havens Realty*, 455 U.S. at 379).

Defendants’ efforts to distinguish *Tri-State* from this case are unavailing. Defendants maintain that in *Tri-State*, the defendants had been directly harming animals, whereas here Defendants are merely funding third parties whose experiments allegedly harm the animals. ECF No. 57 at 11. This distinction does not alter the injury-in-fact analysis. Defendants and the grant recipients are partners in causation—the researchers conduct the experiments made possible because of Defendants’ funding. That PETA chooses only to sue Defendants for

alleged violations of the APA does not undermine that PETA has diverted significant resources to thwart NIH's frustration of its mission to protect animals. This is sufficient to satisfy organizational standing.

Defendants alternatively claim the Complaint fails make plausible how the alleged wrongdoing is both traceable to PETA's alleged injury and redressable through this litigation. ECF No. 39-1 at 22. Traceability and redressability "rise or fall together," and thus are best addressed jointly. *Friends for Ferrell Parkway, LLC v. Stasko*, 282 F.3d 315, 323 n. 1 (4th Cir. 2002). Traceability requires a plaintiff to make plausible that the alleged injury "was caused by the challenged conduct of the defendant, and not by the independent actions of third parties not before the court." *Id.* at 320. To establish redressability, Plaintiff must allege that it is "likely, and not merely speculative" that the requested relief will redress its injuries. *Id.*

Here, the alleged injury is directly traceable to Defendants' approval of the grants because NIH funding enables the research that causes harm to animals. Accordingly, if PETA prevails in this case and obtains an injunction that restricts NIH funding of animal sepsis experiments, PETA's injury would be redressed. That PETA's success in this lawsuit may not halt *all* animal-involved sepsis experiments is beside the point: PETA's alleged injury does not stem from experimentation on animals *in general*, but rather from Defendants' decision to fund animal-involved sepsis research. ECF No. 39-1 at 24; *see Massachusetts v. EPA*, 549 U.S. 497, 525 (2007) (Plaintiff "need not show that a favorable decision will relieve his *every* injury."). Thus, viewing the Complaint in the light most favorable to PETA, the Court concludes that PETA has alleged sufficient facts to establish organizational standing. Defendants' motion to dismiss for lack of subject matter jurisdiction is denied.<sup>4</sup>

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<sup>4</sup> Defendants argue—in a footnote and without analysis—that PETA's claims alternatively should be dismissed for lack of prudential standing because PETA's alleged harms do not satisfy the "zone of interests" test. ECF No. 39-1



The Court next turns to whether the Complaint sufficiently states a cause of action under the APA.

### III. Failure to State a Claim

#### A. Standard of Review

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the complaint. *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006). The Court accepts “the well-pled allegations of the complaint as true,” and construes all facts and reasonable inferences most favorably to the plaintiff. *Ibarra*, 120 F.3d at 474. To survive a motion to dismiss, a complaint’s factual allegations “must be enough to raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). The Court must be able to deduce “more than the mere possibility of misconduct”; the facts of the complaint, accepted as true, must demonstrate that the plaintiff is entitled to relief. *Ruffin v. Lockheed Martin Corp.*, 126 F. Supp. 3d 521, 526 (D. Md. 2015) (quoting *Iqbal*, 556 U.S. at 679), *aff’d in relevant part*, 659 F. App’x 744 (4th Cir. 2016).

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at 24 n. 13; *see also* ECF No. 57 at 11–12 (brief treatment of prudential standing in reply). The “zone of interests” test is not jurisdictional, but rather asks whether plaintiff can maintain a cause of action under the statute. *See Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n. 4 (2014). Given that Defendants only raise this issue in passing, the Court need not address it in depth. But the Court nonetheless concludes that PETA’s interests in protecting animals are protected by the peer review requirements of the PHSA. 42 U.S.C § 289a(a)(1). Animal protection is “arguably” amongst “the purposes implicit” in the PHSA’s peer review requirements. *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012). This is demonstrated by the fact that Section 289a(a)(1)’s implementing regulations require consideration of animal protection, 42 C.F.R. § 52h.8, and that a separate PHSA provision requires NIH to prepare a plan for reducing the use of animals in research and the pain caused to animals during such research, 42 U.S.C. § 283e(a)(1). Accordingly, PETA has satisfied the “not ‘especially demanding’” requirements of the zone of interests test. *Lexmark Int’l*, 572 U.S. at 130 (citing *Patchak*, 567 U.S. at 225).

## B. Analysis

Defendants first maintain that the Complaint fails to identify any “final agency action,” as needed to state a valid APA claim. The APA provides a right to judicial review of any “final agency action for which there is no other adequate remedy in a court.” 5 U.S.C. § 704.

Defendants specifically argue that grants which have not been awarded, or for which funding has not been disbursed, do not constitute final agency actions. ECF No. 39-1 at 30.

Defendants’ argument misses the mark. The APA defines the “grant of money” as agency action. 5 U.S.C. § 551. An agency action is considered final when it marks the “consummation of the agency’s decisionmaking process” and determines “legal consequences.” *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (internal quotations and alterations omitted). Accordingly, NIH’s decision to approve the grant is the “consummation of the agency’s decisionmaking process” that is of sufficient “legal consequence[.]” to make the action “final” under the APA. *Id.* Put simply, it is NIH’s final decision to award the grant to a particular study that determines the consequences to the parties, not when the agency parts company with the funding itself. *Cf. Planned Parenthood of N.Y.C., Inc. v. U.S. Dep’t of Health and Human Servs.*, 337 F. Supp. 3d 308, 328 (S.D.N.Y. 2018).

Here, the Complaint enumerates five mice-involved studies for which NIH awarded grants. ECF No. 1 ¶¶ 77–94. Each study allegedly involves harming the mice in a manner unnecessary to the advancement of sepsis research, and so, in plain contravention of the PHSA regulations. *Id.* Because NIH has “awarded” each grant, it has taken final agency action, and so the allegations involving these grants survive challenge.

Apart from the five named grants, however, the Complaint allegations sweep too broadly. Count One also challenges any “approvals of grants to conduct sepsis experiments on animals

since October 23, 2019.” ECF No. 1 ¶ 96. Similarly in Count Two, the Complaint alleges as an APA violation “NIH’s ongoing policy, pattern and practice,” as reflected in the agency’s written response to PETA’s October 23, 2019 letter. ECF No. 1 ¶ 98. But as a matter of law, the Court cannot construe a generalized description of a potential course of conduct as a final agency action. “‘Agency action’ not only has a limited meaning, but it also must be ‘circumscribed [and] discrete,’ as those characteristics are inherent in the APA’s enumeration of the categories of agency action subject to judicial review . . . .” *Vill. of Bald Head Island v. U.S. Army Corps of Eng’rs*, 714 F.3d 186, 194 (4th Cir. 2013) (quoting *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 62 (2004)). By contrast, where the challenged conduct is so broad as to encompass the agency’s day-to-day decisions, it invites the type of roving judicial review that “the Supreme Court has explicitly held the APA does not authorize.” *Id.*

To the extent PETA intends in Count One to pursue a “catch all” claim for any possible animal-involved sepsis research grants apart from the five specific grants, the claim fails as a matter of law. Similarly, the generalized allegation in Count Two for a “pattern and practice” claim premised on NIH’s commitment only to take PETA’s concerns “under advisement” is so vague and nonspecific that it cannot survive challenge. These averments, devoid of particularity, would impermissibly invite this Court to sit in review on all grant decisions for sepsis-related research involving animals. *Id.* Accordingly, the claims challenging grantmaking generally, without more, will be dismissed for failure to plausibly identify a sufficiently circumscribed and discrete final agency action.

Defendants separately contend that NIH grant approvals are unreviewable because they are “committed to agency discretion by law.” 5 U.S.C. § 701(a)(2); *see* ECF No. 39-1 at 26. Presumptively, the APA permits judicial review of final agency action. *Weyerhaeuser Co. v.*

*U.S. Fish and Wildlife Serv.*, 139 S. Ct. 361, 370 (2018) (citing *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140 (1967)). But challenged agency decisions “committed to agency discretion by law” are beyond the reach of such review. 5 U.S.C. § 701(a)(2). That said, the exception must be read “quite narrowly,” *Weyerhaeuser*, 139 S. Ct. at 370; it is confined to “those rare circumstances where the relevant statute is drawn” in such a manner that the “court would have no meaningful standard against which to judge the agency’s exercise of discretion.” *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993) (internal alterations and citations omitted). Further, even where an underlying statute does not include meaningful standards by which the agency action may be measured, implementing regulations “can provide standards for judicial review.” *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 346 (4th Cir. 2001) (quoting *CC Distribs., Inc. v. United States*, 883 F.2d 146, 154 (D.C. Cir. 1989)).

Defendants maintain that the PHSA and its implementing regulations are simply too broad and vague to provide the Court meaningful guidance. ECF No. 39-1 at 27. The Court disagrees. The PHSA requires that NIH’s grant approval process include “appropriate technical and scientific peer review,” as defined by regulation. 42 U.S.C. § 289a(a)(1). The regulations, in turn, require NIH to consider such factors as the “adequacy of the approach and methodology” of the research, its “innovativeness and originality,” and the “adequacy of the proposed protection for . . . animals.” 42 C.F.R. § 52h.8. Although Defendants press that such metrics are overbroad, “[e]ven broad statutory grants of agency authority can contain enough content to guide judicial review.” *Deese v. Esper*, 483 F. Supp. 3d 290, 308 (D. Md. 2020); *see also Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2568 (2019) (Census Act provision directing the Commerce Secretary to conduct the census in “such form and content as he may determine” provided meaningful standard for the Court to apply, despite the “broad authority” conferred by

this statutory provision.). These factors provide concrete metrics by which the Court may evaluate whether NIH's grantmaking process as to the five challenged grants was arbitrary and capricious. Although the Court will not displace the scientific expertise of the agency, it can nonetheless evaluate, for example, whether NIH wholly failed to consider "the adequacy of the approach and methodology" and "the adequacy of the proposed protection for . . . animals." 42 C.F.R. § 52h.8. Even though such factors implicate technical or scientific judgment, they can provide meaningful standards for the Court to apply. *See Deese*, 483 F. Supp. 3d at 310 (Regulatory requirement to assess whether an individual is "medically capable" provides a meaningful standard for the court to apply.). The Court thus finds that this is not one of the "rare instances" in which the operative statutes and regulations provide "no law to apply." *Mayor and City Council of Balt. v. Trump*, 416 F. Supp. 3d 452, 495 (D. Md. 2019). Accordingly, Count One is reviewable under the APA.

Defendants lastly argue that as to the five enumerated grants, no facts make plausible that NIH's funding decisions were "arbitrary and capricious." ECF No. 39-1 at 30–31.<sup>5</sup> To survive challenge at the motion to dismiss stage, the Complaint must make plausible that NIH's funding decisions fell outside "the bounds of reasoned decisionmaking." *Balt. Gas and Elec. Co. v. NRDC*, 462 U.S. 87, 104 (1983). That is, PETA must allege sufficient facts that the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not

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<sup>5</sup> In the Complaint, PETA also alleges that the grant approvals exceed NIH's statutory authority under 5 U.S.C. 706(2)(C). ECF No. 1 ¶¶ 96, 98. But in its opposition to the motion to dismiss, PETA maintains only that the grant approvals were arbitrary and capricious. ECF No. 44 at 30–32. PETA has thus abandoned the contention that Defendants violated Section 706(2)(C). *Ferdinand-Davenport v. Children's Guild*, 742 F. Supp. 2d 772, 777 (D. Md. 2010). Accordingly, the Court will consider only whether PETA has stated a plausible "arbitrary and capricious" claim under 5 U.S.C. 706(2)(A).

be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Viewing the Complaint facts as true and most favorably to PETA, the claim survives challenge. The Complaint avers that NIH arbitrarily disregarded no fewer than fifteen peer reviewed studies published over eighteen years which demonstrate how sepsis in humans fundamentally differs from sepsis in other animals. ECF No. 1 ¶ 67. Indeed, according to NIH’s own working group on the subject, the growing body of literature has called into question whether using mice in sepsis related studies is still a “best practice” because mice are a poor proxy for humans in this context. *Id.* PETA thus makes plausible that NIH’s continued funding of such experiments runs “counter to the evidence” or reflects the agency’s failure to consider an “important aspect of the problem.” *State Farm*, 463 U.S. at 43. These facts also call into question whether NIH is subjecting the proposed studies to “appropriate technical and scientific peer review” in advance of issuing the awards. 42 U.S.C § 289a(a)(1). This is especially so when considering that NIH must, per regulation, consider whether the study adequately addresses “proposed protection for . . . animals.” 42 C.F.R. § 52h.8.

Defendants, in response, press that NIH did in fact follow its own “well-established” review process and subjected the grant applications to “appropriate” peer review. ECF No. 39-1 at 31. This amounts to a mere “not so” argument to sufficiently pleaded allegations. *Cf. City of Columbus v. Trump*, 453 F. Supp. 3d 770, 795 (D. Md. 2020). At the motion to dismiss stage, without the benefit of the administrative record, the Court must take the Complaint facts as true and not wade into the merits of the APA claim based solely on Defendants’ denial and a “partial and truncated record.” *Id.* (quoting *Banner Health v. Sebelius*, 797 F. Supp. 2d 97, 112–13

(D.D.C. 2011)) (internal quotations omitted). Defendants' motion to dismiss Count One for failure to state a claim is denied.

**IV. Conclusion**

Based on the foregoing, the Court grants in part and denies in part Defendants' motion to dismiss. Count Two of the Complaint is dismissed. Defendants are directed to answer the remaining allegations in the Complaint within 21 days. A separate Order follows.

3/21/2023  
Date

/S/  
Paula Xinis  
United States District Judge