

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITE COAT WASTE PROJECT, INC.,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, et al.,

Defendants.

Civil Action No. 22-0006 (CJN)

**OMNIBUS REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS
AND MOTION FOR RELIEF FROM LOCAL RULE 7(n)**

MATTHEW M. GRAVES
United States Attorney

BRIAN P. HUDAK
Chief, Civil Division

MICHAEL E. YOHANNAN
Special Assistant United States Attorney
U.S. Attorney's Office for the District of Columbia

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Defendants moved under Rule 12(b)(1) to dismiss in this matter because the Plaintiff, the White Coat Waste Project, Inc. (“White Coat”), has not established standing. ECF No. 21 (“Defendants’ Motion”) (“Def. Mot.”). White Coat challenges Defendants’ implementation of Section 495 of the Public Health Services Act (“Services Act”) (42 U.S.C. § 289d). Specifically, White Coat challenges the guidance issued by Defendant the National Institutes of Health (“NIH”) that allows a foreign grant applicant to obtain approval of an animal welfare assurance (“foreign assurance”) under 42 U.S.C. § 289d(c) without organizing an entity in the research institution called an Institutional Animal Care and Use Committee (“institutional animal committee”).¹ The allegations in White Coat’s Amended Complaint are plainly insufficient to confer standing to challenge NIH’s foreign assurance guidance under the Administrative Procedures Act (“APA”). White Coat cannot establish standing by alleging that the challenged guidance prevents it from receiving information under the Freedom of Information Act (“FOIA”). *See* Amended Complaint, ECF No. 17, (Am. Compl.) at ¶ 17. Nor can White Coat establish organizational standing by alleging that the challenged NIH guidance “frustrates its organizational mission[.]” *Id.* Such allegations do not establish informational or organizational standing in this Circuit.

Now, White Coat attempts to correct the deficiencies in its Amended Complaint by offering the Court a detailed step-by-step description of how it conducts research for its

¹ As Defendants stated in the opening brief, all recipients of NIH grants that propose to use laboratory animals in NIH funded research are required to have an animal welfare assurance approved pursuant to 42 U.S.C. § 289d(c). Def. Mot. at 11. NIH has established an alternative process for foreign research institutions to obtain approval of an animal welfare assurance. Institutions receiving a foreign animal welfare assurance (“foreign assurance”) must assure NIH that they will comply with the International Guiding Principles for Biomedical Research Involving Animals, which includes oversight and recordkeeping provisions, as well as any laws on the welfare of laboratory animals that apply in the institution’s local jurisdiction. *Id.* at 12.

advocacy activities related to the use (or alleged misuse) of laboratory animals in NIH funded medical research. But these details do not cure its failure to establish standing to challenge Defendants' implementation of 42 U.S.C. § 289d with respect to foreign institutions that apply for NIH grants that would fund research involving animals. First, White Coat is incorrect that the FOIA entitles it to information about foreign NIH grant recipients that NIH does not and is not required by statute to collect. As Defendants argued in their opening brief, White Coat has not identified any provision of the Services Act that requires NIH to make available to the public the records White Coat alleges are being unlawfully withheld. White Coat has still not identified any such provision of the Services Act or any other federal statute. White Coat's efforts to revive its organizational standing theory fare no better. Rather, White Coat tries to frame its more complex research activities as operational impediments that give rise to an organizational injury. But White Coat's failure to identify a specific change to its operations and how such a change hindered its ability to provide any services other than advocacy defeats its claim to organizational standing.²

Even if Plaintiff has standing, its injury falls outside the zone of interests protected by Section 289d and therefore should be dismissed under Rule 12(b)(6). All claims brought under the APA such as those brought by White Coat in this case must satisfy the zone-of-interests test.

² Section IV(A) of White Coat's opposition includes an argument on the merits of its allegation that Defendants' guidance to foreign research institutions on compliance with Section 289d is *ultra vires*. Pl. Op. at 10-25. This reply will not address those arguments because, at this juncture, Defendants have moved dismiss under Rule 12(b)(1) for lack of standing and under Rule 12(b)(6) for alleging an injury that is not protected by Section 289d. Additionally, White Coat inaccurately asserts that Defendants "admit[ed] that it has issued . . . a rule." Pl. Op. at 51. It is unclear what "rule" White Coat refers to here, but Defendants at no time conceded that any of the challenged NIH guidance is a rule. After these threshold questions raised in the instant motion are decided, Defendant reserves the right to contest the claims made in Section IV(A) of Plaintiff's Opposition.

Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak, 567 U.S. 209, 224 (2012).

The zone-of-interests test is all the more important where, as here, the Plaintiff brings suit based on an alleged deprivation of information. Indeed, “a continuous line of circuit precedent holds that claims of information injury can surmount the zone of interest threshold only in very special statutory contexts.” *Animal Legal Def. Fund, Inc. v. Espy*, 23 F.3d 496, 502 (D.C. Cir. 1994).

No such special circumstance exists here. The Services Act does not require that any information about NIH’s approval of assurances under Section 289d(c) be made public and does not contemplate a specific role for an organization like White Coat in the oversight of the use of laboratory animals by foreign NIH grant recipients. White Coat’s theory of the zone-of-interests test carries sweeping consequences, because any organization with a policy interest in a federal agency’s activities could sue to require that agency to collect additional records for the purpose of aiding the plaintiff organization in its advocacy activities. That understanding of the zone-of-interests test would eviscerate the test entirely.

Finally, relief from Local Civil Rule 7(n) is appropriate here where the certified list of contents of the administrative record would not help the Court decide the threshold legal questions raised in Defendants’ motion to dismiss. Plaintiff’s argument that it is prejudiced in responding to Defendants’ Motion without the certified list of the contents of the administrative record is wholly without merit. Indeed, Plaintiff fails to explain how this certified list could cure the deficiencies in its Amended Complaint.

ARGUMENT

I. WHITE COAT FAILS TO SHOW EITHER INFORMATIONAL OR ORGANIZATIONAL STANDING

A. White Coat Has Not Established Informational Standing Because It Identifies No Statutory Entitlement to Any Allegedly Withheld Information

To establish standing based on an alleged deprivation of information, a plaintiff must allege that “(1) it has been deprived of information that, on its interpretation, a statute requires the government or a third party to disclose to it, and (2) it suffers, by being denied access to that information, the type of harm Congress sought to prevent by requiring disclosure.” *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016). Defendants’ Motion demonstrated that White Coat’s Amended Complaint failed to identify what information it is entitled to receive by statute. Def. Mot. at 20. White Coat still has not identified a statute that entitles it to the information it seeks.

Instead, in its opposition to Defendants’ Motion, White Coat incorrectly argues that the FOIA entitles it to records that NIH does not possess. Plaintiff’s Opposition to Defendants’ Motion, ECF No. 24, (“Pl. Op.”) at 39-40. Attempting to specify what records it believes it should receive, White Coat refers to a provision of NIH’s Public Health Service Policy on Human Care and Use of Laboratory Animals (“Humane Care Policy”)³ that requires a grantee’s institutional animal committee to report certain information to NIH. Pl. Op. at 39. Obviously, the Humane Care Policy is not a statute and does not require that NIH make any information available to the public anyhow. Therefore, it does not confer a statutory right to information that might give rise to informational standing.

³ Public Health Service Policy on the Humane Care and Use of Laboratory Animals, <https://olaw.nih.gov/policies/phs-policy.htm> (last visited Dec. 14, 2022).

White Coat then advances the novel proposition that Defendants’ regulations implementing the FOIA require that NIH collect information from foreign research institutions that seek NIH approval of a foreign assurance. *Id.* The FOIA and Defendants’ regulations implementing the FOIA may give a right of access to agency records, but these authorities certainly do not create a statutory right of access to records that are not in Defendants’ possession and that Defendants are not required by statute to collect.

To satisfy the first element of the test for informational standing, a plaintiff must identify “a statute”—not a regulation and not an agency policy—that “directly requires the defendant[s] to disclose information that the plaintiff has a right to obtain.” *Env’t Integrity Project v. McCarthy*, 139 F. Supp.3d 25, 36 (D.D.C. 2015). The FOIA does no such thing. Rather, the FOIA may create an obligation to disclose an agency record only after such an agency record exists. *Schoenman v. F.B.I.*, 573 F.Supp.2d 119, 140 (D.D.C. 2008) (citing *Kissinger v. Reps. Comm. for Freedom of the Press*, 445 U.S. 136, 152 (1980)). Informational standing, by contrast, is found where “[d]efendants have already incurred an obligation to disclose information.” *Elec. Priv. Info. Ctr. v. Presidential Advisory Comm’n on Election Integrity*, 266 F.Supp.3d 297, 311 (D.D.C. 2017). The FOIA also does not require the government to collect documents. *See SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1201 (D.C. Cir. 1991) (noting that the FOIA does not require agencies to “recreate or to reacquire a document that it no longer has.”).

It is therefore unsurprising that White Coat points to not a single case in which a court has ever accepted its theory of informational injury by a disappointing FOIA response. In fact, courts in this district have rejected similar theories of informational injury on at least three occasions. *See Architects & Eng’rs for 9/11 Truth v. Raimondo*, 1:21-cv-2365, 2022 WL

3042181 at * 5 (D.D.C. Aug. 2, 2022) (holding that “FOIA...does not meet the first step for an informational injury”); *Pub. Citizen Rsch. Grp. v. Pizzella*, 513 F. Supp.3d 10, 21 (D.D.C. 2021) (stating that “to hold that FOIA is a statute that satisfies the first requirement for informational injury would all but eviscerate the requirement.”); *Jud. Watch, Inc. v. Off. of Director of Nat’l Intel.*, Civ. A. No. 1:17-0508, 2018 WL 1440186, at *3 (D.D.C. Mar. 22, 2018) (stating that “FOIA does not require the government to create documents but merely to produce documents that it already maintains.”).

White Coat also references Defendants’ regulations implementing the FOIA, *see* Pl. Op. at 41-42, but it is unclear how this helps their cause. By their own terms, those regulations apply only to records that are subject to the FOIA. 45 C.F.R. § 5.1. It is nonsensical to suggest that Defendants’ FOIA regulations create a right of access to records that Defendants do not have. White Coat also attempts to cobble together an argument using 2 C.F.R. § 200.338 but gets nowhere. Pl. Op. at 40-41. This regulation promulgated by the Office of Management and Budget (“OMB”) provides that a federal agency may not place certain restrictions on a non-federal entity that would limit public access to records pertinent to a Federal procurement award. It is unclear what this regulation has to do with this case since White Coat is not alleging that it suffered harms because Defendants are placing restrictions on non-Federal entities. Moreover, the same regulation states that non-Federal entities are not required to permit public access to their records unless required by statute.

By failing to satisfy the first element of the informational injury test, White Coat does not and cannot address the second which requires that the plaintiff assert harms that Congress sought to prevent by requiring the disclosure of the withheld records. Not only does the FOIA not require NIH to collect any particular information, the Services Act does not require NIH to

collect the information it alleges Defendants have withheld. White Coat points to a provision of the Humane Care policy that instructs institutional animal care committees to submit certain documentation to NIH. Pl. Op. at 39. But since Congress did not require that these records be made public, White Coat's inability to obtain any such records that NIH does not have could not have been an injury that Congress sought to prevent. Accordingly, White Coat fails to plead informational standing because it fails to identify a cognizable informational injury.

B. White Coat Does Not Have Organizational Standing

For White Coat to show an injury for purposes of organizational standing, it must show that NIH's guidance and procedures for the approval of foreign animal welfare assurances injured White Coat's organizational interest, and that White Coat used its resources to counteract that particular organizational harm. *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015) (quoting *Equal Rts. Ctr. v. Post Props., Inc.* 633 F.3d 1136, 1138 (D.C. Cir. 2011)); 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"). A plaintiff pleading organizational standing must allege both elements of the test. In reviewing the injury analysis, the government activity must "perceptibly impair [] the organization's ability to provide services." *Citizens for Resp. & Ethics in Wash. ("CREW") v. Off. of Special Counsel*, 480 F.Supp. 3d 118, 127 (D.D.C. 2020). It is not enough that the organization's mission has been compromised. *Id.* (citing *Abigail All. for Better Access to Dev. Drugs v. Eschenbach*, 469 F.3d 129, 133 (D.C. Cir. 2006)).

Defendants' opening brief pointed out that White Coat expressly alleged that its purported injury was the frustration of its organizational mission. Def. Mot. at 17; see Am. Compl. ¶ 7 ("[White Coat] brings this action on its own behalf, and on behalf of its members, because the challenged conduct conflicts with, impairs, and frustrates its organizational

mission”). White Coat now alleges that the challenged NIH guidance adversely impacts the organization’s “daily operations.” Pl. Op. at 30. But White Coat does not allege that the foreign assurance guidance has caused it to undertake any activities it was not already doing. White Coat cannot manufacture organizational standing by reframing its deficient allegation of an informational injury as an operational problem that impairs its ability to provide services. Indeed, White Coat’s supposed operational problems are just descriptions of the complexities of some of its research on foreign research institutions. To accept White Coat’s allegations as stating an injury in fact would substantially expand the scope of organizational standing.

1. White Coat Fails to Show Injury to its Organizational Interests

White Coat attempts bolster its theory that Defendants’ alleged frustration of its organizational mission by recharacterizing frustration of its mission as an impact on its operations. *See* Pl. Op. at 11 (“White Coat has organizational standing because its mission...and its daily operations are directly impacted and perceptibly impaired” by the NIH foreign assurance guidance). This allegation, however, is just White Coat’s attempt to shoehorn its deficient informational injury into an organizational standing theory. Specifically, White Coat alleges that the challenged NIH guidance causes an “information blackout” that “force[s]” White Coat “to deviate from its normal operations and instead sort through an exponentially larger volume of documents, none of which originate from [NIH].” Pl. Op. at 31-32. This theory organizational injury depends on the existence of an informational harm which White Coat cannot establish and, therefore, its organizational standing theory fails with it. *See Architects & Eng’rs*, 2022 WL 3042181 at *3 (holding that the plaintiff failed to establish organizational standing based on an informational injury). Moreover, White Coat’s description of the alleged impact on its operations of NIH’s foreign assurance guidance is just a description of how White Coat researches foreign NIH grantees and how that is more complex than research into domestic

grantees. Pl. Op. at 32-33. But White Coat does not allege any specific new expenditures such as additional staff it had to hire or services it had to procure as a result of the NIH foreign assurance guidance.

An organization's expenditure of its resources does not constitute an injury in fact unless such an expenditure "subjects the organization to operational costs beyond those normally expended." *Animal Legal Def. Fund v. Vilsack*, Civ. A. No. 1:21-1539 (CJN), 2022 WL 16921506, at *6 (D.D.C. Nov. 14, 2022). In support of its theory that the complexity of some of its research is a cognizable organizational injury, White Coat cites to cases in which, unlike White Coat, the plaintiff organization actually changed or undertook new activities as a result of the challenged government action. For example, in *Am. Anti-Vivisection Society v. USDA*, 946 F.3d 615 (D.C. Cir. 2020), the Court held that the plaintiff alleged an organizational injury by alleging that it had to "fill the void" caused by USDA's failure to enact a regulation as required by statute. *Id.* at 619. The plaintiff in that case alleged that it had to issue guidance that would have otherwise been provided by USDA. *Id.* But here, White Coat identifies no particular change in its operations. White Coat's research operations into foreign NIH grantees may involve more steps than its research into domestic grantees, but White Coat does not allege that these operations at some point changed as a result of Defendants' actions. In short, White Coat appears to be doing what it has always done.

White Coat also cites to *People for the Ethical Treatment of Animals ("PETA") v. USDA*, 797 F.3d 1087 (D.C. Cir. 2015) but misstates the holding in that case. White Coat asserts that the Court in *PETA* found that USDA's failure to promulgate animal welfare regulations pertaining to birds "frustrated [PETA's] mission- forcing PETA to divert organizational resources to conduct cruelty investigations of bird abuse and related educational efforts to offset

the impact.” Pl. Op. at 27. That is incorrect. The Court in *PETA* did not find that plaintiff’s organizational injury was the frustration of its mission. Rather, the Court found organizational standing because plaintiff alleged that USDA’s failure to promulgate the regulations at issue precluded plaintiff “from preventing cruelty and inhumane treatment of [birds] through its normal process of submitting USDA complaints and it deprived [plaintiff] of key information that it relies on to educate the public.” *PETA*, 797 F.3d at 1094. According to the plaintiff, USDA’s action had the concrete effect of preventing it from using an established process for redressing the mistreatment of animals due to USDA’s failure to promulgate the regulation at issue. *Id.* at 1095. Here, White Coat identifies no formal process for it to request an investigation into the use of laboratory animals by any NIH grant recipient and therefore cannot establish organizational standing on the same theory accepted by the Court in *PETA*.

To be sure, the Court in *PETA* held that the plaintiff alleged an organizational injury because of the plaintiff’s inability to file complaints with USDA about the mistreatment of birds, which also caused the plaintiff to be deprived of information that would have resulted from those investigations. *Id.* at 1094. But the Court did not find that plaintiff had informational standing on the basis that it was deprived of information to which it was entitled by law. Rather, the information at issue in *PETA* apparently consisted of inspection reports that USDA voluntarily produced after investigative and enforcement efforts taken as a result of complaints involving other animals. *See id.* at 1095 (noting that PETA alleged that the “resulting USDA inspection reports are made available in an online database”). White Coat, by contrast, cannot show that it would have automatically obtained additional information about foreign NIH grantees had Defendants implemented the foreign assurances a different way because there is no statute that gives White Coat access to that information and, as White Coat makes abundantly clear, the

information it seeks is not made public as part of an agency process because White Coat requests the information through the FOIA.

White Coat also claims that the foreign assurance guidance “obfuscates the identity and number of foreign grantees conducting taxpayer-funded animal experimentation.” Pl. Op. at 30. As an initial matter, it is not at all clear what White Coat believes is being “obfuscated” since White Coat acknowledges that NIH makes public the identities of “foreign entities” with assurances under the Services Act. *Id.* To the extent White Coat believes that additional information would be helpful to its “daily operations[,]” it does not identify what that information is or why it is entitled to such information. White Coat only claims that Section 298d requires that “certain documents” be filed with NIH “at least annually.” Pl. Op. 30. But Section 289d only requires that animal care committees file an annual certification that they conducted a compliance review and, if the committee observed violations, assurances that the grantee has returned to compliance. *See* 42 U.S.C. § 289d(b)(3)(C). It does not require that any of these records be made public. Crucially, White Coat does not claim that the alleged withholding of this information hindered its ability to provide services. Indeed, White Coat’s own detailed description of how it obtains the information it claims it was deprived of suggests that White Coat is able to acquire such information by “querying public databases and triangulating the findings with published research.” Pl. Op. at 31. The Court should not permit White Coat solve its informational standing problem by extending the holding in *PETA*.⁴ Indeed, the *PETA* decision “marks the outer bounds of the Circuit’s highly permissive

⁴ Notably, White Coat does not argue that the alleged “informational blackout” and “obfuscation” of the “identity and number of foreign grantees conducting tax-payer funded animal experimentation” constitutes an informational injury.

organizational standing doctrine.” *Ctr. for Democracy & Tech. v. Trump*, Civ. A. No. 20-1456, 2020 WL 7318008, at *5 (D.D.C. Dec. 11, 2020).

Rather than alleging that the NIH foreign assurance guidance hindered its ability to provide services, White Coat alleges that the NIH foreign assurance guidance has “increase[ed] [its] workload.” Pl. Op. at 11. But this is based on White Coat’s bald assertion that NIH’s foreign assurance guidance “increases the prevalence of animal welfare violations” and that it “increases the incidents of waste and abuse the [it] must discovery and investigate, while simultaneously making it harder for White Coat to investigate them.” *Id.* at 35. White Coat offers no basis for its assertion that NIH’s foreign animal guidance results in the mistreatment of laboratory animals or waste and abuse of NIH grant funds. Moreover, White Coat does not allege what particular steps it took to deal with an allegedly increased workload or how this impacted its ability to provide any service. The closest it comes is in the Amended Complaint wherein White Coat alleges that Defendants’ actions “hinder[] the development of other organizational projects that would better advance [White Coat’s] mission[.]” Am Compl. ¶ 7. But Defendants’ Motion pointed out that White Coat does not say what alternative projects were hindered by Defendants’ actions. Def. Mot. at 18. White Coat still has not identified any alternative activities it had to forego because of the challenged NIH guidance. White Coat’s inability to articulate when its workload supposedly increased or how having more work hindered its ability to deliver services further forecloses the availability or organizational standing to bring this case.

2. White Coat’s Diversion of Resources to Advocacy Does Not Confer Standing

White Coat alleges that the foreign assurance guidance caused it to “divert resources from enacting its mission and daily operations” when White Coat engaged in lobbying activities

“to force NIH to comply with its duties under [Section] 289d.” Pl. Op. at 35-36. White Coat further alleges that it “diverted resources to report to the media, the general public, and White Coat’s...members and supporters about the [NIH foreign assurance guidance] to further pressure NIH[.].” *Id.*⁵ White Coat’s use of its resources to advocate for changes to the NIH foreign assurance guidance is insufficient to show that it used its resources to counteract an injury to its organizational interests. *See CREW*, 480 F. Supp. 3d at 128. “[T]he 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.” *CREW*. at 128 (citing, among others, *Ctr. for Resp. Sci. v. Gottlieb*, 346 F. Supp. 3d 29, 37 (D.D.C. 2018)). These are considered “self-inflicted” injuries. *Id.* (citing *Abigail All.*, 469 F.3d at 133). “[A]n organization’s use of resources for litigation, investigation in anticipation of litigation, or advocacy is not sufficient to give rise to an Article III injury.” *Food & Water Watch*, 808 F.3d at 919 (quoting *PETA*, 797 F.3d at 1094).

In sum, Plaintiff fails both elements of the test for organizational standing. Neither the Amended Complaint nor Plaintiff’s Opposition identifies a cognizable organizational injury to White Coat. As for the second element, to the extent White Coat identifies any specific actions it has taken to counteract alleged injuries, such actions consist only of lobbying and advocacy,

⁵ White Coat also alleges that it “has diverted at least \$25,372.96 in organizational resources in response” to the NIH foreign assurance guidance. Pl. Op. at 37. But a review of White Coat’s explanation for how it arrived at this cost estimate reveals that it reflects the proportion of the salaries of two of its staff members that corresponds to the amount of time those staff members claim to have spent on researching institutions with foreign assurances. It does not reflect any additional expenditures that White Coat has made. White Coat was not forced to “divert” resources, rather it simply chose to have two employees conduct relatively more complicated research.

which are insufficient to establish organizational standing. Accordingly, White Coat had not established organizational standing to bring this lawsuit.

II. WHITE COAT LACKS PROCEDURAL STANDING TO BRING ITS ALTERNATIVE CLAIMS FOR RELIEF

Defendants’ Motion argued that White Coat failed to establish procedural standing for its alternative claims for relief because it had not alleged a cognizable informational or organizational injury in fact. Def. Mot. at 23. The Supreme Court stated that “deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing.” *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009). The requirement of an injury-in-fact is a “hard floor” for Article III standing. *Id.* at 497. White Coat’s only response to Defendants’ argument that it lacks procedural standing to bring its alternative claims for relief is a two-sentence footnote in which White Coat asserts that its proffered grounds for informational and organizational standing satisfy the test for procedural standing. Pl. Op. at 51, n.11. “In order to make out [a] constitutionally cognizable injury, plaintiffs must demonstrate that the allegedly deficient procedures implicate distinct substantive interests as to which Article III standing requirements are independently satisfied.” *Freedom Republicans, Inc. v. Fed. Election Comm’n*, 13 F.3d 412, 416 (D.C. Cir. 1994). Here, White Coat has not adequately pled an informational or organizational injury so any possible violation of notice-and-comment procedures, does not establish standing for White Coat’s procedural claims under the APA.⁶

⁶ White Coat inaccurately claims that Defendants’ “assert[ed] [they] performed notice-and-comment rulemaking regarding the [NIH foreign assurance guidance] contained in the [Humane Care Policy]. Pl. Op. at 52. Defendants did no such thing. Rather, Defendants’ opening brief pointed out that “NIH has in fact offered the public the opportunity to submit comments on the Humane Care Policy” and cited one instance when this occurred. Def. Mot. at 22-23. Defendants’ Motion challenged White Coat’s procedural claim on issue of standing, not the merits. After the Court addresses the threshold questions in Defendants’ Motion, Defendants reserve the right to

III. WHITE COAT DOES NOT SATISFY THE HEIGHTENED ZONE OF INTERESTS TEST FOR INFORMATIONAL INJURIES

To satisfy the zone-of-interests test, a plaintiff must show that the interest it seeks to protect is arguably within the zone of interests to be protected or regulated by the statute in question. *Assoc. of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 153 (1970). The Supreme Court has made clear that the zone-of-interests test “is a requirement of general application” and “always applies and is never negated[.]” See *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014) (quoting *Bennett v. Spear*, 520 U.S. 154, 163-64 (1997)). “Protected interests are ones asserted either by intended beneficiaries of the statute at issue or by other suitable challengers—i.e., parties whose interests coincide systemically, not fortuitously with those of intended beneficiaries.” *Twin Rivers Paper Co., LLC v. SEC*, 934 F.3d 607, 616 (D.C. Cir. 2019) (quoting *Hazardous Waste Treatment Council v. Thomas*, 885 F.2d 918, 921-22 (D.C. Cir. 1989)).

White Coat first asserts that “a plaintiff need not satisfy the zone of interests analysis for *ultra vires* claims” and cites to *Ctr. for Biological Diversity v. Trump*, 453 F. Supp. 3d 11, 48-49 (D.D.C. 2020) in support of that proposition. Pl. Op. at 43. But, unlike in this case, the *ultra vires* claim in *Ctr. for Biological Diversity* was not brought under the APA.⁷ *Ctr. for Biological Diversity*, at 24. Rather, in that case, the APA violations were alternative claims. *Id.* at 46.

contest White Coat’s procedural challenges including whether NIH’s foreign assurance guidance requires notice-and-comment under the APA.

⁷ White Coat also asserts that “cases related to animal welfare proceeded without zone of interests analysis” and cites *PETA* and *Am. Anti-Vivisection* as examples. Pl. Op. at 44, n.9. This is misleading. Whether the claims in those cases satisfied the zone-of-interests test was not raised and then considered by the Court. Indeed, White Coat itself cites to cases involving animal welfare where the Court applied the zone-of-interests test. Pl. Op. at 36. White Coat is therefore incorrect to the extent it argues that the zone-of-interests test need not apply to claims involving animal welfare.

Indeed, the Court in *Ctr. for Biological Diversity* applied the zone-of-interests test to the APA claims in that case. *Id.* at 39. Here, White Coat brought its *ultra vires* claims under the APA (*see* Am. Compl. at 11-18) and, therefore, it must still show that its interest in obtaining information about foreign assurances approved by NIH falls within the zone of interests protected or regulated by Section 289d.

White Coat urges the Court to use a “lenient standard” when applying the zone-of-interests-test to its claims. Pl. Op. at 45. But the D.C. Circuit has been clear that zone-of-interests test is particularly narrow in the context of an alleged informational injury. *See Animal Legal Def. Fund v. Espy*, 23 F.3d 496, 502 (D.C. Cir. 1994) (noting that “informational injury can surmount the zone of interests threshold only in very special statutory contexts”). The heightened standard for an informational injury to clear the zone-of-interests test is unsurprising given that any plaintiff with an interest in an agency’s activities could sue the agency to change its policies so that the plaintiff could obtain more information through vehicles such as FOIA. Thus, to satisfy the zone-of-interests test, White Coat must demonstrate that Section 289d protects its right to receive the specific information about institutions with NIH approved foreign assurances.

White Coat does not explain how Section 289d of the Services Act protects its right to obtain information about foreign assurances. Rather, White Coat incorrectly asserts that Section 289d “[w]as crafted to generate public records[.]” Pl. Op. at 50. This is obviously incorrect since Section 289d does not require that any information be made public. White Coat also assumes that because it “routinely rel[ies] upon such records for investigation,” its alleged informational injury “must be considered within [Section 289d’s] zone of interest.” *Id.* This self-serving theory puts the statute in service of White Coat regardless of what the statute says.

Section 289d requires NIH to collect very minimal information and does not require that any such information be made public. Therefore, Section 289d does not even arguably protect White Coat’s ability to receive information about foreign institutions with NIH approved foreign assurances.

White Coat asserts that its “organizational injuries plainly fall within the zone of interests of [Section] 289d[.]” Pl. Op. at 49. It proffers two reasons for this, neither of which has anything to do with whether White Coat’s purported organizational injuries (which, again, are based entirely on an insufficient allegation of an informational injury) are protected by the Services Act. First, White Coat claims that grant applicants seeking NIH approval of animal welfare assurances are “conflicted by economic considerations” and therefore will not sue Defendants over their implementation of Section 289d of the Services Act Pl. Op. at 47. But the Services Act does not prescribe any particular role for an organization such as White Coat.⁸ Rather the Services Act provides that it is the responsibility of the Director of NIH to determine that a grant applicant or recipient has submitted an adequate animal welfare assurance. 42 U.S.C. § 289d(c)(1). White Coat also claims that “NIH routinely relies on and acts upon the investigations of animal welfare organizations.” *Id.* at 47. Even if this were true, it could not be characterized as White Coat’s organizational injury.

It follows that White Coat is not a “suitable challenger” of Defendants’ compliance with Section 289d of the Services Act because, though it characterizes its injury as an organizational one, White Coat’s alleged injury is fundamentally about how NIH’s implementation of Section

⁸ Defendants acknowledge that the U.S. Government Accountability Office is presently engaged in an audit of NIH’s oversight of the use of animals in foreign research that it funds. A report on this audit is expected next year. This underscores that White Coat is incorrect that only its deficient APA claims can prompt oversight of these activities. In fact, that oversight is occurring.

289d affects the scope of the public records it can acquire through the FOIA. But this is not an interest that the Services Act protects and, therefore, White Coat is not a “peculiarly suitable challenger” to the way in which Defendants implement Section 289d.

IV. PRODUCTION OF THE CERTIFIED LIST OF THE CONTENTS OF THE ADMINISTRATIVE RECORD IS PREMATURE

Simultaneous with the filing of its Motion to Dismiss, Defendants also moved for relief from Local Civil Rule 7(n)(1) to file a certified list of the contents of the administrative record (“certified index”). ECF No. 22. White Coat opposes that motion and claims that it is prejudiced in responding to Defendants’ Motion to Dismiss without the certified index. *See* ECF No. 25. White Coat claims that one reference to a Federal Register notice in Defendants’ Motion to Dismiss “put the administrative record at issue” and “represent[ed] to the Court that the Humane Care Policy underwent notice-and-comment. *Id.* at 3. That is simply not true.

At no time did Defendants “put the administrative record at issue” or represent that the Humane Care Policy underwent notice-and-comment rulemaking. Moreover, White Coat does not coherently or adequately explain why this reference to a Federal Register notice prejudiced its ability to respond to Defendants’ legal arguments as to Article III standing and whether its APA claims are within the zone of interests of the Services Act. Plaintiff’s claims of being prejudiced in responding to Defendants’ Motion to Dismiss are based on mischaracterizations and are all the more unconvincing given that Plaintiff in fact responded to Defendants’ standing and zone of interests arguments without the certified index. Indeed, Plaintiff fails to articulate with any specificity how the administrative record would establish standing, which is clearly lacking here. In any event, the certified index of the administrative record would not help the Court address the questions raised in Defendants’ Motion and is therefore unnecessary at this juncture.

CONCLUSION

Defendants present numerous justifications for the dismissal of the Complaint. In sum, dismissal is warranted under Rules 12(b)(1) and 12(b)(6) as Plaintiff lacks Article III standing and fails to state a claim. Furthermore, the Court should grant Defendants' motion for relief from Local Civil Rule 7(n)(1).

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Washington, D.C

Respectfully submitted,

MATTHEW M. GRAVES

United States Attorney

BRIAN P. HUDAK

Chief, Civil Division

By: /s/ Michael E. Yohannan
MICHAEL E. YOHANNAN
Pennsylvania Bar No. 307575
Special Assistant United States Attorney
U.S. Attorney's Office, Civil Division
601 D Street, N.W.
Washington, D.C. 20530
Tel: (202) 815-8969
Michael.Yohannan@usdoj.gov

Counsel for Defendants