UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND

RISE FOR ANIMALS, et al., Plaintiffs, v. TOM VILSACK, et al., Defendants.	)	Civ. No. 22-00810 Honorable Julie R. Rubin

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Table of Contents

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTRODUCTION

In their opening brief, Plaintiffs demonstrated that the Animal and Plant Health Inspection Service ("APHIS"), a division of the United States Department of Agriculture ("USDA"), secretly adopted a new inspection policy (the "Policy" or the "AAALAC Inspection Policy") that violates the Animal Welfare Act's ("AWA") mandatory inspection provision, 7 U.S.C. § 2146(a). Under the Policy, if a research facility is accredited by the industry-dominated Association for the Assessment and Accreditation of Laboratory Animal Care ("AAALAC"), inspectors are *required* to inspect only *one* aspect of the facility—paperwork, facilities, animals, or a sampling of any such category—unless the facility requests a full inspection. Plaintiffs explained that this new Policy not only prevents the agency from ensuring that research animals are treated according to AWA standards, but also deprives Plaintiffs of key information about the facilities' AWA compliance and about whether AWA standards are functioning to "insure" that animals used in research "are provided humane care and treatment." 7 U.S.C. §2131. This Court has already expressed doubts about the legality of this Policy in the related case concerning the psychological well-being of primates used in research. *New Eng. Anti-Vivisection Soc'y v. Goldentyer*, No. 8:20-CV-02004-JRR, 2023 WL 2610867 (D. Md. Mar. 23, 2023) (granting Plaintiffs' summary judgment motion in challenge to USDA's denial of rulemaking petition to improve the standard to promote the psychological well-being of primates). Plaintiffs' opening brief further explained how the agency's secret adoption of the Policy, despite overwhelming public opposition, was arbitrary and capricious for numerous reasons.

In response, the USDA offers a tortured interpretation of the AWA to assert that its adoption of the new Policy is not judicially reviewable and that the Policy does not violate the AWA. The agency attempts to rely on an impermissible post-hoc declaration, asserting that a lack

of agency resources to conduct full annual inspections made the Policy necessary. Not only is this assertion prohibited at this stage of litigation, but it is also completely belied by the fact that, at the same time the agency was adopting the Policy, it asked Congress to substantially *decrease* funding for the USDA's Animal Care program—the part of the agency that conducts inspections. *See* U.S. Dep't. of Agric., *Excerpts from 2019 USDA Budget Explanatory Notes*, at 20-52, Pl. Ex. J (asking Congress for a *reduction* of $258,000 for USDA's Animal Welfare program).

As further demonstrated below, none of the USDA's arguments have any merit. Accordingly, Plaintiffs are entitled to summary judgment in this case.

ARGUMENT

I. PLAINTIFFS HAVE ARTICLE III STANDING.

In their opening brief, Plaintiffs demonstrated that they have ample Article III standing—namely, (1) they suffer concrete and particularized injuries-in-fact, (2) these injuries are "fairly trace[able]" to the Defendants' challenged conduct, and (3) their injuries are likely to be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–561 (1992).

Plaintiffs Rise for Animals ("Rise") and Animal Legal Defense Fund ("ALDF") both suffer concrete injuries stemming from the AAALAC Inspection Policy, which Plaintiffs assert violates the plain language of the AWA. The Policy deprives Plaintiffs of information that would necessarily be generated and reported in inspection reports if the USDA were complying with the statutory mandate to conduct complete inspections of research facilities each year. 7 U.S.C. § 2146(a). The AWA requires all such inspection reports to be made available to the public, including Plaintiffs. 7 U.S.C. § 2146a. Thus, Plaintiffs suffer informational injuries akin to those ruled sufficient by the Supreme Court in *Federal Election Commission v. Akins,* 524 U.S. 11, 21 (1998). The Policy also substantially impairs Plaintiffs' ability to effectuate their missions,

resulting in a drain on their resources and satisfying the injury-in-fact requirement described in *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 376 (1982).

A. Contrary To the USDA's Assertions, Plaintiffs Have Suffered Concrete Informational Injuries.

The USDA incorrectly contends that Plaintiffs have not suffered informational injury under *Akins.* Defendants' Opposition Brief ("Def.'s Opp'n. Br.") at 12. Defendants attempt to distinguish *Akins* by arguing that the *Akins* plaintiffs "were denied specific information from an organization that the applicable statute would require to be disclosed." *Id.* at 13. As Plaintiffs explained in their opening brief, *Akins* held that "the 'injury in fact' that respondents have suffered consists of their inability to obtain information . . . that, *on respondents' view of the law*, the statute requires" be made public. *Akins*, 524 U.S. at 21 (emphasis added). The informational injury asserted here is strikingly similar to the injury upheld in *Akins.*

The USDA is required to "inspect each research facility at least once each year" for the express purpose of identifying "deficiencies or deviations from the standards promulgated under this chapter," in which case the USDA "shall conduct follow-up inspections as may be necessary *until all deficiencies or deviations from such standards are corrected*." 7 U.S.C. § 2146 (emphasis added). Therefore, under any reasonable reading of the statute, the USDA must, at a minimum, complete a full annual inspection of each facility for the agency to ensure that all deviations and deficiencies have been both identified and corrected. Such inspections would necessarily generate inspection reports with more information than those produced under the AAALAC Inspection Policy, where inspectors only look at *one limited aspect* of the facility, or a sample, each year. Indeed, as this Court already observed in *Goldentyer*, "[w]ithout conducting full inspections as required by [the AWA], the Agency *lacks the necessary information to determine . . . whether the existing standards are sufficient to meet the needs of the animals in*

research facilities in accordance with AWA." *Goldentyer*, 2023 WL 2610867 at *11 (emphasis added). Thus, on Plaintiffs' theory of the merits, by failing to conduct inspections of all aspects of the facility, the USDA is not collecting information it would otherwise collect.

Information that would be generated by complete inspections, in turn, would necessarily become available to Plaintiffs. The AWA requires the USDA to make "all final Animal Welfare Act inspection reports" "publicly available . . . in their entirety." 7 U.S.C. § 2146a(b)–(b)(1). Therefore, Plaintiffs are suffering precisely the kind of informational injury the Supreme Court upheld in *Akins.* There, plaintiffs contended that a particular organization was a "political committee" subject to the reporting requirements of the Federal Election Act, and that, if they prevailed on this theory, (a) the organization would be required to report certain information and (b) the statute would require disclosure of all such information to the public. *Akins,* 524 U.S. at 16. The Supreme Court held that this statutory right to information—information that would have to be reported if the plaintiffs prevailed—was sufficient to satisfy the injury-in-fact requirement of standing. *Id.* at 24–25. *See also Pub. Citizen v. U.S. Dep't of Just.*, 491 U.S. 440, 449 (1989) ("refusal to permit appellants to scrutinize [American Bar Association] activities to the extent [the statute] allows constitutes a sufficiently distinct injury to provide standing to sue."); *Friends of Animals v. Salazar*, 626 F. Supp. 2d 102, 111 (D.D.C. 2009) ("by alleging that the challenged regulation effectively denies plaintiff information required to be made publicly available . . . plaintiff has alleged a concrete injury . . ." (cleaned up)).

Defendants respond by asserting that, in contrast to *Akins*, the AWA does not require "any particular *content*," that must be disclosed to the public, and only requires the USDA to "publish the applicable documents *it does create*." Def.'s Opp'n. Br. at 13 (emphasis added). But this argument ignores the fact that Section 2146(a) requires the agency to conduct full inspections of

each facility in order to identify any and all "*deficiencies or deviations from the standards*," and to ensure that "*all"* such deficiencies and deviations "*are corrected*." 7 U.S.C. § 2146(a) (emphasis added). Thus, under Plaintiffs' theory of the case, the USDA would necessarily be collecting more information that would have to be reported to the public about whether research facilities are complying with all applicable AWA standards—precisely the kind of injury the Supreme Court upheld in *Akins.* This plain reading of the statute, and its requirements, shows that there is no merit to Defendants' attempt to distinguish *Akins* and its progeny. *See also* Plaintiffs' Opening Brief ("Pl.'s Opening Br.") at 27.

Moreover, the agency itself stated in a document filed with this Court in the related primate standards case that, when they do their inspections, the agency inspectors "*document all areas* of care and treatment that are covered by the AWA." Betty Goldentyer, U.S. Dep't. of Agric., 2019 Denial of Rulemaking Petition, at 2, Pl. Ex. K (emphasis added); *see also New Eng. Anti-Vivisection Soc'y v. Goldentyer*, No. 8:20-CV-02004-JRR (2023), Defendants' Exhibit C, at 2, ECF No. 38-4. In their appeal of this Court's ruling in that case, the government likewise informed the Fourth Circuit Court of Appeals that USDA inspectors "conduct inspections of research facilities, they look for violations, *and they document any deficiencies*." *New England Anti-Vivisection Society v. Elizabeth Goldentyer* (4th Cir., 2023), Defendants' Appellate Brief, at 24, ECF No.14. Therefore, to the extent the agency is contending that, if Plaintiffs prevail in this case, inspectors will suddenly no longer "document any deficiencies" in their inspection reports, *id.,* this would run counter to what the agency itself has already assured Plaintiffs, this Court, and the Court of Appeals that inspectors do in reality.

Furthermore, in stating that "Congress has imposed no standards whatsoever on the content or manner of any inspection under the Act," Def.'s Opp'n. Br. at 11, Defendants once

again mislead this Court. In fact, concerned that the agency was *not* reporting all non-compliances in its inspection reports, in 2022 Congress enacted special appropriations legislation *specifically prohibiting* the agency from spending any funds on activities that involve the "*non-recording of observed violations of the Animal Welfare Act or its regulations on official inspection reports*." Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, § 756, 136 Stat 4459 (2022) (7 U.S.C. § 2146 note) (emphasis added). The associated House Committee Report explains that Congress was "concerned about APHIS's Animal Care program and the steep decline in enforcement related to violations of the Animal Welfare Act." H.R. Rep. No. 117-392, at 33 (2022). Thus, as the House Report further explains, the Appropriations Act "directs the agency to . . . ensure . . . *each violation or failure to comply with animal welfare standards, is documented on an inspection report*" and "ensure that there is no use of . . . any . . . program *that obscures findings during inspections*." *Id.* (emphasis added).

Therefore, it is beyond legitimate dispute that full inspections would necessarily generate additional information that, under Section 2146a, the agency would be *required* to disclose to Plaintiffs. 7 U.S.C. § 2146a. *See also* Def.'s Opp'n. Br. at 14 (acknowledging that Plaintiffs "would attain additional information" if "a facility deemed low-risk was substantially noncompliant in one area, but the area the inspector chose to inspect was compliant."). Access to these inspection reports would then allow Plaintiffs to ascertain which facilities are operating in compliance with the AWA, to gauge how the agency construes the applicable AWA standards, and to determine whether the agency is complying with its various statutory mandates to ensure the humane treatment of animals covered by the AWA.

Defendants rely, to their detriment, on *National Veterans Legal Services Program v. U.S. Department of Defense*, 990 F.3d 834 (4th Cir. 2021), where the Court of Appeals for this Circuit

explained that the Department of Defense's failure to publicly disclose its decision documents—which the relevant statute and regulations *require* it to disclose—"is just the kind of injury found to have established standing in *Akins*." 990 F.3d at 838; Def.'s Opp'n. Br. at 14. However, this injury is akin to Plaintiff's injury, i.e., the USDA's failure to disclose to the public the results of full annual inspections, as required by the AWA. *Weisberg v. U.S. Department of Justice*, 705 F.2d 1344 (D.C. Cir. 1983), similarly fails to counter Plaintiffs showing of injury. *Weisburg* interpreted the Freedom of Information Act ("FOIA") to only require disclosure of information that already exists—not to mandate that agencies create new documents. 705 F.2d at 1363. However, FOIA is very different from the statute at issue here, which requires the agency to (a) conduct full inspections, and then (b) disclose the results of those inspections. 7 U.S.C. §§2146, 2146a.

As *Akins* itself explains, when determining whether an injury-in-fact exists, the court must accept Plaintiffs' legal theory of the merits. *See, e.g.*, *Akins,* 524 U.S. at 21; *Ctr. for Biological Diversity v. U.S. Int'l Dev. Fin. Corp.*, 77 F.4th 679, 685 (D.C. Cir. 2023) (noting, in the context of an informational injury, "[f]or purposes of standing, we assume the merits in favor of the plaintiff." (internal quotation omitted)). Here, accepting Plaintiffs' legal theory, the USDA has denied them information that the AWA mandates the agency prepare and make public.

Nor is there any merit to Defendants' contention that the informational injury asserted here "is unduly speculative." Def.'s Opp'n. Br. at 14. The sole case relied on for this proposition, *Clapper v. Amnesty International, USA*, 568 U.S. 398 (2013), is clearly distinguishable. There, the Court found that the "highly attenuated chain of possibilities" it would have to accept was far too speculative to demonstrate the kind of imminent injury required for standing. *Clapper,* 568 U.S. at 410 (citing, inter alia, *Lujan*, 504 U.S. at 565, n.2). Here, in sharp contrast to *Clapper,*

Plaintiffs are *presently* being denied information to which they are entitled and will *continue to suffer such informational injury* unless and until the agency actually complies with its statutory obligation to conduct full inspections—the results of which must be publicly disclosed.

Plaintiffs also have thoroughly demonstrated precisely how this lack of information impairs their ability to carry out their advocacy programs, as well as their ability to monitor the agency's implementation of the statute. *See, e.g.*, Butler Decl., Pl. Ex. H ¶¶ 8, 11 ("For years, Rise has relied heavily on information generated by APHIS inspections," and "[t]his lack of information impedes Rise's ability to support its own and other grassroots efforts to stop the mistreatment of animals in research and to educate the public."); Melrose Decl., Pl. Ex. I ¶ 7 (noting that ALDF relies on information in inspection reports "to ensure that the USDA is fulfilling its statutory duties, to identify noncompliant facilities, to calibrate its advocacy for animals at noncompliant facilities, and to educate the public, policymakers, and others about these matters"); *see also TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2214 (2021) (noting the requirement for "downstream consequences" from the denial of information required by statute). Accordingly, Plaintiffs have amply demonstrated their standing based on informational injury.

B. <u>Plaintiffs Have Established Organizational Standing Under Havens.</u>

Although Plaintiffs have already demonstrated they have standing due to informational injuries, Pl.'s Opening. Br. at 26–29, Plaintiffs also suffer resource-drain injuries recognized by *Havens*, 455 U.S. at 372–75, .and adopted by this Circuit. The USDA's failure to conduct annual inspections as required by the AWA is also injuring Plaintiffs by depriving them of information they need to carry out their basic organizational functions. *See id.* at 379; *CASA de Md., Inc. v. Trump*, 971 F.3d 220, 239-40 (4th Cir. 2020); *PETA. v. Tri-State Zoological Park of W. Md., Inc.*, 843 F. App'x 493, 496-97 (4th Cir. 2021).

Defendants assert that Plaintiffs rely on "decisions that lie far outside the bounds of the Circuit's precedent," Def.'s Opp'n. Br. at 17, and quote a *dubitante* opinion from a *D.C. Circuit* case*, PETA v. U.S. Department of Agriculture*, 797 F.3d 1087, 1099–1106 (D.C. Cir. 2015) (Millett, J., *dubitante*). This ignores the *majority* opinion in that case, which held that plaintiffs had Article III standing due to a "denial of access to bird-related AWA information including, in particular, investigatory information, and a means by which to seek redress for bird abuse." *PETA*, 797 F.3d at 1095. Plaintiffs face a similar plight—they are being denied information they use to further their missions, as well as the means to identify unlawful animal research activities. As explained in the uncontested declarations submitted in support of Plaintiffs' motion for summary judgment, "Rise uses APHIS inspection reports . . . to direct its efforts and resources by prioritizing laboratories that are the most noncompliant with the AWA" and to "develop and maintain its Animal Research Laboratory Overview (ARLO) database," which is "one of Rise's most important advocacy tools." Butler Decl., Pl. Ex. H ¶ 8; *see also* Melrose Decl., Ex. I ¶ 7 (detailing how ALDF relies on USDA inspection reports to further its organizational mission).

Defendants attempt to distinguish *PETA* and *American Anti-Vivisection Society (AAVS) v. United States Department of Agriculture*, 946 F.3d 615 (D.C. Cir. 2020), by arguing that the injury-in-fact in both cases consisted of a combination of two injuries: a denial of information and a means to seek redress for animal abuse. Def.'s Opp'n. Br. at 17. Plaintiffs in *AAVS* were deprived of information that "would provide the substance from which the [plaintiff] would 'educat[e]' the 'public' and 'promot[e] [ ] humane treatment of birds,' and would be used to gauge 'cruelty to birds.'" *AAVS*, 946 F.3d at 619 (alterations in original). Here, Plaintiffs describe similar injuries; the denial of the inspection information impairs their ability to ascertain which

facilities are operating in violation of the AWA, as well as their ability to advocate that the USDA take measures to bring such facilities into compliance. *See, e.g.*, Melrose Decl., Pl. Ex. I, at ¶ 7.

Furthermore, in sharp contrast to *Lane v. Holder*, 703 F.3d 668, 675 (4th Cir. 2012), Plaintiffs are suffering injuries to their longstanding advocacy efforts. While it is well-established that spending resources on litigation and lobbying is not a cognizable injury for purposes of organizational standing, *see, e.g.*, *Am. Soc. for Prevention of Cruelty to Animals v. Feld Ent., Inc.,* 659 F.3d 13, 25–26 (D.C. Cir. 2011), Defendants are incorrect to suggest that impairment of other forms of advocacy is also not cognizable, Def.'s Opp'n. Br. at 17. *See Feld,* 659 F.3d at 27 ("many of our cases finding *Havens* standing involved activities that could just as easily be characterized as advocacy—and, indeed, sometimes are.").[1]

Unlike the plaintiffs in *Lane*, Plaintiffs are not undertaking a *new* project in response to recently enacted legislation. Rather, the unlawful AAALAC Inspection Policy has impaired their ability to engage in advocacy that has long been at the core of their missions. Indeed, in *PETA v. Tri-State,* the Court of Appeals for this Circuit distinguished the voluntary budgetary choices in *Lane* from expenditures that are necessary to continue an organization's pre-existing, mission-based programs. 843 F. App'x at 496. The Court recognized PETA's mission "to protect animals from abuse, neglect, and cruelty," and noted a number of pre-existing programs that PETA used to further its mission, including "public education, cruelty investigations and research, the rescue of animals, and protest campaigns." *Id*. The Court made clear that, unlike the voluntary

[1] Defendants also cite *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015), but that case explains that an organization *does* suffer an injury where it "expends resources to educate its members and others" when "doing so subjects the organization to operational costs beyond those normally expended." 808 F.3d at 919. Furthermore, while Defendants selectively quote *Turlock Irrigation District v. FERC*, 786 F.3d 18, 24 (D.C. Cir. 2015), for the assertion that "the expenditure of resources on advocacy is not a cognizable Article III injury," they fail to note that, *in the very next sentence*, the court makes clear that it is discussing advocacy only in the context of litigation or administrative proceedings. *Id.*

budgetary choices in *Lane,* PETA's actions were necessary to maintain the organization's longstanding programs. *Id.*

Similarly, in the present case, Plaintiffs are "required by [their] mission[s]," *id.*, to "protect and advocate for animals used in research," Melrose Decl., Pl. Ex. I ¶ 4, and to "protect animals in research facilities and prevent their suffering." Butler Decl., Pl. Ex. H ¶ 3. The AAALAC Inspection Policy has frustrated Plaintiffs' organizational purposes and required Plaintiffs to devote resources to further their long-standing advocacy programs and missions by "responding to complaints about illegal or inhumane animal treatment at research facilities, identifying and investigating such facilities, and working to remedy deficiencies and violations of AWA standards," Melrose Decl., Pl. Ex. I ¶ 10, as well as requiring Plaintiffs to divert resources to "ascertaining whether research labs comply with the AWA," Butler Decl., Pl. Ex. H ¶ 10.

Judge Hazel of this Court relied heavily on *PETA v. Tri-State* in denying the government's motion to dismiss the related primate standards case. *New England Anti-Vivisection Soc'y v. Goldentyer*, No. GJH-20-2004, 2021 WL 4459217, at *8 (D. Md. Sept. 29, 2021). He found that the plaintiffs had alleged standing under *Havens* due in part to "the added burden caused by the denial of information regarding the conditions under which primates are being maintained in laboratories." *Id.* Judge Hazel found those alleged injuries similar to the organizational injuries in both *PETA v. Tri-State* and *PETA v. USDA*, and ruled that the "lack of informative reports under the current rules" "perceptibly impaired" NEAVS's mission. *Id.* Thus, because NEAVS had "expended resources to counter these injuries," it had alleged sufficient Article III standing. *Id.* at *8–9. Judge Hazel also found that plaintiff ALDF had alleged

sufficient injury "on the basis that the current rules require it to divert resources to data collection for its advocacy campaigns, when APHIS should be providing the necessary data." *Id.* at *11.

Judge Hazel's reasoning applies equally here: Plaintiff Rise's mission is impaired by the denial of information that would be in inspection reports, but-for the USDA's new Policy. Rise now must expend resources to counter these injuries and fill the informational gap created by this unlawful Policy. Butler Decl., Pl. Ex. H ¶ 11. *See also* Melrose Decl., Pl. Ex. I ¶ 10. (Plaintiff ALDF "can at best only attempt to reconstruct" information that should be available through inspection reports.). Accordingly, Plaintiffs have established standing under *Havens.*

II. THE USDA'S ADOPTION OF THE SECRET AAALAC INSPECTION POLICY IS JUDICIALLY REVIEWABLE.

A. Plaintiffs Are Not Challenging Any Agency Enforcement Decision.

In its responsive brief, Defendants argue that the Inspection Policy is not judicially reviewable. Def.'s Opp'n. Br. at 6–12. This contention is incorrect. There is "a 'strong presumption' favoring judicial review of administrative action." *Mach Mining, LLC v. E.E.O.C.*, 575 U.S. 480, 486 (2015). Indeed, the Administrative Procedure Act's ("APA") "central purpose" is "providing a broad spectrum of judicial review of agency action." *Ohio River Valley Env't Coal., Inc. v. Kempthorne*, 473 F.3d 94, 100 n.5 (4th Cir. 2006). The APA contains a "very narrow exception" to this presumption of reviewability. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971). That exception applies only where the agency action at issue "is committed to agency discretion by law," 5 U.S.C. § 701(a)(2), or where "statutes expressly preclude judicial review." *Kempthorne*, 473 F.3d at 101 (citing 5 U.S.C. § 701(a)(1)). Neither circumstance applies here.

First, nothing in the AWA's text "expressly preclude[s] judicial review" of USDA policy decisions. *Id.* Second, the challenged action is *not* "committed to agency discretion by law." 5

U.S.C. § 701(a)(2). Plaintiffs challenge USDA's adoption of a new policy that dictates how its inspectors will conduct annual inspections of research facilities required by the AWA. 7 U.S.C. §2146. Because Plaintiffs challenge the Policy for violating an AWA mandate, "[p]lainly, there is 'law to apply,'" i.e., the plain text of the statute itself. *Overton Park*, 401 U.S. at 413. The AWA provides that "[t]he Secretary *shall* inspect each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this chapter, *shall* conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected." 7 U.S.C. § 2146(a) (emphasis added). This mandatory language indicates Congress's "intent to circumscribe agency . . . discretion" and provides "meaningful standards for defining the limits of that discretion." *Heckler v. Chaney*, 470 U.S. 821, 834 (1985). Thus, "[a]ny contention that the relevant provision … is discretionary would fly in the face of its text, which uses the imperative 'shall.'" *Bennett v. Spear*, 520 U.S. 154, 175 (1997); *see also Air Line Pilots Ass'n, Int'l v. U.S. Airways Grp., Inc.*, 609 F.3d 338, 342 (4th Cir. 2010) ("it is uncontroversial that the term 'shall' customarily connotes a command"). Although the USDA would like to cast this case as challenging an agency's enforcement decision, Plaintiffs in fact are challenging the agency's wholesale abandonment of its statutory duties.

As the Court of Appeals for this Circuit has recognized, "[m]ajor agency policy decisions are 'quite different from day-to-day agency enforcement decisions.'" *Casa De Md. v. U.S. Dep't of Homeland Sec.*, 924 F.3d 684, 699 (4th Cir. 2019). Specifically, general policies "are more likely to be direct interpretations of the commands of the substantive statute rather than the sort of mingled assessments of fact, policy, and law that drive an individual enforcement decision and that are … peculiarly within the agency's expertise and discretion." *Id.* (internal citation omitted). Accordingly, "an agency's expression of a broad or general enforcement policy based

on the agency's legal interpretation is subject to review." *Id.* at 699; *see also OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 811–12 (D.C. Cir. 1998) (holding courts had jurisdiction because challenged agency action was general policy of refusing to enforce provision of substantive law and not a "single-shot non-enforcement decision").[2]

Indeed, the agency itself concedes that the challenged Policy is a "new policy." Def.'s Opp'n. Br. at 34. Therefore, because the AAALAC Inspection Policy is a new general policy, the agency cannot overcome the strong presumption for judicial review that applies.

B. <u>The AAALAC Inspection Policy Is a Reviewable Final Agency Action.</u>

The USDA also errs by contending that the AAALAC Inspection Policy does not qualify as a reviewable "final agency action" under the APA, 5 U.S.C. § 704, because "no legal consequences flow from the issuance of this policy." Def.'s Opp'n. Br. at 10. The new Policy plainly satisfies the criteria for final agency action. A final, reviewable agency action is a "governmental act[] that determin[es] rights and obligations." *City of N.Y. v. U.S. Dep't of Def.*, 913 F.3d 423, 431 (4th Cir. 2019) (internal quotation omitted)). As the agency itself acknowledges, "[t]o meet this requirement, a party must demonstrate that the challenged act . . . altered the legal regime in which it operates." Def.'s Opp'n. Br. at 10 (quoting *City of N.Y.*, 913 F.3d at 431) (alteration in original); *see also Nat'l Veterans Legal Servs. Program v. U.S. Dep't of Def.*, 990 F.3d 834, 840 (4th Cir. 2021) (holding final agency action "must be one by which rights or obligations have been determined, or *from which legal consequences will flow*")

[2] The agency relies on various cases that are clearly distinguishable from the present one. Def.'s Opp'n. Br. at 8. In *Animal Legal Defense Fund, Inc. v. Glickman*, 943 F. Supp. 44, 62 (D.D.C. 1996), *vacated*,130 F.3d 464 (D.C. Cir. 1997), the court acknowledged that even "nonenforcement decisions are reviewable where … an agency engages in a pattern of non-enforcement of clear statutory language." *Id.* at 63 n.6. Both *PETA v. U.S. Dep't of Agric.*, 861 F.3d 502, 511 (4th Cir. 2017), and *Hawthorn Corp. v. United States*, 98 F. Supp. 3d 1226, 1241 (M.D. Fla. 2015), address only the USDA's discretion to investigate licenses, and *not* its statutory mandate to inspect research facilities annually. Moreover, *Moor-Jankowski v. Board of Trustees of New York University,* Case No. 96 civ 5997, 1998 U.S. Dist. LEXIS 4006, at *11 (S.D.N.Y. Mar. 30, 1998), sought review of a specific USDA investigation, whereas the present case seeks the Court's review of a general policy and *not* a specific enforcement decision.

(emphasis added) (internal quotation omitted); *Golden & Zimmerman, LLC v. Domenech*, 599 F.3d 426, 433 (4th Cir. 2010) (explaining that final agency action could be found when an agency "modif[ies] the applicable legal landscape by interpreting the scope [of the applicable law]").

By the USDA's own admission, the AAALAC Inspection Policy, finalized in February 2019, was a "new policy," Def.'s Opp'n. Br. at 34, under which the agency no longer conducts full inspections of all research labs. As such, it necessarily altered the legal regime and generated new legal consequences. Prior to institution of the Policy, the USDA allowed inspectors, at their discretion, to use focused inspections in limited contexts—e.g., when conducting re-inspections of noncompliances or "follow[ing] up on a public complaint concerning animal welfare." AR 03317. By contrast, under the new Policy, inspectors are *required* to conduct a focused inspection at AAALAC accredited facilities. As an internal agency document obtained under FOIA explains, "[t]his focused inspection counts as the facility's annual inspection" under the AWA, 7 U.S.C.§ 2146(a). AR 03728. *See also id.* ("in February 2019, we issued guidance that *made it mandatory (rather than discretionary)* for inspectors to perform focused inspection [sic] at AAALAC-accredited research facilities unless the research facility requested a full inspection" (emphasis added)); Jones Decl. ¶¶ 6, 11 (admitting that a routine inspection is a full, complete inspection and that the USDA no longer does annual routine inspections for all research facilities). Therefore, the Policy clearly modified the legal landscape by *mandating* focused inspections for research facilities in lieu of the annual routine inspections required by the statute.

The AAALAC Inspection Policy altered the legal regime by denying the animals covered by the AWA the full protections of the statute. Likewise, it altered the legal regime with respect to Plaintiffs' ability to protect these animals: Plaintiffs can no longer find out which facilities are in compliance with all AWA standards, nor can they discern how the agency is construing the

standards and whether the agency is even enforcing the statute. The Policy also altered the legal regime for the regulated industry. Mandating focused inspections for AAALAC-accredited research facilities ensures that the agency will never know whether such facilities are violating the AWA, thereby immunizing facilities from potential enforcement actions. This case is similar to *Clean Air Council v. Pruitt*, 862 F.3d 1 (D.C. Cir. 2017), where environmental groups challenged the EPA's decision to stay implementation of a final rule regarding greenhouse-gas emissions. The stay constituted "final agency action" because it "affect[ed] regulated parties' 'rights or obligations'" within the meaning of *Bennett v. Spear*. *Pruitt*, 862 F.3d at 7 (quoting *Bennett*, 520 U.S. at 178). Specifically, the stay indefinitely extended the industry's deadline to comply with the rule, thereby eliminating the threat of "civil penalties, citizens' suits, fines, and imprisonment" for noncompliance and "reliev[ing] regulated parties of liability they would otherwise face." *Id.* Similarly, AAALAC-accredited research facilities are being immunized from liability for violations of the AWA that would otherwise be detected if the USDA were conducting full annual inspections. *See also Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 313-17, 320 (D.C. Cir. 2016) (finding agency guidance document final agency action because it "b[ound] EPA regional directors" and authorized them to approve plans that did not include collection of certain penalties from polluters.) Accordingly, there is no merit to the argument that the Policy is not a reviewable final agency action.

III. THE USDA'S SECRET POLICY VIOLATES THE PLAIN LANGUAGE OF THE ANIMAL WELFARE ACT.

A. The Court Should Use Normal Tools of Statutory Construction to Interpret the Requirements of the AWA.

As Plaintiffs explained in their opening brief, Congress amended the AWA in 1985 to require the Secretary to conduct annual inspections of each research facility. Pl.'s Opening Br. at

2–3. The USDA dismisses the significance of the 1985 amendment to 7 U.S.C. § 2146(a) because the language was "added later," arguing instead that the Court should give more weight to the earlier language of the statute that authorized the Secretary to "make such investigations or inspections as he deems necessary" to determine if a regulated entity is operating in violation of the statute. Def.'s Opp'n. Br. at 21–22. However, as the Supreme Court long ago explained, statutory text "may not be read isolated from its legislative history and the revision process from which it emerged, all of which place definite limitations on the latitude we have in construing it." *Muniz v. Hoffman*, 422 U.S. 454, 468 (1975). When Congress amends a statute, the newly added, more particular language must govern over the older, more general language. *See I.N.S. v. Cardoza-Fonseca*, 480 U.S. 421, 442–44 (1987) ("Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." (internal quotation marks omitted) (quoting *Nachman Corp. v. Pension Benefit Guaranty Corp.*, 446 U.S. 359, 392-393 (1980))). Accordingly, the Court should apply the plain language of 7 U.S.C. § 2146(a), which includes the 1985 mandate that the agency conduct an annual inspection of each research facility to determine whether it is in compliance with all applicable AWA standards. This Court should not accept the agency's invitation to read this amendment out of the statute.

As the USDA itself notes, "when the statute's language is plain, the sole function of the courts . . . is to enforce it according to its terms." Def.'s Opp'n. Br. at 21 (quoting *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004)). Furthermore, as the agency also acknowledges, "the Court is 'obliged to give effect, if possible, to every word Congress used.'" *Id.* at 20 (quoting *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 583 U.S. 109, 128–29 (2018)). Moreover, "'the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" *Id.* at 21

(quoting *West Virginia v. EPA*, 142 S. Ct. 2587, 2607 (2022)). By following these fundamental tenets of statutory construction, the Court should easily conclude that the statute requires the USDA to complete annual inspections of research facilities *sufficient to identify any deficiencies or deviations* from all applicable AWA standards for the purpose of ensuring that they are "corrected" so that the animals receive the statute's protections. 7 U.S.C. § 2146.

First, the plain language of Section 2146(a) makes clear that a focused inspection fails to comply with the Congressional mandate. It states, in relevant part: "The Secretary *shall inspect* each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this chapter, *shall conduct* such follow-up inspections as may be necessary until *all deficiencies or deviations* from such standards are corrected." 7 U.S.C. § 2146(a) (emphasis added). As Plaintiffs have explained, "shall" is a nondiscretionary word of command. Pl.'s Opening Br. at 13; *see also* discussion of "shall" *supra* at 13. Therefore, the phrase "shall inspect" requires the USDA to inspect each research facility at least once yearly. 7 U.S.C. § 2146(a).

Further, the phrase "shall conduct" requires the USDA to perform follow-up inspections to determine that "*all* deficiencies or deviations" from the AWA standards have been rectified. *Id.* (emphasis added). Under the most natural reading of the statute, this additional mandate requires the agency to ascertain and record *all AWA deviations* during the requisite annual investigation. A focused inspection simply cannot identify *all* AWA noncompliance issues because, as Plaintiffs have explained, it "prohibit[s] its inspectors from even looking at more than one part of a facility during an annual inspection." Pl.'s Opening Br. at 13. Similarly, Congress's use of the word "inspect," which means "to view closely in *critical appraisal*," indicates a highly detail-oriented and thorough investigation. *Inspect*, Merriam-Webster, https://www.merriam-

webster.com/dictionary/inspect (emphasis added); *see also, e.g.*, *Taniguchi v. Kan Pac. Saipan, Ltd.,* 566 U.S. 560, 569 (2012) (surveying dictionary definitions to determine the ordinary meeting of a statutory term). Thus, a partial, focused inspection—*by which agency inspectors may not look at a single animal in possession of the lab for 3-4 years*—simply fails to comply with Congress's plain directive.

Using a bizarre clause-by-clause parsing of the statute, the USDA argues that the second clause, "in the case of deficiencies or deviations from the standards promulgated under this chapter," is conditional—i.e., it only applies if the agency's inspection actually identifies a violation of the statute. Def.'s Opp'n. Br. at 19 (quoting 7 U.S.C. § 2146(a)). However, the agency fails to explain *how* it will identify such violations of the Act if the inspectors are now *prohibited* from looking for, and identifying, all deficiencies and deviations.

The statutory context further demonstrates that Congress intended to mandate complete inspections each year. The whole purpose of the AWA is to "insure" that research animals are treated humanely. 7 U.S.C. § 2131. As this Court recently held, focused inspections contravene this purpose by "fail[ing] to consider basic features *essential to safeguarding animal welfare* in a research setting – starting with the animals." *Goldentyer*, 2023 WL 2610867 at *11 (emphasis added). *See also id.* (holding that focused inspections deprive USDA of "the necessary information to determine … whether the existing [facility] standards are sufficient to *meet the needs of the animals* in research facilities in accordance with AWA") (emphasis added).

The USDA boldly asserts that its contrived interpretation is the "the most natural reading of the statute." Def.'s Opp'n. Br. at 20. But the "most natural reading of the statute" surely would not allow years to pass before an inspector observes a single animal, as the USDA's interpretation provides. *See Goldentyer*, 2023 WL 2610867 at *6 ("According to the internal

USDA Annual Inspections Document … the Agency's mandatory 'focused inspection' practice may result in up to four years passing before an inspector lays eyes on a single research animal – and in years when animals are observed, it may be a 'sampling' of the research animals, not a facility's entire stock of subjects."). Indeed, this Court has already rejected the government's argument that its reading is the most natural: "[T]he court rejects the notion that substituting a severely abridged version of proper, full annual inspections is consistent with AWA's expression of congressional intent to protect the welfare of animals in research settings." *Id.* at *11. Therefore, the plain language of the statute, along with its overall purpose, demonstrates that focused inspections fly in the face of both the language and intent of the AWA.

B. <u>The USDA's Interpretation of the AWA Is Not Entitled to Any Deference.</u>

Not surprisingly, the USDA urges the Court to defer to its interpretation of the statute, asserting that, "if the text is ambiguous, then the USDA's interpretation of the statute must be given controlling weight because it is reasonable." Def.'s Opp'n. Br. at 25 (citing *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–44 (1984)). To begin, there is no reason to reach the question of deference, because the plain language of the statute, together with its overall purpose, is clear, *see* discussion of *Overton Park supra* at 12–13. Should the Court nevertheless believe the language is ambiguous, it should not defer to the agency's interpretation, which is not only unreasonable but also undercuts the purpose of the entire statute, i.e., ensuring that all the animals governed by the AWA are treated humanely and in accordance with all AWA standards. [3]

[3] The extent to which *Chevron* continues to apply is currently unclear. *See* Ryan D. Doerfler, *Late-Stage Textualism*, 2021 Sup. Ct. Rev. 267, 297 (2021) (noting that "*Chevron* has been unmentionable" in the Supreme Court for years). In recent years, the Supreme Court has resolved agencies' statutory interpretations without mentioning *Chevron*, *see, e.g.*, *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, 1899 (2022); *Becerra v. Empire Health Found., for Valley Hosp. Med. Ctr.*, 142 S. Ct. 2354, 2358 (2022)), and the issue of whether *Chevron* still applies is currently under review by the Supreme Court. *Loper Bright Enterprises v. Raimondo*, 143 S. Ct. 2429 (2023). Nonetheless, this does not change the fact that the agency's interpretation of the statute is unreasonable.

Under *Chevron*, a court reviewing an agency's interpretation of a statute it administers must disregard the agency's interpretation if "it is 'arbitrary or capricious in substance, or manifestly contrary to the statute.'" *Schafer v. Astrue*, 641 F.3d 49, 61 (4th Cir. 2011) (quoting *Mayo Found. For Med. Educ. & Research v. U.S.*, 562 U.S. 44, 53 (2011)). *See also MCI Telecommc'ns Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 229 (1994) ("an agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear"); *Kentuckians for Commonwealth Inc. v. Rivenburgh*, 317 F.3d 425, 441 (4th Cir. 2003) ("evasion of a statute's core mandate and purpose can scarcely be considered a reasonable interpretation") (cleaned up). As already discussed, *see* discussion of AWA's purpose *supra* at 19, the AAALAC Inspection Policy undercuts the statute's core mandate and purpose of "insur[ing] that animals intended for use in research facilities … are provided humane care and treatment." 7 U.S.C. § 2131. Therefore, the agency's interpretation of the AWA cannot be upheld even under the application of *Chevron* deference.

IV. THE USDA HAS UNLAWFULLY DELEGATED ITS INSPECTION DUTIES TO AAALAC.

Contrary to the USDA's assertion that it does not "'defer' to AAALAC-accreditation," Def.'s Opp'n. Br. at 27–28, the agency clearly *has* delegated to AAALAC the agency's own statutory duty to conduct annual inspections of all research facilities. *See* Pl.'s Opening Br. at 15–17. In fact, as mentioned earlier, the agency's own internal documents make clear that the new Policy *mandates* deference to AAALAC accreditation, making it "mandatory (rather than discretionary) for inspectors to perform focused inspection [sic] at AAALAC-accredited research facilities unless the research facility requested a full inspection." AR 03728. Consequently, as this Court recently concluded, the USDA "has fairly abdicated the full scope of its inspection obligations" through its new Policy. *Goldentyer*, 2023 WL 2610867 at *14.

The USDA now asserts that it cannot possibly have delegated its authority to AAALAC because AAALAC accreditation is not the sole factor triggering the Policy—the Policy is instituted only if an AAALAC-accredited facility also has a "low risk of noncompliance." Def.'s Opp'n. Br. at 31 (citing Jones Decl. ¶12). However, this explanation hardly follows from the plain text of the Policy itself, which requires the performance of focused inspections "*at AAALAC-accredited research facilities* unless the research facility requested a full inspection," without regard to any other factor. AR 03728 (emphasis added). In any event, application of such an additional factor does not change the fact that the USDA still *assumes* that AAALAC accreditation means the facility is likely operating in compliance with most, if not all, AWA standards—even though, as Plaintiffs and the applicable Administrative Record demonstrate, this assumption is completely unfounded. Moreover, the agency cannot plausibly determine whether any facility has a "low incidence of noncompliance," Def.'s Opp'n. Br. at 31, if inspectors are performing extremely truncated inspections of only one aspect of each facility per year.

Moreover, as Plaintiffs' opening brief explains—and the USDA fails to negate—"Congress *unanimously rejected proposals for inspection regimes that deferred to AAALAC accreditation*, and made absolutely clear that it wanted the USDA itself to perform the annual inspections required by the statute." Pl.'s Opening Br. at 15 (emphasis added); *see also id.* at 4–7 (detailing how "Congress considered, but *expressly rejected*, the notion that the USDA should defer to AAALAC []accreditation," both when it enacted the AWA in 1966 and when it amended the AWA in 1985). Thus, although the government urges this Court to "respect" Congressional intent, Def.'s Opp'n. Br. at 20, it would have this Court completely *ignore* Congress's repeated decision that the agency not defer to the industry-dominated AAALAC to carry out the agency's own statutory obligations. *See* Pl.'s Opening Br. at 3–7. The USDA's response to this point—i.e.,

that the agency, not AAALAC, is actually conducting the inspections, Def.'s Opp'n. Br. at 28—is disingenuous in the extreme because the challenged Policy *prohibits* the agency inspectors from conducting a full inspection if a facility is AAALAC-accredited.

V. THE USDA'S DECISION TO ADOPT THE SECRET AAALAC INSPECTION POLICY WAS ARBITRARY AND CAPRICIOUS.

A. The Court May Not Rely on the Agency's Post-hoc Declaration.

To rationalize its arbitrary and capricious *"sub silentio"* departure from "prior policy," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009), the USDA now argues that the new AAALAC Inspection Policy is a "means" of "ensur[ing] the efficient and appropriate use of inspection resources," Def.'s Opp'n. Br. at 5 (citing Jones Decl. ¶4), in light of "limited resources," *id.* at 10. Not only is this argument an impermissible post-hoc rationalization which the Court must disregard, but it also fails to rescue the agency's position.

To start, the only citation supporting this argument is the Declaration of Andrew Jones, which offers an impermissible post-hoc rationalization for the AAALAC Inspection Policy. As this Court noted in the related primate standards case, "'[P]ost-hoc rationalizations … have traditionally been found to be an inadequate basis for review' and, at bottom, an agency 'must defend its actions based on the reasons it gave when it acted.'" *Goldentyer*, 2023 WL 2610867, at *8 (alteration in original) (quoting *Roe v. U.S. Dep't of Def.,* 947 F.3d 207, 220 (4th Cir. 2020); *Dep't of Homeland Sec. v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020)). *See also Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 539 (1981); *Overton Park*, 401 U.S. at 419; *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Moreover, this Court has already observed that limited resources are not an excuse for violating the plain language of the AWA. In *Goldentyer*, this Court considered the agency's argument that focused inspections "were developed to take the place of full annual inspections

for AAALAC-accredited facilities 'in response to concerns from inspectors about workload …'" *Goldentyer*, 2023 WL 2610867 at *11 (internal citation omitted). However, this Court rejected the premise that resource limitations are a factor that the USDA could consider in developing a regulatory framework for inspections, observing that "[t]he language of AWA makes plain that Congress enacted the statute to protect the welfare of animals in laboratory and research settings," and that "[t]he court is unconvinced that Congress intended the Agency to consider inspector workload as a factor when developing standards and protocols for protecting the welfare of animals." *Id.*

Furthermore, the USDA's complaint about limited resources is completely undermined by the agency's own budgetary requests to Congress. Those records show that in 2019, just prior to instituting the new AAALAC Inspection Policy, the agency requested a *decrease of over $250,000* in Congressional funding for the Animal Welfare Program. Pl. Ex. J at 20-52 (requesting a "Reduction for Animal Welfare enforcement efforts" of *$258,000 in Fiscal Year 2019*). The agency cannot seriously argue that it instituted the Policy due to a shortage of resources when at the same time it requested that Congress give it $258,000 *less* in resources for such tasks. *See, e.g.*, *Brnovich v. Biden*, 630 F. Supp. 3d 1157, 1176 (D. Ariz. 2022) (denying defendants' motion to dismiss where plaintiffs showed that defendants' complaint of "insufficient agency resources" was "pretextual" because *"[d]efendants ha[d] actively sought to decrease the resources available to enforce the immigration laws*") (emphasis added).[4]

The Jones Declaration further provides additional assertions that are (a) impermissible post-hoc rationalizations to be afforded no consideration and (b) without merit. Specifically,

[4] The Court is permitted to take judicial notice of the agency's own reports to Congress. *See United States v. Doe*, 962 F.3d 139, 147 n.6 (4th Cir. 2020) ("…we may take judicial notice of governmental reports."); *United States v. Cecil*, 836 F.2d 1431, 1452 (4th Cir. 1988) ("…courts may take judicial notice of official governmental reports and statistics.").

based on the Jones Declaration, the agency now conveniently asserts that "the USDA subjects all research facilities, including those that qualify for the focused inspection policy, to routine inspections at regular intervals." Def.'s Opp'n. Br. at 5 (citing Jones Decl. ¶12). Further relying on the Jones Declaration, the agency also contends that "if an inspector determines that circumstances warrant additional investigation, he or she will expand a focused inspection into a routine inspection." Def.'s Opp'n. Br. at 24–25 (citing Jones Decl. ¶12). However, the March 2019 Inspection Guide, to which the Jones Declaration refers and allegedly explicates, contains no such provisions. *See* AR 3246–85. Furthermore, nothing in the Administrative Record states that routine inspections will be performed at regular intervals or defines what is even meant by the term "regular intervals." Meanwhile, the Administrative Record—which governs the Court's review— indicates that, under the AAALAC Inspection Policy, focused inspections can be converted to routine inspections *only if requested by the regulated facility, not at the discretion of the inspector. See, e.g.*, AR 03728 (internal guidance stating that "in February 2019, we issued guidance that made it *mandatory* … for inspectors to perform focused inspections at AAALAC-accredited research facilities *unless the research facility requested a full inspection*") (emphasis added); AR 03729 (internal guidance stating that "regulated research facilities . . . have worked hard to be AAALAC accredited. . . . They have a right to expect that each inspector will follow this guidance."); AR 3731 (internal FAQ stating that even if an inspector wants to do a routine inspection during their first visit to a facility, "a focused inspection should be conducted" instead).

The impermissible post-hoc Jones Declaration includes additional misleading statements. For example, it states that "USDA inspectors … examine whether the facility is noncompliant with *any applicable provision of the Animal Welfare Act or its implementing regulation*." Jones

Decl. ¶ 7 (emphasis added). Yet this statement is simply not true; under the AAALAC Inspection Policy, many years will pass before an inspector looks at a single animal, let alone *all* of the animals in the possession of the facility, to determine if they are being treated in compliance with all applicable standards. *See* Pl.'s Opening Br. at 1, 10, 20 –21. Additionally, the Jones Declaration falsely asserts that the USDA's inspection regime "allows for … less frequent and/or less in-depth inspections at those [facilities] that are *consistently in compliance*." Jones Decl. ¶ 10 (emphasis added). Not only is it impossible for the agency to know if a facility is "consistently in compliance" with all AWA standards if the inspectors fail to conduct full inspections of those facilities each year, but the only peer-reviewed study on the topic found that AAALAC-accredited facilities are consistently *less* compliant with AWA regulations than other facilities. *See* Pl.'s Opening Br. at 21 (citing Goodman et al., AR 01385–95). Accordingly, this Court must ignore the agency's belated attempt at such post-hoc rationalizations, which are belied by the actual Administrative Record that *does* govern the Court's review.[5]

B. The USDA Failed to Consider Public Comments Opposing Reliance on AAALAC Accreditation.

As Plaintiffs further explained in their opening brief, the agency also acted arbitrarily and capriciously by failing to heed the comments it received from the public in 2018, which strongly opposed the agency relying on AAALAC accreditation as a basis for deciding the timing and scope of inspections of AWA-covered entities. *Id.* at 18–19. In response, the agency contends that it had no obligation to consider such comments because the issue on which it had public comment was "entirely distinct" from the matter at hand. Def.'s Opp'n. Br. at 32. However, this attempt to disavow the relevance of those comments has no merit.

[5] The USDA has also repeated the same misleading statement to Congress. *See* U.S. Dep't. of Agric., *Excerpts from 2022 USDA Budget Explanatory Notes*, at 22-115, Pl. Ex. L (stating that "[d]uring inspections, Agency officials examine and inspect *all areas of animal care and treatment* covered under the AWA.") (emphasis added).

The agency's 2018 Federal Register Notice advised the public that APHIS was collecting "data and information from the public to aid in the development of criteria for *recognizing the use of third-party inspection and certification programs as a positive factor when determining APHIS inspection frequencies at facilities licensed or registered under the Animal Welfare Act*." Third-Party Inspection Programs Under the Animal Welfare Act, 83 Fed. Reg. 2959 (Jan. 22, 2018), AR 1 (emphasis added). The agency further referred to this inquiry as relevant to its "Risk-Based Inspection System"—the same system it relies on here to defend the challenged Inspection Policy. *Id.; see* Def.'s Opp'n. Br. at 4.

As Plaintiffs demonstrated, the public response to the agency's 2018 Federal Register Notice overwhelmingly opposed relying on AAALAC accreditation "as a reason to reduce the scope or frequency of inspections." Pl.'s Opening Br. at 18; *see also id.* at 7–8, 18–24. Thus, the public clearly understood that the government was proposing reliance on AAALAC accreditation as a factor in determining both the scope and frequency of any such inspections. Indeed, determining that inspectors need only look at one aspect of a facility every three years demonstrably affects the "frequency" of inspections—i.e., *under the Policy, it can be three to four years before an inspector ever looks at a single animal at an AAALAC-accredited facility*. Moreover, the USDA ostensibly recognized that the comments had focused on the *general nature* of AAALAC accreditation when it announced that "the vast majority of the comments we received [were] not … in favor of establishing new criteria for *recognizing third party inspection and certification programs*," and, for that reason, the USDA informed the public that the agency had decided *not* to adopt the policy. AR 01571 (emphasis added).

Therefore, the agency's subsequent adoption of the AAALAC Inspection Policy was arbitrary and capricious because it ran "counter to the evidence before the agency," *State Farm*,

463 U.S. at 43, by completely disregarding "the numerous grounds cited by animal protection groups for *not* deferring to AAALAC accreditation." Pl.'s Opening Br. at 18. Indeed, all of those comments, which the agency urges this Court to ignore, are included in the *Administrative Record for the present case*. Therefore, they are clearly relevant to the matter at hand. *See also Goldentyer*, 2023 WL 2610867, at *12 (finding that the USDA acted arbitrarily and capriciously by "categorically ignor[ing]" the public comments on the matter).[6]

C. The USDA Fails to Refute Plaintiffs' Arguments that the AAALAC Inspection Policy Is Arbitrary and Capricious.

In their opening brief, Plaintiffs demonstrated myriad *additional* reasons why the agency's reliance on AAALAC accreditation is arbitrary and capricious. Namely, AAALAC is an industry-dominated organization with patent conflicts of interests; AAALAC does not perform annual inspections or even employ the AWA standards to determine accreditation; the record shows that AAALAC-accredited facilities have a higher incidence of non-compliance with the AWA than other facilities; AAALAC allows facilities to maintain their "accreditation" even when the facility is operating in violation of AAALAC criteria; and AAALAC is immune from public scrutiny. *See* Pl.'s Opening Br. at 19–24. Notably, the USDA fails to grapple with *any* of these arguments and instead insists that these points are irrelevant because the agency is *not* deferring to AAALAC accreditation. Indeed, the USDA places much weight on its assertion that an AAALAC-accredited facility is only eligible for a focused inspection if the facility also "presents a low risk of noncompliance based in part on that facility's compliance history during past USDA inspections." Def.'s Opp'n. Br. at 31 (citing Jones Decl. ¶ 12). However, in addition

[6] Contrary to the agency's assertion, Plaintiffs have not taken the position that the agency was "required" to "publish a[ ] decisional document addressing public comments." Def.'s Opp'n. Br. at 33. Rather, Plaintiffs simply have asserted that the agency acted arbitrarily and capriciously by failing to address any of the public comments on the matter and by failing to provide any rationale for this drastic change in policy. Pl.'s Opening Br. at 18–19.

to relying on their impermissible post-hoc Declaration for this argument, the agency fails to explain how the USDA knows that an AAALAC-accredited facility has a history of AWA compliance if the agency is no longer conducting full routine inspections every year.

As this Court already aptly noted in *Goldentyer,* "mandatory focused inspections *turn a blind eye to the constellation of considerations AWA requires the Agency to consider*." *Goldentyer*, 2023 WL 2610867 at *10 (emphasis added). Thus, as this Court has already recognized, "[t]he practice of annual focused inspections in lieu of annual standard inspections deprives the Agency of basic, essential information about a facility's standards in place 'during actual research or experimentation' such that an inspector cannot know whether a facility deviates from 'the standards promulgated under' AWA." *Id.* at *11; *see also id.* at *8 ("Under a 'focused inspection' the inspector … does not inspect all areas of the facility to ensure compliance with AWA standards … nor does the inspector, therefore, gather information regarding the adequacy of the AWA standard in practice."); *id.* ("a 'focused inspection' may not: examine all areas of care and treatment; observe regulated animals; or review pertinent facility plan documents and records as required by AWA"). Therefore, as this Court summarized, "[w]ithout conducting full inspections as required by [the AWA], the Agency *lacks the necessary information to determine … whether the existing standards are sufficient to meet the needs of the animals in research facilities in accordance with AWA*." *Id.* at *11 (emphasis added).

Finally, the USDA is also unable to disprove its "deliberate effort to *conceal* the fact that it was adopting a new policy." Pl.'s Opening Br. at 25. The agency attempts to mislead the Court by asserting that it did not announce the adoption of the AAALAC Inspection Policy solely because its details "concern law enforcement sensitive information about the agency's enforcement efforts." Def.'s Opp'n. Br. at 34 (citing Jones Decl. ¶¶ 9, 12). If the agency's true

aim had been "prevent[ing] the public from adjusting its behavior to evade enforcement," *id.* at 34, the USDA surely would not have informed the *regulated industry* about the Policy. Yet according to internal agency documents obtained under FOIA, the USDA did just that, instructing its inspectors to "share information about the focused inspections with *members of key industry* and stakeholder groups." AR 03728 (emphasis added); *see also* AR 03732 (instructing inspectors to convey the new Policy only to "their facilities"). Thus, the USDA's disclosure of the Policy to the very facilities it regulates, but not to the public, reveals the agency's clear attempt to hide the very existence of the Policy from the general public. Indeed, had Plaintiffs not pursued their FOIA request for this information, neither they—nor the Court—would even know that the agency had adopted this unlawful Policy four years ago.

CONCLUSION

For all the foregoing reasons, including those set forth in Plaintiffs' opening brief, Plaintiffs' motion for summary judgment should be granted and Defendants' motion for summary judgment should be denied.[7] [8]

Respectfully submitted,

/s/ Rebecca L. Garverman
admitted pro hac vice
Staff Attorney, Animal Law & Policy Clinic
Harvard Law School
1585 Massachusetts Ave.
Cambridge, MA 02138
631-896-2105 (c)
rgarverman@law.harvard.edu

/s/ Katherine A. Meyer
Md. Bar No. 07823
Of Counsel, Animal Law & Policy Clinic
Harvard Law School
1585 Massachusetts Ave.
Cambridge, MA 02138
202-257-5145 (c)
kmeyer@law.harvard.edu
Attorneys for Plaintiffs

[7] Given that Plaintiffs had already moved for summary judgment in this case, it is unclear why the agency has cross-moved for summary judgment and also moved to dismiss this case. However, for all of the reasons set forth here, and in Plaintiffs' opening brief, both motions should be denied.

[8] Plaintiffs wish to acknowledge and thank Harvard Law School students Magdalene Beck and Jonathan Smith for their invaluable assistance in preparing this brief.