CASE NO. 23-1556

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

NEW ENGLAND ANTI-VIVISECTION SOCIETY, et. al.,
Plaintiff-Appellees.

v.

ELIZABETH GOLDENTYER,[1] et. al.,
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FROM THE DISTRICT COURT OF MARYLAND

RESPONSE BRIEF OF APPELLEES

Katherine A. Meyer
Of Counsel
Animal Law & Policy Clinic
Harvard Law School
1585 Massachusetts Ave.
Cambridge, MA 02138

SUBMITTED BY:
Rebecca L. Garverman
Animal Law & Policy Clinic
1585 Massachusetts Ave.
Cambridge, MA 02138
617-496-5145
rgarverman@law.harvard.edu
Attorneys for Plaintiff

[1] Defendants-Appellants are Deputy Administrator Roxanne Mullaney, Animal and Plant Health Inspection Service, and Secretary Sonny Perdue, Department of Agriculture, each in their official capacities. Deputy Administrator Mullaney is automatically substituted as an Appellee for former Deputy Administrator Elizabeth Goldentyer. *See* Fed. R. App. P. 43(c)(2).

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 23-1556 Caption: New Eng. Anti-Vivisection Soc'y v. Goldentyer

Pursuant to FRAP 26.1 and Local Rule 26.1,

New England Anti-Vivisection Society, Animal Legal Defense Fund
(name of party/amicus)

---

who is Appellees, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: _____ Date: 06/07/2023

Counsel for: Appellees

Print to PDF for Filing Reset Form

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

Regulations

STATEMENT OF THE ISSUE

Did the district court properly rule that the USDA acted unlawfully when, in denying Plaintiffs' Rulemaking Petition, the agency relied on an erroneous description of its inspection process that the agency itself ultimately conceded was incorrect, otherwise failed to justify its decision, and relied on an impermissible *post hoc* declaration to explain the decision?

STATEMENT OF THE CASE

To demonstrate the fallacies of the government's position on appeal, it is important to review the history of the standard at issue and the proceedings below.

A. The Animal Welfare Act

Congress enacted the original Animal Welfare Act ("AWA") in 1966 to "insure that animals intended for use in research facilities. . . are provided humane care and treatment." 7 U.S.C. § 2131(1). As explained during the 1966 passage of the AWA by Senator Mike Monroney, "[t]he reason [f]ederal legislation [wa]s needed in the first place [wa]s the *shocking failure of self-policing by the medical community*." 112 Cong. Rec. 13,893 (1966) (emphasis added). The statute directed the United States Department of Agriculture ("USDA") to "promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors." 7 U.S.C. § 2143(a)(1).

In enacting the original legislation, Congress specifically rejected the idea of deferring to the Association for Assessment and Accreditation of Laboratory Animal Care ("AAALAC"), an industry-dominated non-governmental organization, to determine compliance with AWA standards. *See, e.g.*, 112 Cong. Rec. 13,888–93 (1966) (Senator Monroney warning that deferring to AAALAC accreditation would only reinforce the failure of self-policing because "the inspectors would be drawn from the same scientific community involved in being

inspected, a situation where there would be no serious impartiality."); *Animal Dealer Regulation: Hearings Before the S. Comm. on Commerce*, 89th Cong. 89-61 (1966) at 202 (Senator Joseph Clark describing reliance on AAALAC as "setting a fox to watch the chicken coop.").

While the original AWA required the Secretary of Agriculture to "promulgate standards to govern the humane" care of *all* animals subject to the statute, 7 U.S.C. § 2143(a)(1), by 1985 Congress had recognized the need for specific standards to provide for the unique psychological needs of nonhuman primates. *See* 7 U.S.C. § 2143(a)(2)(B); *see also* 131 Cong. Rec. 22,257 (1985) (finding that "[c]urrent standards [left] too much room for shoddy care and inhumane treatment"). Therefore, in 1985, Congress amended the AWA by specifically requiring the Secretary to promulgate a standard that provides "a physical environment adequate to promote the psychological well-being of primates." 7 U.S.C. § 2143(a)(2)(B).

To assure compliance with the overriding objective of the statute, the AWA, as amended in 1985, further provided 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).

B. The USDA's 1991 Regulations

In 1991, the USDA promulgated a regulation intended to implement the 1985 amendment, to promote the psychological well-being of primates. 9 C.F.R. § 3.81. The regulation—which has remained unchanged for over three decades—provides that each research facility that uses or houses nonhuman primates "must develop, document, and follow" its own "environment enhancement plan" to provide "environment enhancement adequate to promote the psychological wellbeing of nonhuman primates." *Id*. The regulation states that each "plan must be in accordance with the currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian." *Id*. However, the regulation does not contain any information about what those "currently accepted professional standards" are, or which "professional journals or reference guides" are "appropriate." *See id.*

Further, there is no requirement that the facilities' environment enhancement plans be pre-approved by the USDA, or even submitted to the agency. *See id.* (providing only that the plan be accessible at the facility). Consequently, there is no way for the public to monitor the adequacy of such plans under the Freedom of Information Act ("FOIA"). *See Forsham v. Harris*, 445 U.S. 169, 182 (1980) (only records in the possession of a federal agency are subject to disclosure under FOIA).

The 1991 regulation also fails to provide concrete, enforceable standards. For example, although the regulation indicates that certain categories of vulnerable primates—i.e., infants and primates who show signs of psychological distress—are to be afforded "special considerations," 9 C.F.R. § 3.81(c), it does not describe what these "special considerations" should be. The regulation also states that "[t]he physical environment in the primary enclosures must be enriched by providing means of expressing noninjurious species-typical activities," *id.* § 3.81(b), but does not provide any information about what those sources of enrichment must be, or explain how to ascertain whether any of the primates are actually being enriched. These vague, standard-less requirements stand in sharp contrast to the agency's implementing regulations for many other matters covered by the AWA, which impose concrete, enforceable standards. *See, e.g.*, 9 C.F.R. § 3.5(a) ("The ambient temperature must not fall below 45°F (7.2°C) for more than 4 consecutive hours when dogs or cats are present, and must not exceed 85°F (29.5°C) for more than 4 consecutive hours when dogs or cats are present.").[2]

[2] *See also* 9 C.F.R. § 3.103(c) (outdoor housing facilities for marine mammals "must be enclosed by a perimeter fence that is of sufficient height to keep animals and unauthorized persons out. Fences less than 8 feet high for polar bears or less than 6 feet high for other marine mammals must be approved in writing by the Administrator").

By 1996 the USDA itself had concluded that the regulation was insufficient for ensuring that facilities were adequately addressing the psychological needs of primates. *See* J.A.372. The agency's Animal and Plant Health Inspection Service ("APHIS"), which is responsible for enforcing the AWA, issued a report documenting that more than half of its inspectors found that "the criteria in the primate environmental enrichment plans" were not "adequate for . . . [i]nspectors to judge if a facility is meeting them," J.A.235, and that "more definition of the requirements" was needed, including "more stringent guidelines and/or policies concerning group housing, space variety, and areas of enrichment." J.A.254. The agency also found that the regulation was sowing "confusion among the regulated public concerning on what basis they will be judged by inspectors as meeting or not meeting the requirements," and its own "inspectors requested information and clarification on how to judge whether someone was meeting the requirements in § 3.81." J.A.372. Thus, APHIS concluded that "additional information on how to meet the standards in § 3.81 [was] necessary." J.A.372.

To rectify these problems, in 1999 APHIS formulated a "Draft Policy" intended "to be used by dealers, exhibitors, and research facilities as a basis in developing plans under § 3.81 for environment enhancement." J.A.372. The 1999 Draft Policy specifically addressed five elements APHIS identified as "the minimum" needed to comply with the AWA and adequately promote the

psychological well-being of nonhuman primates. J.A.372. These elements were: (a) social grouping; (b) social needs of infants; (c) structure and substrate; (d) foraging opportunities; and (e) manipulanda (i.e., the types of objects that can be moved or used by primates' hands or feet). J.A.372, J.A.375. APHIS considered these factors "*critical* to environments that adequately promote the psychological wellbeing of nonhuman primates." J.A.372 (emphasis added). Although the Draft Policy was published for public comments in the Federal Register on July 15, 1999, J.A.371, it was never finalized. Therefore, to date, no changes have been made to the primate regulations since they were initially promulgated in 1991.[3]

1. The National Institutes of Health Determines Additional Standards Are Required to Meet the Needs of Chimpanzees.

In early 2011, the Institute of Medicine convened the Committee on the Use of Chimpanzees in Biomedical and Behavioral Research to consider the necessity

[3] While the Draft Policy was still pending, Plaintiff ALDF challenged the sufficiency of the 1991 regulation on the grounds that it did not contain enough specific enforceable standards necessary to comply with the 1985 statutory mandate. *See Animal Legal Def. Fund, Inc. v. Glickman*, 204 F.3d 229, 231–32 (D.C. Cir. 2000). Although holding at that time that the regulation was not arbitrary and capricious, the D.C. Circuit observed that "[Plaintiff] may well be correct that some of the Secretary's regulations may prove difficult to enforce, or even difficult to augment through subsequent 'interpretation.'" *Id.* at 235 (citation omitted). However, citing the pending 1999 Draft Policy—which was never finalized—the Court went on to stress that "the Secretary has begun to offer interpretations likely to assist both regulatees and enforcers." *Id*. (citation omitted).

of continuing to use chimpanzees in research funded by the National Institutes of Health (NIH). J.A.391. The Committee's subsequent report introduced the concept of "ethologically appropriate physical and social environments" — meaning "captive environments that do not simply allow but also, importantly, *promote* a full range of behaviors that are natural for chimpanzees." J.A.431–432 (emphasis added). As the report explained, "to perform rigorous (replicable and reliable) biomedical and behavioral research, it is critical to minimize potential sources of stress on the chimpanzee." J.A.405.

In response to this report, the NIH formed a Working Group on the Use of Chimpanzees in NIH-Supported Research. J.A.410. The Working Group analyzed the then-current use of chimpanzees in research and developed final recommendations for the future use of chimpanzees. J.A.410. On June 26, 2013, the NIH accepted nine out of ten of the Working Group's recommendations regarding ethologically appropriate environments for chimpanzees. J.A.432–438, J.A.453. The recommendations provided concrete minimum standards for environments in which chimpanzees are held, including standards to address specific physical and social needs. *See* J.A.432–438. Thus, even though all federally funded laboratories were *already* required to follow all applicable AWA standards, including the USDA's 1991 regulation, *see* J.A.058 n.2, the NIH determined that *additional* requirements were necessary to meet the psychological

needs of chimpanzees. The standards were explicit and actionable, e.g., "[c]himpanzees should have the opportunity to climb at least 20 ft. (6.1 m) vertically." J.A.411. In fact, many of the adopted standards correspond to the same elements that APHIS identified in its 1999 Draft Policy as critical for promoting the psychological well-being of all primates, including the need for social housing and the importance of foraging. *See* J.A.373, J.A.411.[4]

C. Plaintiffs' Rulemaking Petition to Improve the Standard for the Psychological Well-Being of All Primates

1. Plaintiffs' Rulemaking Petition

On May 7, 2014, Plaintiffs—Rise for Animals and the Animal Legal Defense Fund (hereinafter the "Animal Advocates") —submitted a Petition for Rulemaking requesting that the USDA follow NIH's example and update the 1991 standard by promulgating specific, enforceable regulations to promote the psychological wellbeing of *all* primates used in research—regardless of species and whether they are being maintained by federally-funded labs. J.A.143, J.A.145–146, J.A.190. The Petition also asked the USDA to adopt regulations for

[4] *See also* J.A.411 ("Chimpanzees must have the opportunity to live in sufficiently large, complex, multi-male, multi-female social groupings, ideally consisting of at least 7 individuals."); J.A.411 ("Progressive and ethologically appropriate management of chimpanzees must include provision of foraging opportunities and of diets that are varied, nutritious, and challenging to obtain and process.").

identifying how and when primates exhibit psychological distress, as well as what must be done to ameliorate such symptoms. J.A.190.

The Rulemaking Petition provided examples of the extreme psychological distress and unnecessary suffering of individual primates as a result of the lack of clear and enforceable standards in the current regulatory framework. *See* J.A.184–187. For example, the Petition explained that macaques—an "inquisitive," "inventive," and "caring" species with "culture" and a "sense of justice and fairness"— develop pathological behaviors due to their confinement and lack of access to social or mental enrichment, including self-harm and mutilation. J.A.163; *see* J.A.180–181.

The Petition also documented how psychological distress experienced by primates used in research, and the physical manifestation of that stress, can have serious adverse effects on the scientific validity of research results. J.A.188–189. The Petition laid out detailed expert information explaining how the NIH's recommendations could be tailored and implemented for other primate species commonly used in research and relied on current scientific evidence from leading primatologists to document the myriad abilities and psychological needs of non-human primates, and the kinds of environments they need to "promote" their psychological well-being, as required by the AWA. J.A.162–189.

The Animal Advocates' Petition stressed that Congress's recognition in 1985 that primates have psychological needs that must be met if they are to be treated humanely, "is even clearer today given the overwhelming body of scientific evidence that has been amassed over the last 30 years as to the psychological capabilities and needs of primates, our ethical responsibilities towards them, and the implications of psychological well-being for scientifically valid research results." J.A.147. The Petition asserted that the current USDA regulatory regime is insufficient to properly prevent psychological distress, *see* J.A.152–159, and that "the current lack of clear, enforceable minimum standards to accomplish this objective has contributed to the proliferation of severe maladaptive behaviors and other psychosocial and cognitive symptoms in nonhuman primates that are held in captivity." J.A.184. The Petition therefore urged the USDA to amend the current regulations to include specific criteria for enhancing the psychological well-being of primates and to adopt regulations for determining when primates are experiencing psychological distress and the steps that must be taken to ameliorate those symptoms. J.A.190.

2. The USDA Solicits Public Comments to Receive Input on the Petition.

By letter dated May 20, 2014 then-Deputy Administrator for Animal Care, Chester Gipson, responded to the Animal Advocates' Rulemaking Petition by

stating that because "the issues raised in the petition are important" and "many parties will have an interest in them," the agency had decided to "publish the petition in a Federal Register notice in the near future to solicit public comment." J.A.367. Dr. Gipson further assured the Animal Advocates that the agency would "analyze[] all of the comments received" before deciding what action to take. J.A.367. On May 1, 2015, APHIS published notice of the Rulemaking Petition in the Federal Register, announcing that the USDA was "making this petition available to the public and soliciting comments regarding the petition and any issues raised by the petition *that [the agency] should take into account as [it] consider[ed] this petition*." J.A.368 (emphasis added).

APHIS received a total of 10,137 comments: 71% of those comments (7,232), were in favor of granting the Animal Advocates' Rulemaking Petition, only 1% (63 comments) opposed the Petition, and the rest of the comments addressed other matters. J.A.206.

Many comments documented the inadequacy of the current regulatory framework in ensuring the psychological wellbeing of primates used in research. For example, Dr. E. O'Halloran, a physician with experience in laboratories using primates, witnessed "abused" primates and observed primates "become insane, biting themselves, spinning in circles hours without end." Comment from Dr. E. O'Halloran, Docket ID APHIS-2014-0098-0893 (May 16, 2015); *see also*

Comment from Sanctuary Founder Sharon Strong, at 1–2, Docket ID APHIS-2014-0098-9781 (Aug. 28, 2015) (reporting observing an elderly primate, retired from a laboratory, whose "muscles were damaged from repeated self-biting"). The director of the Fauna Foundation, a sanctuary for chimpanzees retired from laboratory settings, noted that *all* the chimpanzees in the sanctuary rescued from the Laboratory for Experimental Medicine and Surgery in Primates "displayed a range of psychological and emotional behaviors much like those of humans who suffer post-traumatic stress disorder (PTSD)," where "some symptoms remain[ed] entrenched" even decades after leaving research facilities. J.A.094.[5]

Other public comments emphasized the extent to which the 1991 regulation's vagueness has allowed research facilities to ignore, rather than incorporate, scientific developments into the "currently accepted professional standards," 9 C.F.R. § 3.81. For example, the Laboratory Primate Advocacy Group, a nonprofit organization with decades of experience caring for primates in laboratories, zoos, and sanctuaries, explained that "'professional standards' allow . . . laboratory industries to self-regulate" because the concept of what is "currently

[5] Although the USDA agreed that all of these comments are part of the Administrative Record, it did not place them in that Record but instead, agreed that the parties could cite to the comments as they are lodged at the agency's website: https://www.regulations.gov/docket/APHIS-2014-0098/comments. *See also* Joint Status Report, at 1–2, Dec. 14, 2021, ECF No. 28 (Status Report explaining that all such comments may be relied on by the parties).

accepted" is set by the labs themselves. J.A.073. As a result, in over thirty years, "these industries have not been incentivized to develop new professional standards." J.A.073. As People for the Ethical Treatment of Animals ("PETA") similarly emphasized, laboratories are able to "take[] cover behind the nebulous language of Section 3.81" to continue "unacceptable" practices such as housing single primates in barren metal cages. J.A.088. The Director of the Fauna Foundation further explained that the result of the scientific stagnation of the regulation is plain: "without stringent oversight," the USDA has been "a major contributor to [the] unnecessary and prolonged suffering" of countless primates in laboratories. J.A.094–095.

Commenters also stressed the *feasibility* of adapting the NIH chimpanzee requirements to apply to other primate species used in research. As explained by preeminent animal behaviorist Dr. Marc Bekoff, Professor Emeritus at the University of Colorado, Boulder:

> *[s]ince all primates share a common mammalian brain and are social, intelligent beings, the degree of similarities in their needs far outweighs any differences* which have been inflated by industry to try to convince USDA to not help their own investigators identify components in primates' environments or caregiving that would enhance rather than further compromise their psychological wellbeing.

J.A.106 (emphasis added).[6]

D. The USDA Denies the Animal Advocates' Petition for Rulemaking.

On October 10, 2019, APHIS denied Plaintiffs' Rulemaking Petition. J.A.206–210. The USDA's denial letter, authored by Elizabeth Goldentyer, then Acting Deputy Administrator of Animal Care, stated that the agency had decided that no changes to the regulation were required. J.A.206–211. In support of its decision, the USDA provided several reasons:

[6] Many of the comments provided additional reasons for granting Plaintiffs' Petition. For example, PETA explained that "nonhuman primates who are held and used in U.S. laboratories suffer tremendously as a result of the extreme privation of their impoverished living conditions. Deprived of companionship, sufficient space, access to outdoor spaces, opportunities for exercise and sufficiently complex environments—and assaulted by loud, distressing noise and manipulated by unpredictable, intimidating humans who may conduct confusing, terrifying and sometimes painful procedures on them—primates in laboratories are physiologically and psychologically compromised." J.A.078. Frances Burton, a primatologist, explained that: "[t]here is no longer any doubt that monkeys are sentient, aware of themselves, of others, their environment and how these interact. Commercial films and videos of non-human primates give evidence to their lifeways, documenting their needs and abilities. Caged animals are under tremendous stress. They are limited in space, the ability to interact, and cues to understand their environment and above all, to predict their circumstances." J.A.100. *See also* Comments of Janine Perlman, a biomedical scientist, J.A.102 ("standards should incorporate the social (being housed with compatible conspecifics), physical (opportunity for exercise with appropriate structures/substrates), and intellectual (environmental enrichment) needs of the animals . . . . [t]hey should provide generous amounts of space in three dimensions, and must include sufficient, appropriate hiding places where animals can shelter."); Comments of Primatologist Dr. Jessica Ganas, J.A.104 ("We have a moral obligation to see that these cognitively complex and sentient beings are looked after with the highest standards in the labs, enforced by your agency.").

First, the agency stated that the contention that the current standard was "too vague to be enforceable" could not be correct because, between 2007 and 2015, the USDA had, in fact, cited facilities for various violations of the regulation. J.A.206–207. Second, the agency suggested that it had provided sufficient guidance to the regulated industry about how to apply the standard because it held a Symposium in 2017 concerning "the needs of NHPs [nonhuman primates,]" and in 2018 issued "eight Animal Care Aids based on scientific literature and advancements to support PWB [psychological well-being] of NHPs and the development of compliant EEPs [Environment Enhancement Plans]." J.A.207.

Third, the agency explained that no changes to the current standard were necessary because "[t]he regulation allows entities to develop and/or modify the plan to respond to ever-evolving strategies for ensuring animal welfare," and because:

> APHIS inspectors evaluate a facilities' [sic] compliance with the regulation during the inspection. *They examine and document all areas of care and treatment that are covered under the AWA, including the plan. The inspector also observes the regulated animals; inspects the facilities, including enclosure or housing materials space, and records*. If the inspector observes that the facility is not in full compliance with the AWA requirements, he or she will explain all deficiencies and appropriately document the findings.

J.A.207 (emphasis added).

Fourth, with respect to the Animal Advocates' request that the agency adopt regulations for determining how and when primates exhibit psychological distress,

and the measures that must be taken to ameliorate those symptoms, the agency also declined to make such a change in the regulation, stressing that the existing regulation allows the facility's veterinarian "to tailor . . . special attention to the needs of each individual" primate. J.A.210.

The agency's denial letter did not respond to *any* of the more than 10,000 public comments it received in response to its Federal Register request for comments on the Rulemaking Petition, nor point to any evidence acquired since 1996 when more than half the APHIS inspectors found that the regulation was inadequate to judge compliance with the standard, to demonstrate that this was no longer the case. J.A.235.

E. District Court Proceedings

Following the agency's denial, the Animal Advocates heard a rumor that APHIS had secretly implemented a new inspection policy under which it no longer conducted full annual inspections of any research facility that is accredited by AAALAC, *see* Complaint at 23, J.A.023, the industry dominated organization that accredits the vast majority of major research labs in this country, *see* J.A.508; *see also* 7 U.S.C. § 2146(a) (requiring annual inspections of all research labs). Because the existence of such a policy would mean that the USDA misrepresented critical facts in its denial letter—i.e., that every year USDA inspectors "examine and document *all areas of care and treatment*," J.A.207 (emphasis added)—on June

17, 2020, the Animal Advocates submitted a request to the USDA under FOIA to obtain access to records that would reflect the existence of any such policy.

The Animal Advocates also filed this case on July 9, 2020, challenging the denial of their Rulemaking Petition as arbitrary, capricious, and an abuse of discretion within the meaning of the APA, 5 U.S.C. § 706 (2)(A). Complaint at 3, J.A.003. Because, at the time they filed their Complaint, the agency had not responded to their FOIA request, the Animal Advocates alleged "on information and belief" that the USDA had instituted a new inspection policy, whereby inspectors "may *choose* which aspects of a particular facility they may wish to inspect" for AAALAC-accredited facilities. Complaint at 23, J.A.023 (emphasis in original). The Animal Advocates further alleged that, consequently, this means that when APHIS inspectors conduct the annual inspections required by the statute, the inspectors are *not "*required to inspect *all* of the animals, *all* aspects of the facility, or even the environmental enrichment plans currently being used by such facilities when completing the annual inspections that are required by the AWA. 7 U.S.C. § 2143(a)(2)(B)." Complaint at 23, J.A.023 (emphasis in original). Thus, the Animal Advocates asserted that any such policy undermined the agency's insistence, in its denial letter, that no changes to the existing regulation were required because, when completing annual inspections, inspectors could adequately determine a

facility's compliance with the psychological well-being standard. Complaint at 23, J.A.023.

On October 16, 2020, when the agency failed to respond to the Animal Advocates' FOIA request in compliance with the relevant statutory deadlines, the Animal Advocates filed a separate FOIA suit, as a related case, to obtain access to documents relating to the rumored inspection policy. *New England Anti-Vivisection Soc'y v. Animal Plant Health & Inspection Serv.*, Civ. No. 8:20-cv-03013 (D. Md. Oct. 16, 2020).

On October 19, 2020, Defendants filed a motion to dismiss the present case, challenging the Animal Advocates' Article III standing. Defs.' Mot. Dismiss, Oct. 19, 2020, ECF No. 7. In their accompanying memorandum, the government argued that the Animal Advocates could not demonstrate the requisite redressability for their alleged injuries because "when the agency inspects a facility, the inspectors already 'examine and document *all areas of care and treatment* that are covered under the [Animal Welfare Act].'" Defs.' Mot. Dismiss Mem., at 22, Oct. 19, 2020, ECF No. 7-1 (emphasis altered). Thus, the USDA repeated to the district judge the *same statement* about the thoroughness and scope of its annual inspections that it included in its denial letter.

1. FOIA Documents Reveal the Existence of a Secretly Implemented Inspection Policy That Prohibits Inspectors from Conducting Full Inspections of AAALAC-Accredited Laboratories.

Following the filing of the motion to dismiss in the present case, the Animal Advocates obtained responsive records from the agency as a result of their FOIA case. Those records revealed that, in fact, in February 2019 the agency adopted a new policy "that made it *mandatory* (rather than discretionary) for inspectors *to perform focused inspections at AAALAC-accredited research facilities unless the research facility requested a full inspection*." J.A.454 (emphasis added).

Under the new policy, APHIS instructed its inspectors that, with respect to AAALAC-accredited facilities, they may *only* inspect *either* (1) the "animals" at the facility, (2) the "facilities" themselves, (3) the relevant "records" maintained at each facility, or (4) a *sampling* of one or all of these categories. J.A.109. Further, under the new inspection policy, inspectors are *prohibited* from conducting full inspections of each such facility, unless specifically requested to do so by the facility itself, *see* J.A.454, and they are required to "rotate [their] focus for each visit." J.A.456. This means that three to four years may pass before an inspector looks at a single animal.[7] As stressed by the documents obtained under FOIA,

[7] Thus, for example, under the policy, in year one the inspector may look at some of the paperwork; in year two the inspector may look at whether the facility is using expired medicines to treat the animals; and in year three, the inspector may

"[t]his focused inspection *counts as the facility's annual inspection*" under the AWA, J.A.454 (emphasis added)—i.e., the annual inspection that is required by the statute, 7 U.S.C. § 2146 (a).[8]

Documents obtained under FOIA further revealed that APHIS instructed its inspectors not to publicly release the new terms of the focused inspection policy, but only to share the new approach with the regulated facilities. *See* J.A.458 ("We are using a low key approach. There will be no stakeholder announcement. The message is to be conveyed by the inspector to their facilities.").

2. The USDA Files a Notice with the Court "Correcting" its Statement.

After it became clear that Plaintiffs had received documents revealing the secret inspection policy, on March 18, 2021 the agency filed a "Notice" with the district court, to "correct" the USDA's prior assertion in its motion to dismiss memorandum that inspectors "examine and document all areas of care and treatment that are covered under the [Animal Welfare Act]." Defs.' Notice, at 1–2, Mar. 18, 2021, ECF No. 19 (alteration in original). That Notice explained that the

---

finally look at a "sampling" of the animals in the possession of the facility. *See* J.A.109, J.A.456.

[8] This particular sentence in the document was originally redacted by the agency, which claimed that this information "would disclose techniques and procedures for law enforcement investigations or prosecutions." 5 U.S.C. § 552(b)(7)(E); *see* J.A.226. However, after Plaintiffs challenged that redaction in the FOIA case, the government released the document without the redacted information. *See* J.A.454.

"USDA believes that *it is necessary to correct this statement* to the extent it suggests that every agency inspection covers 'all areas' of a facility." *Id.* (emphasis added). Thus, retracting its previous statement in its redressability argument, the agency explained that inspectors conduct "focused inspections" of AALAC-accredited facilities that do "*not* 'examine and document all areas of care and treatment that are covered under the [Animal Welfare Act].'" *Id*. (emphasis added). The agency further informed the district court that "[i]n light of this clarification," and the fact that the agency does *not* conduct full annual inspections of such labs, the USDA "no longer intend[ed] to rely on" its previous, contrary statement for its redressability argument. *Id.* However, the agency did not request a voluntary remand to retract that same statement as a basis for its denial of Plaintiffs' Rulemaking Petition.

3. The District Court Denies the USDA's Motion to Dismiss.

On September 29, 2021, the district court (Hazel, J.) denied the USDA's motion to dismiss, holding that the Animal Advocates had alleged sufficient Article III standing. Order Denying Mot. Dismiss, Sept. 29, 2021, ECF No. 23. On July 29, 2022, the Animal Advocates filed a motion for summary judgment arguing that the agency's denial of their Rulemaking Petition was arbitrary, capricious, and an abuse of discretion within the meaning of the APA, Section 706(2), Pls.' Mot. Summ. J.,

July 29, 2022, ECF No. 35, and, on October 27, 2022, Defendants filed a cross-motion for summary judgment, Defs.' Mot. Summ. J., Oct. 27, 2022, ECF No.38.

In support of its summary judgment motion, the USDA filed a declaration by Elizabeth Goldentyer purporting to set forth "the contemporaneous reasons" she had "for denying Plaintiffs' petition for rulemaking." Goldentyer Decl. at ¶ 18, J.A.218. Defendant Goldentyer explained that when she made the statements in the decision document that "APHIS inspectors evaluate a facilities' [sic] compliance with the regulation [for the psychological well-being of primates] during the inspection," "*examine and document all areas of care and treatment that are covered under the [Animal Welfare Act]*, including the plan," and "*observe[] the regulated animals; inspect[] the facilities, including enclosure or housing materials space, and records*," she did *not* mean to suggest that the inspectors actually conducted such complete inspections, but merely "to convey that the *overall USDA inspection process* is designed to appropriately examine and document all areas of care and treatment." *Id.* ¶¶ 17, 21–22, J.A.218–220. (emphasis added).

The Animal Advocates responded by urging the district court to disregard the agency's *post hoc* explanation for the denial of their Rulemaking Petition, as required by well-established Supreme Court and Fourth Circuit precedent. *See, e.g.*, *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020) ("[a]n agency must defend its actions based on the reasons it gave when it acted"); *Dow*

AgroSciences LLC v. Nat'l Marine Fisheries Serv., 707 F.3d 462, 467–68 (4th Cir. 2013) ("[A] reviewing court may look only to … *contemporaneous* justifications in reviewing the agency action.") (emphasis in original).[9]

4. The District Court Ruling

On March 23, 2023, the district court (Rubin, J.) held that the agency's denial of the Animal Advocates' Petition for Rulemaking was arbitrary and capricious under Section 706(2) of the APA. Opinion at 19–27, J.A.348–356. Judge Rubin held that the Goldentyer Declaration was an impermissible *post-hoc* rationalization. Opinion at 16–17, J.A.345–346. She explained that:

> [a] *post-hoc* declaration that explains what Dr. Goldentyer meant to say in the Agency Denial is not background information; *it is corrective*. It does not merely explain the agency record so the court can better understand the basis of the Agency Denial. It *changes material facts on which the Agency Denial is based*. The Declaration does not clarify or illuminate the agency record; it is different from, and *contradictory to*, the Agency Denial. . . . [t]he plain impression, if not the literal meaning, is that each inspector observes the animals, facility, and records during each inspection. And that, apparently, is untrue."

Opinion at 17, J.A.346 (emphasis added).

---

[9] In the event the district court nevertheless decided to rely on the Goldentyer Declaration, Plaintiffs explained that because "that Declaration raises far more questions than it resolves concerning the basis for the agency's decision to deny Plaintiffs' Rulemaking Petition," they would need to take discovery regarding the statements contained therein to further demonstrate that the agency has acted arbitrarily and capriciously. *See* Pls.' Summ. J. Reply Mem., at 15 n.5, ECF No. 39; Supplemental Decl. of Ed Butler at ¶ 5, J.A.229; Fed. R. Civ. P. 56(d)(2).

The court further observed that the government's argument, that the Animal Advocates should have known what Dr. Goldentyer "meant to convey," J.A.220, was particularly disingenuous given that the agency went to great lengths to hide the inspection policy from the public. Thus, the court explained:

> inasmuch as the Agency Denial was issued before [the new inspection policy] was made public—which is to say before Plaintiffs knew about the focused inspections practice—suggestion that a reader of the Agency Denial would somehow appreciate that the Agency did not "intend to convey" that all AWA-covered areas of care and treatment are inspected at each inspection when it said "[t]hey examine and document all areas of care and treatment that are covered under the AWA, including the plan" approaches absurd.

Opinion at 19, J.A.348. Consequently, Judge Rubin noted, "[t]he Goldentyer Declaration is precisely *the sort of after-the-fact cleansing of an agency record that the law prohibits the court to consider on judicial review*." Opinion at 19, J.A.348 (emphasis added).

Noting that "[t]he court may, however, consider the Declaration 'for the limited purposes of ascertaining whether the agency considered all the relevant factors or fully explicated its course of conduct or grounds of decision,'" Judge Rubin observed that the Declaration "supports the court's conclusion that the Agency did not provide a full explanation for its reasoning, but rather *based its Petition denial on facts known by it to be false*." Opinion at 19, J.A.348 (emphasis added) (internal citation omitted). Thus, she concluded that the agency's truncated inspection policy—under which three to four years may pass before an inspector

looks at a single animal during the annual inspection mandated by the AWA—"turn[s] a blind eye to the constellation of considerations AWA requires the Agency to consider," and that, therefore, "the Agency clearly ignored and failed to consider 'all the relevant factors' when concluding that the current AWA standards adequately fulfill the Agency's statutory mandate." Opinion at 19–20, J.A.348–349. Thus, she explained, "the practice of focused inspections, by definition, fails to consider basic features essential to safeguarding animal welfare in a research setting—*starting with the animals*." Opinion at 21, J.A.350 (emphasis added).

Judge Rubin further found the agency's denial of the Petition unlawful because, although the agency itself had informed the public that the issues raised in the Petition were "important," that "many parties w[ould] have an interest" in the subject matter, and that the USDA "would render its decision on the [Animal Advocates'] Petition once it had 'analyzed all of the comments,'" the agency failed to address a single one of the more than 10,000 comments that were submitted on this matter. Opinion at 23, J.A.352. Thus, the court explained:

> the Agency's failure to address even one comment (or one category of comment) in its denial adds heft to the court's conclusion that the Agency did not consider evidence relevant to the subject matter it was tasked with deciding, that it failed to offer a plausible, reasoned explanation of how it considered relevant public comments, and/or that it failed to explain the basis for its conclusion that there were no relevant public comments.

Opinion at 23–24, J.A.352–353.

The district court also found that the USDA's reliance on a non-binding symposium and various animal care aids provided a "logical disconnect between offering non-mandatory, non-binding educational tools and concluding that the Agency regulation standards are therefore meaningfully enforceable." Opinion at 26, J.A.355. Judge Rubin concluded that, "inasmuch as the Agency has fairly abdicated the full scope of its inspection obligations, the Agency's reliance on 'guidance provided by' non-mandatory educational tools comes up far short of providing the foundation necessary to justify its unequivocal conclusion that the current standards 'are, in fact, enforceable.'" Opinion at 26, J.A.355. She also stressed that the agency's reliance on its pre-2019 citations "fails to account for the Agency's February 2019 procedural update prohibiting full annual inspections of AAALAC-accredited facilities." Opinion at 26, J.A.355. Thus, Judge Rubin explained, by relying on citations it issued before 2019 to demonstrate the enforceability of the standard at issue, "the Agency *overlooked its actual, considerably withered, inspection protocols in place at the time of its denial of the Petition*." Opinion at 27, J.A.356 (emphasis added).

For all those reasons, the district court granted summary judgment to the Animal Advocates and denied the USDA's cross-motion for summary judgment. Opinion at 28, J.A.357.

SUMMARY OF THE ARGUMENT

Instead of rationally evaluating the Animal Advocates' Rulemaking Petition and providing a reasoned explanation for refusing to improve the over 30-year-old standard for the psychological well-being of primates, which the agency had already determined *in 1996* was inadequate, the USDA relied on a demonstrably false justification. The agency insisted in its denial letter that there was no need to upgrade the standard because agency inspections each year "examine and document *all areas of care and treatment* that are covered by the AWA, including the [environment enhancement] plan" required by the existing 1991 regulation. J.A.207 (emphasis added). In fact, as revealed by the documents the Animal Advocates obtained under FOIA, months *before* the agency denied the Animal Advocates' Petition the USDA had initiated a secret new policy under which it no longer conducts full annual inspections of research labs accredited by AAALAC. J.A.454–458. In light of this blatant misrepresentation contained in the agency's decision document, the district court properly held that the agency's decision was arbitrary and capricious and an abuse of discretion.

The agency's contention in this Court that the district court judge somehow "misunder[stood]" and "misconstrued" what the agency said in its denial letter, Defs.' Br. at 21–22, is completely undermined by the agency's actual words in the decision document. This assertion is further belied by the agency's own filing with

the district court explaining the need to "correct" the same statement, and to explain that, contrary to what the agency told both the Animal Advocates *and* the district court in support of its motion to dismiss, the USDA does *not* conduct full annual inspections of AAALAC-accredited labs. Defs.' Notice, at 2, ECF No.19. Thus, the record shows that, in sharp contrast to what the agency stated in its denial letter, inspectors do *not* "examine and document *all areas of care and treatment covered under the AWA*," and, in fact, it may be years before the inspectors look at a single animal or ever review a lab's environment enhancement plan. J.A.207 (emphasis added).

When the agency's misstatement was uncovered and exposed, the agency then tried to *correct* the Administrative Record through the filing of a *post hoc* declaration that the district court properly rejected as a basis for upholding the Petition denial. Opinion at 18–19, J.A.347–48. The agency continues to rely on that impermissible *post hoc* filing in *this* Court to demonstrate the reasonableness of its denial letter. Yet, tellingly, in its opening brief it failed to include any argument as to why the district court erred in rejecting that submission, or, for that matter, why *this* Court should ignore bedrock principles of administrative law and now rely on that *post hoc* filing as a basis for reversing the court below. The agency's failure to include any such argument in its opening brief forecloses it

from making those arguments in its reply brief. *See Grayson O Co. v. Agadir Int'l LLC*, 856 F.3d 307, 316 (4th Cir. 2017).

The district court's additional reasons for finding the agency's decision arbitrary and capricious were equally valid: the USDA ignored all of the over 10,000 comments the agency itself told the public were "important" to its ultimate decision and relied on a handful of pre-2019 noncompliance citations and various non-binding educational opportunities to justify its denial of the Animal Advocates' Petition. Opinion at 22–25, J.A.351–354.

However "limited" the Court's review may be, the USDA is not absolved of its duty to offer a "reasoned explanation," and, in the absence of one, the Court must set aside its decision as arbitrary and capricious. *Massachusetts v. EPA*, 549 U.S. 497, 527–28, 534 (2007).

ARGUMENT

I. STANDARD OF REVIEW

The Court evaluates *de novo* whether the district court correctly granted summary judgment to the Plaintiffs on the grounds that the USDA's action was arbitrary and capricious. *See Casa De Md. v. U.S. Dep't of Homeland Sec.*, 924 F.3d 684, 703 (4th Cir. 2019). Although agency denials of rulemaking petitions are considered under a "highly deferential" standard, *Mass. v. EPA*, 549 U.S. at 527–

28, reviewing courts "should take care under any level of deference to not conduct judicial review with simply a 'rubber stamp,'" *Nat'l Audubon Soc'y v. U.S. Army Corps of Eng'rs*, 991 F.3d 577, 583 (4th Cir. 2021) (quoting *Ohio Valley Env't Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009)); *see also Am. Horse Prot. Ass'n Inc. v. Lyng*, 812 F.2d 1, 4 (D.C. Cir. 1987) (citing *Motor Vehicle Mfrs. Assoc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)) (applying the *State Farm* arbitrary and capricious standard of review to denials of rulemaking petitions); *Mass. v. EPA*, 549 U.S. at 534 (holding Environmental Protection Agency's denial of rulemaking petition was arbitrary and capricious). Accordingly, as with any other challenged agency action, the Court must determine whether the agency provided a "reasoned explanation" for its decision. *Mass. v. EPA*, 549 U.S. at 534; *see also Lyng*, 812 F.2d at 5 ("In these, as in more typical reviews, however, we must consider whether the agency's decisionmaking was 'reasoned.'" (quoting *Pro. Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1220 (D.C. Cir. 1983))).

As the Supreme Court has long recognized, an agency fails to engage in such reasoned decision-making where it "relie[s] on factors which Congress has not intended it to consider, entirely fail[s] to consider an important aspect of the problem, [or] offer[s] an explanation for its decision that runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43. Moreover, "[i]t is well-

established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Id.* at 50 (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962); *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 539 (1981)). This Court must therefore review the record to determine whether the USDA failed to "examine the relevant data and articulate a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43.

II. THE REVIEWING COURT CANNOT RELY ON THE AGENCY'S IMPERMISSIBLE *POST-HOC* RATIONALIZATIONS.

A. The Government Has Waived Any Challenge to the District Court's Rejection of Its Impermissible *Post-Hoc* Declaration.

The USDA's principal argument to this Court—i.e., that the district court "misconstrued" and "misunder[stood]" its denial letter, Defs.' Br. at 21–22—depends on this Court accepting the agency's explanation of what it "meant to convey" set forth in the *post hoc* declaration of Elizabeth Goldentyer. Goldentyer Decl. at ¶¶21–23; J.A.219–220. However, not only is this Court—like the district court—prohibited from relying on such post-record explanations, *Regents of the Univ. of Cal.*, 140 S. Ct. at 1909, but the agency failed to make any argument in its opening brief as to why the district court was wrong to apply this well-established tenet of administrative law, and why *this* Court may nevertheless rely on the agency's *post-hoc* rationalization.

Because the government "fail[ed] to 'develop [any] argument'" challenging the district court's denial of its *post hoc* declaration from Dr. Goldentyer in its opening brief, it has now waived that issue. *Grayson*, 856 F.3d at 316 (quoting *Belk, Inc. v. Meyer Corp.*, 679 F.3d 146, 152 n.4 (4th Cir. 2012)). As this Court has consistently recognized, "Federal Rule of Appellate Procedure 28(a)(9)(A) requires that the argument section of an appellant's opening brief must contain the 'appellant's contentions and the reasons for them, with citations to the authorities and parts of the record on which the appellant relies.'" *Wahi v. Charleston Area Med. Ctr., Inc.*, 562 F.3d 599, 607 (4th Cir. 2009). Accordingly, "[a] party waives an argument by failing to present it in its opening brief." *Grayson*, 856 F.3d at 316.

To the extent the agency attempts in its reply brief to suggest that it can somehow preserve this issue by simply referring to the *post hoc* declaration, without any attendant argument as to why it may be relied on here, this Court has also repeatedly held that merely "tak[ing] a passing shot at the [waived] issue" in an opening brief does not suffice to avoid waiver. *Id.* (finding appellant waived issue by "only assert[ing], without argument or explanation" a challenge to the district court's ruling); *see also United States v. Bartko*, 728 F.3d 327, 334–35 (4th Cir. 2013) (holding appellant waived issue where he referenced it in the fact section but offered little mention of it in the argument section of his opening brief); *Wahi*, 562 F.3d at 607 (finding appellant waived issue where he offered only a

"declarative sentence" in his opening brief without "rais[ing] any argument to support [the] claim"). Accordingly, the government is foreclosed from making any such argument in its reply brief. *Grayson*, 856 F.3d at 316.[10]

B. The District Court Properly Rejected the Agency's *Post Hoc* Submission.

It is "a 'foundational principle of administrative law'" that the reviewing court must limit its review of agency decisions "to 'the grounds that the agency invoked when it took the action.'" *Regents of the Univ. of Cal.*, 140 S. Ct. at 1907 (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)). Here, it is eminently clear that, in denying the Animal Advocates' Petition, the USDA plainly relied on a blatant misrepresentation of its own inspection practices. *Compare* J.A.207 ("[APHIS inspectors] examine and document *all areas* of care and treatment that are covered under the AWA, including the plan. The inspector also *observes the regulated animals; inspects the facilities, including enclosure or housing materials space, **and** records*.") (emphasis added), *with* J.A.454 (explaining agency adoption of "mandatory" truncated inspections in which the inspector only observes

[10] Moreover, any notion that the Goldentyer Declaration merely provided "background" information for the court, Goldentyer Decl. at ¶18, J.A.218—the argument asserted below by the government, Defs.' Br. at 24–25, is belied by the declarant's own candid admission that the purpose of the declaration was to set forth "the *contemporaneous reasons*" she had "for denying Plaintiffs' petition for rulemaking." Goldentyer Decl. at ¶18, J.A.218 (emphasis added).

"[r]ecords, or [f]acilities, or [a]nimals, or" a sampling of these three). Faced with its own false statement, the USDA can neither rewrite that statement through the *post hoc* declaration of its author, nor reframe it through the *post hoc* rationalizations of its counsel. *See Regents of the Univ. of Cal.*, 140 S. Ct. at 1909. Rather, as this Court's precedent establishes, and the district court correctly recognized, the USDA's action must be reviewed "on the basis articulated by the agency itself," and the "'basis articulated by the agency' is the administrative record, not subsequent litigation rationalizations." *N.C. Wildlife Fed'n v. N.C. Dep't of Transp.*, 677 F.3d 596, 604 (4th Cir. 2012) (quoting *State Farm*, 463 U.S. at 50); *see also Am. Textile Mfrs. Inst., Inc.*, 452 U.S. at 539 ("[T]he *post hoc* rationalizations of the agency . . . cannot serve as a sufficient predicate for agency action.").

The government's main argument, that the district court based its decision on an "incorrect understanding of the agency's description of inspection practices," Defs.' Br. at 27, and therefore "failed to meaningfully engage with the actual rationales" included in that decision, Defs.' Br. at 12, *see also id.* at 21–22, is belied not only by the actual language included in that document, but by the agency's own need, in its words, to "correct" that very same statement when it learned that Plaintiffs had obtained access to the secret inspection policy as a result of their related FOIA case, Defs.' Notice, at 2, ECF No.19. Thus, the district court's

conclusion that the agency's *post hoc* submission was "corrective" rather than explanatory is confirmed by the agency's *own characterization of what occurred here*. *See id.* ("USDA believes that *it is necessary to correct this statement* to the extent it suggests that every agency inspection covers 'all areas' of a facility") (emphasis added); *accord* Opinion at 17, J.A.346 ("[a] *post-hoc* declaration that explains what Dr. Goldentyer meant to say in the Agency Denial is not background information; *it is corrective*") (emphasis added).

Moreover, while the government now instructs this Court to uphold the agency's decision "if the agency's path can be reasonably discerned," Defs.' Br. at 25 (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)), it is fairly clear what the agency's path was here—i.e., to make the Animal Advocates, *and any subsequent reviewing court*, believe that there was no need to update the 1991 standard at issue *because* the agency conducts full inspections of each research lab every year, and its inspectors "observe[] the regulated animals; inspect[] the facilities, including enclosure or housing materials space, and records," and that "[i]f the inspector observes that the facility is not in full compliance with the AWA requirements, he or she will explain all deficiencies and appropriately document the findings," J.A.207. However, we now know that none of this is true under the secret inspection policy that was initiated in February 2019—*eight months before the agency issued its denial decision.* Thus, the

agency's insistence that the district court somehow *misunderstood* what the agency was saying, and that the "import of the language [in the denial letter] is readily understood," Defs.' Br. at 25, is completely disingenuous. If the district court was "misguided" as the government now asserts, Defs.' Br. at 24, it was misguided *by the agency itself.* As the district court observed, "[w]hile the Agency's decision to deny the Petition need only be reasoned, surely, it must be truthful." Opinion at 19, J.A.348.

The USDA cannot now obscure what the record makes clear: the USDA's denial letter was found arbitrary and capricious not because of any district court "misunderstanding," Defs.' Br. at 22, but because of the agency's own deliberate misrepresentation. *See Fed. Power Comm'n v. Texaco, Inc.*, 417 U.S. 380, 397 (1974) (rejecting agency's attempt to redefine how its order is "properly understood" because a reviewing court "cannot 'accept appellate counsel's *post hoc* rationalizations for agency action'" (quoting *Burlington Truck Lines, Inc.*, 371 U.S. at 168)).

Furthermore, the government's contorted reading of its own statement requires knowledge that neither the public nor the district court could possibly have had at the time of the denial. As the district court emphasized, because "the Agency Denial was issued before the USDA Annual Inspections Document was made public—which is to say before Plaintiffs knew about the focused inspections

practice"—it "approaches absurd" to suggest, as the USDA now does, that Plaintiffs or any member of the public could have "somehow appreciate[d] that the Agency did not 'intend to convey' that all AWA-covered areas of care and treatment are examined at each inspection when it said '[t]hey examine and document all areas of care and treatment that are covered under the AWA, including the [environment enhancement] plan.'" Opinion at 19, J.A.348.

The government's attempt to downplay the significance of its misrepresentation regarding the scope of the annual inspection "because plaintiffs' petition was not concerned with the manner or scope of inspections," Defs.' Br. at 25, is also without merit. It was *the government* that chose to rely on a false statement about the thoroughness of annual inspections in an effort to justify its denial of the Rulemaking Petition. Having relied on this false description of what goes on during these annual inspections, the agency cannot now escape the consequences of its decision—i.e., it renders that decision unlawful under the APA.

While we understand *why* the agency now attempts to deny that its misstated description of annual inspections was a material basis for its decision, it is well settled that "[o]nce [an agency] has chosen a particular legal rationale . . . familiar principles of administrative law dictate that *its decision must stand or fall on that basis*." *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 455 (1986) (emphasis added); *see also Council for Urological Interests v. Burwell*, 790 F.3d 212, 223 (D.C. Cir.

2015) (rejecting counsel's efforts to minimize the significance of an issue on appeal where the agency decisionmaker made it a key factor in her reasoning); *Gannett Rochester Newspapers v. NLRB*, 988 F.2d 198, 204 (D.C. Cir. 1993) ("Though the Board's counsel before us disavows [the Board's erroneous reasoning], the Board's opinion is before us for review, not the *post hoc* rationalizations of counsel."); *Sierra Club v. U.S. Dep't of Interior*, 899 F.3d 260, 274 (4th Cir. 2018) (recognizing that agencies "cannot rewrite [agency documents] on appeal").

Moreover, although the government asserts that "[n]one of the agency's rationales is materially affected by" the agency's misrepresentation of its inspection process, Defs.' Br. at 21, this argument wholly misses the point: the inspection process need not "materially affect[]," the agency's *other* rationales because the misstatement of the scope of the inspection process was an *independent rationale* offered by the agency. It neither relies on nor negates the other reasons under which the district court found the denial letter to be arbitrary and capricious. The agency attempted to defend its current standard by portraying the combination of environment enhancement plans and annual full inspections as sufficient to detect and resolve psychological distress among primates. *See* J.A.207. Therefore, the agency itself relied on the inaccurately described full inspection process to assure the Animal Advocates that there was no need to

upgrade the current standard *because*, "during the inspection," an inspector would "observe[] the regulated animals" and "examine and document *all areas* of care and treatment that are covered under the AWA, including the plan" to determine whether primates' psychological well-being was being adequately promoted. J.A.207 (emphasis added). Contrary to the government's assertions, therefore, the district court did not need to "meaningfully attempt to connect" the agency's misrepresentation of its inspections "to the grounds for the agency's decision," Defs.' Br. at 22, because the misdescribed inspection process *was* grounds for the agency's decision.

Simply put, the Court cannot allow the USDA to pick and choose which of its proffered reasons to defend based on *post hoc* judgments of their litigation viability. *See Mid-Tex Elec. Coop., Inc. v. FERC*, 773 F.2d 327, 353 (D.C. Cir. 1985) (rejecting agency's attempt to disavow two of its three reasons as a "*post hoc* rationalization . . . by subtraction of old reasons rather than addition of new ones"). To hold otherwise would violate the bedrock principle of administrative law that an agency action "cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained." *SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943).

III. THE DISTRICT COURT PROPERLY RULED THAT THE USDA'S DECISION WAS ARBITRARY AND CAPRICIOUS.

A. The Agency's Truncated New Inspection Policy Shows that the Agency Failed to Consider Relevant Factors.

The district court also correctly concluded that the agency's *post hoc* declaration merely bolstered the court's conclusion that the agency "did not consider 'all the relevant factors' when it denied the Petition." Opinion at 19, J.A.348. Thus, noting that in her *post hoc* declaration Dr. Goldentyer explained that the agency developed its inspection policy "[i]n light of the USDA's limited resources," J.A.215, the district court stated that it was "unconvinced that Congress intended the Agency to consider inspector workload as a factor when developing standards and protocols for protecting the welfare of animals," Opinion at 21, J.A.350. The court further observed that "while inspector workload may well be a practical consideration that may affect the Agency's ability to fulfill congressional intent to protect the welfare of animals, the 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." Opinion at 21, J.A.350.[11]

[11] The agency's concern about limited resources is also completely undermined by the USDA's own budgetary request to Congress which shows that in 2019—the year it instituted its new inspection policy—the agency requested a *decrease of*

The district court further correctly noted that the use of such "focused inspections, by definition, fails to consider basic features essential to safeguarding animal welfare in a research setting—*starting with the animals*." Opinion at 21, J.A.350 (emphasis added). The court stressed that the AWA requires the agency to promulgate a standard that will promote the psychological well-being of primates, and that it also 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 Act, shall conduct such follow-up inspections as may be necessary until *all deficiencies or deviations from such standards are corrected*." Opinion at 20, J.A.349 (quoting 7 U.S.C. § 2146(a)) (emphasis added). Thus, the district court concluded, "[w]ithout conducting full inspections as required by [7 U.S.C. § 2146(a)], *the Agency lacks the necessary information to determine whether there is a problem regarding the welfare of nonhuman primates, or whether the existing standards are sufficient to meet the needs of the animals in*

---

over $250,000 in Congressional funding for the Animal Welfare Program. U.S. Dep't of Agric., 2019 President's Budget: Animal and Plant Health Inspection Service, 20-51–20-52 (2019), https://www.usda.gov/sites/default/files/documents/20aphis2019notes.pdf (requesting a "Reduction for Animal Welfare enforcement efforts" of $258,000 in Fiscal Year 2019); *see also United States v. Doe*, 962 F.3d 139, 147 n.6 (4th Cir. 2020) (the Court may take judicial notice of the agency's own reports to Congress).

research facilities in accordance with [the] AWA." Opinion at 21, J.A.350 (emphasis added).[12]

Indeed, such truncated inspections necessarily impede any effort to ensure that the "specific" subsections of Section 3.81, as well as the "other regulations" on which the agency relies, Defs.' Br. at 17–19, are actually being enforced. For example, while Section 3.81(c) discusses "special considerations" for primates whose "behavior or appearance" shows "psychological distress," 9 C.F.R. § 3.81(c), a focused inspection in which the inspector does not even look at a single animal for several years cannot possibly ascertain whether even this nebulous requirement is being met. *See also id.* § 3.81(a) (the enhancement plan "must include specific provisions to address the social needs of nonhuman primates"); § 3.81(b) ("[t]he physical environment in the primary enclosures must be enriched by providing means of expressing noninjurious species-typical activities"); § 3.81(c) ("[c]ertain nonhuman primates must be provided special attention . . . based on the needs of the individual species"); § 3.81(d) ("[n]onhuman primates must not be maintained in restraint devices unless required for health reasons").

[12] Although in this particular quote the district court cited 7 U.S.C. § 2143(a)(7)(A), it is 7 U.S.C. § 2146(a) that requires the annual inspections of research facilities. However, 7 U.S.C. § 2143(a)(7)(A) similarly requires that "[t]he Secretary shall require each facility to show upon inspection . . . that the provisions of this chapter are being followed."

There simply is no way an inspector can determine that a facility has deviated from any of these requirements without actually observing the animals *and* the records *and* the facilities every year.

The same disconnect applies to the USDA's reliance on "other regulations" that the government invokes as providing "additional protections for primates." Defs.' Br. at 19. There is no way an inspector can reliably ascertain if primates are provided sufficient space as required by 9 C.F.R. § 3.80 when, under the truncated inspection policy, as many as three to four years may pass before the inspector ever even inspects the facility.

In short, because the secret inspection policy reveals that inspectors are actually *prohibited* from conducting full annual inspections of AAALAC-accredited labs, the agency's belated attempt to rely on that policy to explain its decision must fail. Thus, as the district court concluded, "[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*." Opinion at 22, J.A.351 (emphasis added). Therefore, as the district court concluded, "in denying the Petition on the basis that current inspection practices fulfill AWA, the Agency

failed to consider an 'important aspect of the problem.'" Opinion at 22, J.A.351 (quoting *State Farm*, 463 U.S. at 43). [13]

B. The Agency's Failure to Address Any of the Public Comments Was Also Arbitrary and Capricious.

The district court also correctly observed that the agency's own response to the Animal Advocates' Petition emphasized the importance of receiving public comment on the Petition. Having identified these comments as "an important aspect" of the issue pending before it, the agency acted arbitrarily and capriciously when it "entirely failed to consider" *any* of the issues they raised. *State Farm*, 463 U.S. at 43; *see also Sierra Club v. W. Va. Dep't of Env't Prot.*, 64 F.4th 487, 502 (4th Cir. 2023) (agency acted arbitrarily and capriciously where it recognized that certain information warranted consideration but failed to review it).

As the district court correctly recognized, because the agency *itself* highlighted public comment as an important factor to consider, the USDA was *not* "free to categorically ignore" the thousands of comments it received. Opinion at 23–24, J.A.352–353. The USDA assured the Animal Advocates that the issues in their Petition were "important," that "many parties w[ould] have an interest" in

[13] For these reasons, and because Congress specifically made clear that it did *not* want USDA to defer to AAALAC when implementing this statute, *see supra* at 2–3, Plaintiffs-Appellees have also filed a case challenging the legality of the 2019 Inspection Policy, *see Rise for Animals v. Vilsack*, No. 8:22-CV-00810 (D. Md. April 5, 2022).

them, and that, therefore, the agency would decide on the Petition "[o]nce [it] ha[d] analyzed all of the comments." J.A.367. It further emphasized in its Federal Register notice that it was "soliciting comments regarding . . . *any issues raised by the petition that we should take into account*." J.A.368 (emphasis added).

However, despite asking the public for issues it "should take into account," J.A.368, the agency analyzed *none* of the more than 10,000 comments it received. Moreover, simply asserting in its denial letter that it "reviewed every comment," J.A.206; Defs.' Br. at 7, without actually discussing a single such comment, falls far short of demonstrating that the agency took any of these comments into account in deciding to deny Plaintiffs' Petition. Rather, as the district court concluded, the agency's "failure to articulate *anything* about the public comments (other than that they exist and were 'reviewed') . . . fails to live up even to th[e] relatively low bar" of arbitrary and capricious review. Opinion at 24, J.A.353 (emphasis added).

The agency's response—that it was not *required* to publish the Petition for comment to begin with, Defs.' Br. at 28—is a complete non-sequitur. Having told the public that the issues raised by the Petition were "important," and that the agency needed to hear from the public on these matters, the agency itself determined that the public's information and views on these issues were relevant to the USDA's final decision. J.A.367.

The USDA's failure to meaningfully consider any of the public comments is even more glaring given that the vast majority of the responsive comments *supported granting* the Petition, often for reasons that contradict statements made by the agency in its subsequent denial letter. For example, while the USDA alleged that the "flexibilities" of its standard "allow regulated entities to evolve as the scientifically accepted standards change," J.A.208, the comments demonstrated that the standard's vagueness actually allows facilities to *ignore* scientific developments rather than incorporating them into the "currently accepted professional standards." *See, e.g.*, J.A.073 (explaining that, because what is "currently accepted" is set by the labs themselves, in over thirty years, "these industries *have not been incentivized to develop new professional standards or make innovative efforts to promote psychological well-being."* (emphasis added)).

Likewise, the USDA ignored expert comments regarding the feasibility of developing improved standards based on the NIH chimpanzee standards, that would suit a variety of primate species. As animal behaviorist Dr. Marc Bekoff emphasized: "[s]ince *all* primates share a common mammalian brain and are social, intelligent beings*, the degree of similarities in their needs far outweighs any differences* which have been inflated by industry" to prevent USDA from "identify[ing] components in primates' environments or caregiving that would

enhance rather than further compromise their psychological wellbeing." J.A.106 (emphasis added).

As the district court emphasized, given the agency's own assurances that it would "analyze[] *all* of the comments," J.A.367 (emphasis added), along with "the throngs of scientific community members' interest in the subject and considerable, apparently serious-minded contributions from the relevant scientific community, it strains credulity that *none* of the 10,137 comments warranted even the *barest* of consideration." Opinion at 24, J.A.353 (emphasis added). Thus, the agency is demonstrably wrong when it asserts in its brief to this Court that "there is no dispute that the agency 'reviewed' and categorized 'every comment' that it received." Defs.' Br. at 28. As the district court found, there is no evidence whatsoever that the agency did any such thing. Opinion 23–24, J.A.352–353. And while it is true, as the government also argues, that an agency is not required to address every single comment it receives on a matter, Defs.' Br. at 29, here, it failed to address *any* of the more than 10,000 comments it solicited from the public on this issue.

The district court was therefore correct: the agency's decision was arbitrary and capricious because the USDA specifically emphasized the need for public comment only to ignore the ample relevant information that process yielded. *State Farm*, 463 U.S. at 43 (finding the APA requires the agency to consider relevant

factors); *Sierra Club*, 64 F.4th at 502 (holding that agency acted arbitrarily and capriciously where it recognized that certain information warranted consideration but failed to review it).

C. The Agency's Explanations Regarding the Enforceability of its Standard Are Also Arbitrary and Capricious.

The district court also properly ruled that the agency's reliance on a handful of pre-2019 citations for non-compliance with the standard was arbitrary and capricious. Opinion 26–27, J.A.355–356. The mere fact that the 1991 standard can be violated does not mean that it should not be improved. Moreover, citing a facility for failing to follow its own environment enhancement plan does not mean that inspectors know how to judge the adequacy of any such enhancement provided. That the standard is enforceable in some way—e.g., determining that the facility in fact has an environment enhancement plan on file—does not mean that the standard is meaningfully enforceable—i.e., that the environment enhancement plan is actually being implemented and does, in fact, "promote the psychological well-being" of the primates in the lab's possession. 7 U.S.C. § 2143(a)(2)(B). Indeed, because under the new truncated inspection policy inspectors are not even looking at a single animal for several years, it is impossible for them to discern if any particular environment enhancement plan is actually accomplishing the objective of this statutorily required standard. 7 U.S.C. § 2143 (a)(2)(B). In short,

whether a facility has *ignored* primate psychological well-being may be relatively easy to determine; but whether any particular plan has adequately *promoted* the psychological well-being of the primates is much harder. The mere fact that inspectors have cited facilities for the former does not mean that they are able to meaningfully evaluate the latter, *particularly when the inspectors are prohibited from observing the animals each year when they perform the annual inspection required by the AWA*, 7 U.S.C. § 2146(a). Moreover, as the district court observed, the citations relied on by the agency were issued *before* the new policy was implemented, further undermining the relevance of any such actions. Opinion at 26–27, J.A.355–356.

Furthermore, the agency has produced no evidence whatsoever that the inspectors' view of the standard has changed since 1996 when they complained that the 1991 regulation was inadequate for ascertaining whether facilities were providing adequate enrichment to promote the psychological well-being of primates. *See* J.A.235. As the Animal Advocates demonstrated below, during this time USDA inspectors had also been issuing citations for violations of the standard. *See* Pls.' Reply Mem., at 15–16, ECF No. 39; *see also* J.A.247–248. However, this did not dissuade the agency from informing the public that more concrete standards were "necessary" to promote the psychological well-being of primates. J.A.372.

Likewise, the agency's references to various non-binding educational opportunities—i.e., a single symposium and various "animal care aids," J.A.207—provide scant assurance that the entire regulated industry knows what is required to promote the psychological well-being of primates and how to detect and address signs of distress. As the district court emphasized, the agency's rationale can only be described as a "logical disconnect": it "offer[s] *non-mandatory* [*and*] *non-binding* educational tools" as a basis for "concluding that the Agency regulation standards are therefore meaningfully *enforceable*." Opinion at 26, J.A.355 (emphasis added). Therefore, as the district court correctly found, the "[a]gency's reliance on 'guidance provided by' non-mandatory educational tools" and the mere issuance of noncompliance citations "comes up far short of providing the foundation necessary to justify its unequivocal conclusion the current standards 'are, in fact, enforceable.'" Opinion at 26, J.A.355.

CONCLUSION

For the foregoing reasons, the Court should affirm the district court's decision granting summary judgment in favor of the Plaintiffs-Appellees.[14]

[14] Plaintiffs-Appellees wish to acknowledge and thank Harvard Law School students Allyson Gambardella and Aimee Cicchiello for their invaluable assistance in preparing this brief.

REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 34(a), Plaintiffs-Appellees request that oral argument be heard in this matter. Oral argument will enable the parties to address the Court's questions and further develop the arguments discussed in the briefing.

Respectfully submitted, this 5th day of December, 2023.

/s/ *Rebecca L. Garverman*

Rebecca L. Garverman
Staff Attorney
Harvard Animal Law & Policy Clinic
1585 Massachusetts Avenue,
Cambridge MA 02138
617-496-5145
rgarverman@law.harvard.edu

Katherine A. Meyer
Of Counsel
Harvard Animal Law & Policy Clinic
1585 Massachusetts Avenue,
Cambridge MA 02138
617-496-5145
kmeyer@law.harvard.edu

Attorneys for Plaintiffs-Appellees

ADDENDUM

TABLE OF CONTENTS

7 U.S.C. § 2143

§ 2143. Standards and certification process for humane handling, care, treatment, and transportation of animals

(a) Promulgation of standards, rules, regulations, and orders; research facilities; State authority.

(1) The Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors.

(2) The standards described in paragraph (1) shall include minimum requirements–

(A) for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperatures, adequate veterinary care, and separation by species where the Secretary finds necessary for humane handling, care, or treatment of animals; and

(B) for exercise of dogs, as determined by an attending veterinarian in accordance with general standards promulgated by the Secretary, and for a physical environment adequate to promote the psychological well-being of primates.

(3) In addition to the requirements under paragraph (2) the standards described in paragraph (1) shall, with respect to animals in research facilities, include requirements–

(A) for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized, including adequate veterinary care with the appropriate use of anesthetic, analgesic, tranquilizing drugs, or euthanasia;

(B) that the principal investigator considers alternatives to any procedure likely to produce pain to or distress in an experimental animal;

(C) in any practice which could cause pain to animals–

(i) that a doctor of veterinary medicine is consulted in the planning process of such procedures;

(ii) for the use of tranquilizers, analgesics, and anesthetics;

(iii) for pre-surgical and post-surgical care by laboratory workers, in accordance with established veterinary medical and nursing procedures;

(iv) against the use of paralytics without anesthesia;

(v) that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time;

(D) that no animal is used in more than one major operative experiment from which it is allowed to recover except in cases of–

(i) scientific necessity; or

(ii) other special circumstances as determined by the Secretary; and

(E) that such exceptions to such standards may be made only when specified by research protocol and that any such exception shall be detailed and explained in a report outlined under paragraph (7) and filed with the Institutional Animal Committee.

(4) The Secretary shall also promulgate standards to govern the transportation in commerce, and the handling, care, and treatment in connection therewith, by intermediate handlers, air carriers, or other carriers, of animals consigned by any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or of any State or local government, for transportation in commerce. The

Secretary shall have authority to promulgate such rules and regulations as he determines necessary to assure humane treatment of animals in the course of their transportation in commerce including requirements such as those with respect to containers, feed, water, rest, ventilation, temperature, and handling.

(5) In promulgating and enforcing standards established pursuant to this section, the Secretary is authorized and directed to consult experts, including outside consultants where indicated.

(6)

(A) Nothing in this Act [7 U.S.C. §§ 2131 et seq.]–

(i) except as provided in paragraphs [paragraph] (7) of this subsection, shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such research facility;

(ii) except as provided [in] subparagraphs (A) and (C)(ii) through (v) of paragraph (3) and paragraph (7) of this subsection, shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility; and

(iii) shall authorize the Secretary, during inspection, to interrupt the conduct of actual research or experimentation.

(B) No rule, regulation, order, or part of this Act [7 USCS §§ 2131 et seq.] shall be construed to require a research facility to disclose publicly or to the Institutional Animal Committee during its inspection, trade secrets or commercial or financial information which is privileged or confidential.

(7)

(A) The Secretary shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act [7 USCS §§ 2131 et seq.] are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation.

(B) In complying with subparagraph (A), such research facilities shall provide–

(i) information on procedures likely to produce pain or distress in any animal and assurances demonstrating that the principal investigator considered alternatives to those procedures;

(ii) assurances satisfactory to the Secretary that such facility is adhering to the standards described in this section; and

(iii) an explanation for any deviation from the standards promulgated under this section.

(8) Paragraph (1) shall not prohibit any State (or a political subdivision of such State) from promulgating standards in addition to those standards promulgated by the Secretary under paragraph (1).

(b) **Research facility Committee; establishment, membership, functions, etc.**

(1) The Secretary shall require that each research facility establish at least one Committee. Each Committee shall be appointed by the chief executive officer of each such research facility and shall be composed of not fewer than three members. Such members shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility and shall represent society's concerns regarding the welfare of animal subjects used at such facility. Of the members of the Committee–

(A) at least one member shall be a doctor of veterinary medicine;

(B) at least one member–

(i) shall not be affiliated in any way with such facility other than as a member of the Committee;

(ii) shall not be a member of the immediate family of a person who is affiliated with such facility; and

(iii) is intended to provide representation for general community interests in the proper care and treatment of animals; and

(C) in those cases where the Committee consists of more than three members, not more than three members shall be from the same administrative unit of such facility.

(2) A quorum shall be required for all formal actions of the Committee, including inspections under paragraph (3).

(3) The Committee shall inspect at least semiannually all animal study areas and animal facilities of such research facility and review as part of the inspection–

(A) practices involving pain to animals, and

(B) the condition of animals, to ensure compliance with the provisions of this Act [7 USCS §§ 2131 et seq.] to minimize pain and distress to animals. Exceptions to the requirement of inspection of such study areas may be made by the Secretary if animals are studied in their natural environment and the study area is prohibitive to easy access.

(4)

(A) The Committee shall file an inspection certification report of each inspection at the research facility. Such report shall–

(i) be signed by a majority of the Committee members involved in the inspection;

(ii) include reports of any violation of the standards promulgated, or assurances required, by the Secretary, including any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made thereafter;

(iii) include any minority views of the Committee; and

(iv) include any other information pertinent to the activities of the Committee.

(B) Such report shall remain on file for at least three years at the research facility and shall be available for inspection by the Animal and Plant Health Inspection Service and any funding Federal agency.

(C) In order to give the research facility an opportunity to correct any deficiencies or deviations discovered by reason of paragraph (3), the Committee shall notify the administrative representative of the research facility of any deficiencies or deviations from the provisions of this Act [7 USCS §§ 2131 et seq.]. If, after notification and an opportunity for correction, such deficiencies or deviations remain uncorrected, the Committee shall notify (in writing) the Animal and Plant Health Inspection Service and the funding Federal agency of such deficiencies or deviations.

(5) The inspection results shall be available to Department of Agriculture inspectors for review during inspections. Department of Agriculture inspectors shall forward any Committee inspection records which include reports of uncorrected deficiencies or deviations to the Animal and Plant Health Inspection Service and any funding Federal agency of the project with respect to which such uncorrected deficiencies and deviations occurred.

(c) **Federal research facilities; establishment, composition, and responsibilities of Federal Committee.**

In the case of Federal research facilities, a Federal Committee shall be established and shall have the same composition and responsibilities provided in subsection (b), except that the Federal Committee shall report deficiencies or deviations to the head of the Federal agency conducting the research rather than to the Animal and Plant Health Inspection Service. The head of the Federal agency conducting the research shall be responsible for–

(1) all corrective action to be taken at the facility; and

(2) the granting of all exceptions to inspection protocol.

(d) **Training of scientists, animal technicians, and other personnel involved with animal care and treatment at research facilities.**

Each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility as required by the Secretary. Such training shall include instruction on–

(1) the humane practice of animal maintenance and experimentation;

(2) research of testing methods that minimize or eliminate the use of animals or limit animal pain or distress;

(3) utilization of the information service at the National Agricultural Library, established under subsection (e); and

(4) methods whereby deficiencies in animal care and treatment should be reported.

(e) **Establishment of information service at National Agricultural Library; service functions.**

The Secretary shall establish an information service at the National Agricultural Library. Such service shall, in cooperation with the National Library of Medicine, provide information–

(1) pertinent to employee training;

(2) which could prevent unintended duplication of animal experimentation as determined by the needs of the research facility; and

(3) on improved methods of animal experimentation, including methods which could–

(A) reduce or replace animal use; and

(B) minimize pain and distress to animals, such as anesthetic and analgesic procedures.

(f) **Suspension or revocation of Federal support for research projects; prerequisites; appeal procedure.**

In any case in which a Federal agency funding a research project determines that conditions of animal care, treatment, or practice in a particular project have not been in compliance with standards promulgated under this Act [7 USCS §§ 2131 et seq.], despite notification by the Secretary or such Federal agency to the research facility and an opportunity for correction, such agency shall suspend or revoke Federal support for the project. Any research facility losing Federal support as a result of actions taken under the preceding sentence shall have the right of appeal as provided in sections 701 through 706 of title 5, United States Code [5 USCS §§ 701-706].

(g) **Veterinary certificate; contents; exceptions.**

No dogs or cats, or additional kinds or classes of animals designated by regulation of the Secretary, shall be delivered by any dealer, research facility, exhibitor, operator of an auction sale, or department, agency, or instrumentality of the United States or of any State or local government, to any intermediate handler or carrier for transportation in commerce, or received by any such handler or carrier for such transportation from any

such person, department, agency, or instrumentality, unless the animal is accompanied by a certificate issued by a veterinarian licensed to practice veterinary medicine, certifying that he inspected the animal on a specified date, which shall not be more than ten days before such delivery, and, when so inspected, the animal appeared free of any infectious disease or physical abnormality which would endanger the animal or animals or other animals or endanger public health: Provided, however, That the Secretary may by regulation provide exceptions to this certification requirement, under such conditions as he may prescribe in the regulations, for animals shipped to research facilities for purposes of research, testing or experimentation requiring animals not eligible for such certification. Such certificates received by the intermediate handlers and the carriers shall be retained by them, as provided by regulations of the Secretary, in accordance with section 10 of this Act [7 USCS § 2140].

(h) **Age of animals delivered to registered research facilities; power of Secretary to designate additional classes of animals and age limits.**

No dogs or cats, or additional kinds or classes of animals designated by regulation of the Secretary, shall be delivered by any person to any intermediate handler or carrier for transportation in commerce except to registered research facilities if they are less than such age as the Secretary may by regulation prescribe. The Secretary shall designate additional kinds and classes of animals and may prescribe different ages for particular kinds or classes of dogs, cats, or designated animals, for the purposes of this section, when he determines that such action is necessary or adequate to assure their humane treatment in connection with their transportation in commerce.

(i) **Prohibition of C.O.D. arrangements for transportation of animals in commerce; exceptions.**

No intermediate handler or carrier involved in the transportation of any animal in commerce shall participate in any arrangement or engage in any practice under which the cost of such animal or the cost of the transportation of such animal is to be paid and collected upon delivery of the animal to the consignee, unless the consignor guarantees in writing the payment of transportation charges for any animal not claimed within a period of 48 hours after notice to the consignee of arrival of the animal, including, where

necessary, both the return transportation charges and an amount sufficient to reimburse the carrier for all out-of-pocket expenses incurred for the care, feeding, and storage of such animals.

9 C.F.R. § 3.81

§ 3.81 Environment enhancement to promote psychological well-being.

These minimum standards apply only to live nonhuman primates, unless stated otherwise.

Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates. The plan must be in accordance with the currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian. This plan must be made available to APHIS upon request, and, in the case of research facilities, to officials of any pertinent funding agency. The plan, at a minimum, must address each of the following:

(a) Social grouping. The environment enhancement plan must include specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature. Such specific provisions must be in accordance with currently accepted professional standards, as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian. The plan may provide for the following exceptions:

(1) If a nonhuman primate exhibits vicious or overly aggressive behavior, or is debilitated as a result of age or other conditions (e.g., arthritis), it should be housed separately;

(2) Nonhuman primates that have or are suspected of having a contagious disease must be isolated from healthy animals in the colony as directed by the attending veterinarian. When an entire group or room of nonhuman primates is known to have or believed to be exposed to an infectious agent, the group may be kept intact during the process of diagnosis, treatment, and control.

(3) Nonhuman primates may not be housed with other species of primates or animals unless they are compatible, do not prevent access to food, water, or shelter by individual animals. and are not known to be hazardous to the health and well-being of each other. Compatibility of nonhuman primates must be determined in accordance with generally

accepted professional practices and actual observations, as directed by the attending veterinarian, to ensure that the nonhuman primates are in fact compatible. Individually housed nonhuman primates must be able to see and hear nonhuman primates of their own or compatible species unless the attending veterinarian determines that it would endanger their health, safety, or well-being.

(b) Environmental enrichment. The physical environment in the primary enclosures must be enriched by providing means of expressing noninjurious species-typical activities. Species differences should be considered when determining the type or methods of enrichment. Examples of environmental enrichments include providing perches, swings, mirrors, and other increased cage complexities; providing objects to manipulate; varied food items; using foraging or task-oriented feeding methods; and providing interaction with the care giver or other familiar and knowledgeable person consistent with personnel safety precautions.

(c) Special considerations. Certain nonhuman primates must be provided special attention regarding enhancement of their environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Nonhuman primates requiring special attention are the following:

(1) Infants and young juveniles;

(2) Those that show signs of being in psychological distress through behavior or appearance;

(3) Those used in research for which the Committee-approved protocol requires restricted activity;

(4) Individually housed nonhuman primates that are unable to see and hear nonhuman primates of their own or compatible species; and

(5) Great apes weighing over 110 lbs. (50 kg). Dealers, exhibitors, and research facilities must include in the environment enhancement plan special provisions for great apes weighing over 110 lbs. (50 kg), including additional opportunities to express species-typical behavior.

(d) Restraint devices. Nonhuman primates must not be maintained in restraint devices unless required for health reasons as determined by the attending veterinarian or by a research proposal approved by the Committee at research facilities. Maintenance under such restraint must be for the shortest period possible. In instances where long-term (more than 12 hours) restraint is required, the nonhuman primate must be provided the opportunity daily for unrestrained activity for at least one continuous hour during the period of restraint, unless continuous restraint is required by the research proposal approved by the Committee at research facilities.

(e) **Exemptions.**

(1) The attending veterinarian may exempt an individual nonhuman primate from participation in the environment enhancement plan because of its health or condition, or in consideration of its well-being. The basis of the exemption must be recorded by the attending veterinarian for each exempted nonhuman primate. Unless the basis for the exemption is a permanent condition, the exemption must be reviewed at least every 30 days by the attending veterinarian.

(2) For a research facility, the Committee may exempt an individual nonhuman primate from participation in some or all of the otherwise required environment enhancement plans for scientific reasons set forth in the research proposal. The basis of the exemption shall be documented in the approved proposal and must be reviewed at appropriate intervals as determined by the Committee, but not less than annually.

(3) Records of any exemptions must be maintained by the dealer, exhibitor, or research facility and must be made available to USDA officials or officials of any pertinent funding Federal agency upon request.

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 23-1556 **Caption:** New Eng. Anti-Vivisection Soc'y v. Goldentyer

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

Type-Volume Limit, Typeface Requirements, and Type-Style Requirements

Type-Volume Limit for Briefs if Produced Using a Computer: Appellant's Opening Brief, Appellee's Response Brief, and Appellant's Response/Reply Brief may not exceed 13,000 words or 1,300 lines. Appellee's Opening/Response Brief may not exceed 15,300 words or 1,500 lines. A Reply or Amicus Brief may not exceed 6,500 words or 650 lines. Amicus Brief in support of an Opening/Response Brief may not exceed 7,650 words. Amicus Brief filed during consideration of petition for rehearing may not exceed 2,600 words. Counsel may rely on the word or line count of the word processing program used to prepare the document. The word-processing program must be set to include headings, footnotes, and quotes in the count. Line count is used only with monospaced type. See Fed. R. App. P. 28.1(e), 29(a)(5), 32(a)(7)(B) & 32(f).

Type-Volume Limit for Other Documents if Produced Using a Computer: Petition for permission to appeal and a motion or response thereto may not exceed 5,200 words. Reply to a motion may not exceed 2,600 words. Petition for writ of mandamus or prohibition or other extraordinary writ may not exceed 7,800 words. Petition for rehearing or rehearing en banc may not exceed 3,900 words. Fed. R. App. P. 5(c)(1), 21(d), 27(d)(2), 35(b)(2) & 40(b)(1).

Typeface and Type Style Requirements: A proportionally spaced typeface (such as Times New Roman) must include serifs and must be 14-point or larger. A monospaced typeface (such as Courier New) must be 12-point or larger (at least 10½ characters per inch). Fed. R. App. P. 32(a)(5), 32(a)(6).

This brief or other document complies with type-volume limits because, excluding the parts of the document exempted by Fed. R. App. R. 32(f) (cover page, disclosure statement, table of contents, table of citations, statement regarding oral argument, signature block, certificates of counsel, addendum, attachments):

- ☑ this brief or other document contains 11,774 [*state number of*] words
- ☐ this brief uses monospaced type and contains _____ [*state number of*] lines

This brief or other document complies with the typeface and type style requirements because:

- ☐ this brief or other document has been prepared in a proportionally spaced typeface using _____ [*identify word processing program*] in _____ [*identify font size and type style*]; **or**
- ☐ this brief or other document has been prepared in a monospaced typeface using _____ [*identify word processing program*] in _____ [*identify font size and type style*].

(s) Rebecca L. Garverman

Party Name New Eng. Anti-Vivisection Soc'y

Dated: 12/05/2023