UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND

RISE FOR ANIMALS, et al. Plaintiffs, v. ELIZABETH GOLDENTYER, et al. Defendants.	Civ. No. 20-2004 Honorable George Jarrod Hazel ORAL ARGUMENT REQUESTED

PLAINTIFFS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs Rise for Animals ("Rise") and the Animal Legal Defense Fund ("ALDF") challenge a decision by the United States Department of Agriculture ("USDA") to deny their Rulemaking Petition to update a 31-year-old, scientifically outdated, "standard" intended to "promote the psychological well-being of primates" used in scientific research, as required by the Animal Welfare Act ("AWA"), 7 U.S.C. § 2143(a)(2)(B); *see* 9 C.F.R. § 3.81. Plaintiffs submitted their Petition based on decades of research about the needs of primates—none of which was taken into account when the current standard was drafted thirty years ago, despite the fact that the USDA itself long-ago concluded that the "standard" was deficient. They also submitted their Petition on the immediate heels of a decision by the National Institutes of Health ("NIH") to substantially improve the psychological welfare of particular primates—chimpanzees—with respect to research that is federally funded, and on that basis urged the USDA to adopt similar standards for all primates used in research, regardless of their species and whether such research is federally funded.[1]

Plaintiffs' Petition documented the ways in which nonhuman primates in research laboratories suffer, which the USDA's current regulation—having remained unchanged since it was first promulgated in 1991—has done little to abate. The Petition urged the agency to adopt a standard to promote the psychological well-being of all primates, similar to the requirements adopted by NIH for chimpanzees "with species-specific modifications for other primates," and to adopt regulations for determining how and when primates exhibit psychological distress and the actions that must be taken to ameliorate those symptoms. However, on October 10, 2019, the USDA denied Plaintiffs' Petition.

[1] Rise for Animals was formerly called the New England Anti-Vivisection Society.

As demonstrated below, the agency's refusal to significantly improve the 1991 standard is arbitrary, capricious, and an abuse of discretion, within the meaning of the Administrative Procedure Act ("APA"), 5 U.S.C. §706(2)(A). Indeed, as one participant at a government sponsored symposium lamented, because the USDA refuses to update this standard:

> [i]f you show a picture of a primate cage from 40 years ago and a primate cage now, *it's basically the same: it's all metal with a perch added*.

Symposium on Animal Welfare and Scientific Research: 1985-2010 (2011) (emphasis added), Administrative Record ("AR") 20.

STATEMENT OF THE CASE

Before addressing Plaintiffs' arguments, it is helpful to summarize the pertinent statutory framework and facts that underlie this case.

A. The 1985 Amendments to the Animal Welfare Act Required the USDA to Promulgate "Minimum Requirements . . . for a Physical Environment Adequate to Promote the Psychological Well-Being of Primates."

In the early 1960s, Congress began developing proposals for the first federal law to ensure humane treatment of animals used in medical research. As explained by Senator Monroney, one of the AWA's sponsors, "[t]he reason federal legislation is needed in the first place is the shocking failure of self-policing by the medical community." 112 Cong. Rec. 13,256 (1966) (Statement of Senator Monroney). In response to these concerns, the AWA was enacted to "*insure* that animals intended for use in research facilities . . . are *provided humane care and treatment*." Laboratory Animal Welfare Act of 1966, Pub. L. No. 89-544, § 1, 80 Stat. 350, 350 (codified at 7 U.S.C. § 2131(1)) (emphasis added). The AWA was subsequently amended to apply to animals used in exhibition and the pet trade. Animal Welfare Act of 1970, Pub. L. No. 91-579, § 2, 84 Stat. 1560, 1560 (codified at 7 U.S.C. § 2131(1)).

While the Act requires the Secretary of Agriculture to "promulgate standards to govern the humane handling, care, treatment and transportation" of *all* animals subject to the statute, 7 U.S.C. § 2143(a)(1), in 1985 Congress also recognized the need for specific standards to provide for the unique psychological needs of nonhuman primates. *Id*. Finding that "[c]urrent standards leave too much room for shoddy care and inhumane treatment," 131 Cong. Rec. 22,257 (Aug. 1, 1985), Congress sought to require the USDA to take steps to ensure that these facilities provide an environment for primates that is "*consistent with the primate's natural instincts and habits*." H.R. Conf. Rep. 99-147, *reprinted in* 1985 U.S.C.C.A.N. 2251, 2520, AR 512 (emphasis added).

Thus, in 1985 Congress enacted the Improved Standards for Laboratory Animals Act, which amended the AWA by specifically requiring the Secretary to promulgate "minimum requirements" to insure that the regulated entities provide "a physical environment adequate to promote the psychological well-being of primates." 7 U.S.C. § 2143(a)(2)(B). As explained by Senator John Melcher, the author of the amendment—and a veterinarian—this duty was intended to ensure that primates "not only have [] space [,] but . . . interesting things to do, so that they are *not bored to death just waiting to be part of man's quest through true research for better lives for us all*." 131 Cong. Rec. S17881-02 (daily ed. Dec. 18, 1985) (emphasis added).

To ensure that the USDA relies upon sound scientific evidence in crafting the requisite "minimum standards," Congress directed that "[i]n promulgating and enforcing standards established pursuant to this section, the Secretary is . . . *directed to consult experts*, including outside consultants where indicated." 7 U.S.C. § 2143(5) (emphasis added). The Act further provides that in establishing such standards, the Secretary "shall consult . . . with other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used in

research," 7 U.S.C. § 2145(a), and that the Secretary specifically "shall consult with the Secretary of Health and Human Services" with respect to such standards. *Id*.

The AWA further provides that "the Secretary shall inspect each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this chapter, shall conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected." 7 U.S.C. § 2146(a).

B. The USDA's 1991 Regulation

1. The Agency Allows Each Regulated Entity to Devise Its Own Environmental Enrichment Plan.

In 1991, the USDA promulgated a regulation intended to implement the 1985 Amendment for "minimum requirements . . . for a physical environment adequate to promote the psychological well-being of primates." 7 U.S.C. § 2143(a)(2)(B); *see* 9 C.F.R. § 3.81. Under this 1991 regulation—which has remained unchanged for more than thirty years—each research facility that uses or houses nonhuman primates must develop a "plan" to provide "environment enhancement adequate to promote the psychological wellbeing of nonhuman primates." 9 C.F.R. § 3.81. The regulations require 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," nor does it require the research facilities to submit their enrichment plans to the USDA for approval. *Id*. Nor, for that matter, does the regulation even require the regulated facilities ever to submit their plans directly to the agency, *id*.—which means these documents are also shielded from public scrutiny under the

Freedom of Information Act. *See Forsham v. Harris*, 445 U.S. 169 (1980) (the disclosure requirements of FOIA only apply to documents in the actual possession of a federal agency).

The 1991 regulation also fails to provide concrete, enforceable standards. For example, the regulation indicates that certain categories of vulnerable primates—i.e., infants and primates that show signs of psychological distress—are to be afforded "special considerations," 9 C.F.R. § 3.81(c), but it does not describe, even by example, what these "special considerations" should be. The regulation also requires that the "physical environment in the primary enclosures must be enriched by providing means of expressing non-injurious species-typical activities," *id.*, but does not provide any information about what those sources of enrichment must be, or explain how to ascertain that 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. <u>The USDA Itself Determines that the 1991 Standard Is Too Vague and Unenforceable.</u>

After only a few years of implementing the 1991 standard, the USDA itself concluded that it was not sufficient to ensure that facilities were adequately addressing the psychological needs of primates. In 1996, the agency's Animal Plant Health Inspection Service ("APHIS"), which is responsible for enforcing the AWA, issued a report explaining that many of its

[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").

inspectors found that "the primate environmental enrichment criteria [in Section 3.81] were not useful" to judge whether facilities were providing an adequate environment to promote primate psychological well-being, Draft Enhancement Policy, 64 Fed. Reg. 38,146 (July 15, 1999), AR 702, and that the regulations were sowing "confusion among the regulated public concerning on what basis they will be judged by inspectors as meeting or not meeting the requirements." *Id*. Thus, APHIS concluded, "additional information on how to meet the standards of § 3.81 *is necessary*." *Id*. (emphasis added).

In response, in 1999 APHIS published for comment a "Draft Policy" intended "to be used by dealers, exhibitors, and research facilities as a basis in developing plans under § 3.81 for environmental enhancement to promote the psychological wellbeing of nonhuman primates." *Id*. Specifically, the Draft Policy identified five elements as "the currently accepted professional standards [necessary] to meet the *minimum requirements* in § 3.81." *Id*. at 38,146–47 (emphasis added), AR 702–03. These five elements were (1) social grouping; (2) the social needs of infants; (3) structure and substrate; (4) foraging opportunities; and (5) manipulanda—opportunities for primates to physically move objects in their environment. *Id*. at 38,147, AR 703. These five elements were described by the agency as "*critical to environments that adequately promote the psychological wellbeing of nonhuman primates*." *Id*. (emphasis added).

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 (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.'" 204 F.3d at 235. However, citing the pending Draft Policy, the Court went on to stress that "the Secretary *has begun to offer interpretations likely to assist both regulates and enforcers*." *Id*. at 235 (emphasis added) (internal citations omitted).

However, the Draft Policy was never finalized, and, accordingly, not a single change has been made to the primate regulations since they were first promulgated in 1991. 9 C.F.R. § 3.81.

C. NIH Adopts Detailed Recommendations for Environments that Promote the Wellbeing of Chimpanzees Used in Federally Funded Research.

In 2010, the Institute of Medicine("IOM")—at the request of National Institutes of Health ("NIH")—convened a committee to assess the necessity of using chimpanzees in federally funded research, in light of increased scientific evidence of the intelligence and psychological needs of chimpanzees, and concomitant ethical concerns about continuing to use them in research. Institute of Medicine, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity,* The National Academies Press 12–14 (2011), AR 1739–41. The IOM Committee concluded that chimpanzees should no longer be used in federally-funded research unless necessary to advance the public's health, and where no other research model could be used. *Id*. at 4, AR 1731. NIH, Announcement of Agency Decision: Recommendations on the Use of Chimpanzees in NIH-Supported Research 2 (June 26, 2013), AR 220–21. It further concluded that these animals "must be maintained either in ethologically appropriate physical and social environments or in natural habitats." *Id*., AR 221. IOM further observed that "all species, including our own, experience a chronic stress response (comprising behavioral as well as physiological signs) when deprived of usual habitats, which for chimpanzees includes . . . sufficient space and environmental complexity to exhibit species-typical behavior. Therefore, to perform rigorous . . . research, *it is critical to minimize potential sources of stress* on the chimpanzee." AR 1754 (emphasis added).

In response to the IOM Report, the NIH Council of Councils, a federal advisory committee, formed a Working Group on the Use of Chimpanzees in NIH-Supported Research, which spent several years analyzing the use of chimpanzees in research, and exploring the potential to create environments that not only allowed, but actually promoted, natural behaviors and psychological wellbeing for chimpanzees used in federally funded research. The Working Group concluded that any future use of chimpanzees in scientific research must be approved in advance by an independent oversight committee that would determine whether using chimpanzees for the research was necessary, and it provided NIH with a host of specific recommendations for ensuring that chimpanzees were provided environments that would promote their psychological welfare. Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research, Report 3–4 (2013), AR 1933–34.

After receiving over 12,500 public comments on the proposed requirements, on June 26, 2013, NIH accepted nine of ten specific requirements for the care of chimpanzees in a federally funded laboratory setting. Announcement of Agency Decision: Recommendations on the Use of Chimpanzees in NIH-Supported Research, 78 Fed. Reg. 39,741, 39,743–47 (June 26, 2013), AR 3621. In contrast to the USDA's primate regulation, these requirements provide concrete and easy to enforce specifications with which any federally funded laboratory using or housing chimpanzees must comply. *See, e.g.*, Council of Councils Working Group at 3, AR 1933 ("Chimpanzees must have the opportunity to live in sufficiently large, complex, multi-male, multi-female social groupings, ideally consisting of at least 7 individuals."); *id*. ("Chimpanzees should have the opportunity to climb at least 20 ft. (6.1 m) vertically."); *see also* 78 Fed. Reg. 39,741, 39,743–47 (June 26, 2013), AR 3623–30.

Many of the requirements implemented by NIH correspond to the same five elements that APHIS identified years ago in its 1999 Draft Policy as "*critical*" to promoting the psychological wellbeing of primates. 64 Fed. Reg. 38,145, 38,147, AR 701, 703. For example, both the NIH requirements and the USDA's Draft Policy discuss the importance of housing the animals in social groups; providing physical space sufficient for species-appropriate behaviors; providing continued availability of nesting materials; ensuring primates' ability to exercise control over their environment; and considering the physical, health, and behavioral history of each individual primate. *See* 78 Fed. Reg. 39,741, 39,743–47 (June 26, 2013), AR 3623–30; 64 Fed. Reg. 38,145, 38,147–49, AR 703–05.

All researchers are required to abide by the AWA and the USDA's implementing regulations, regardless of whether they are federally funded. *See* Public Health Service, Policy on Humane Care and Use of Laboratory Animals 9 n.2 (2015), Plaintiffs' Exhibit ("Pl. Ex.") A ("Compliance with the USDA regulations is an absolute requirement of this Policy."). Therefore, in issuing these new requirements for the treatment of chimpanzees, NIH necessarily determined that the USDA's existing standard to promote the psychological well-being of primates was inadequate for that purpose.[3]

D. Plaintiffs' Rulemaking Petition

On May 7, 2014, pursuant to the Administrative Procedure Act, 5 U.S.C. § 553(e), Plaintiffs submitted a Petition for Rulemaking to the USDA requesting that the agency follow NIH's lead and update the 1991 standard by promulgating specific, enforceable regulations to

[3] This Court may take judicial notice of official government statements of policy. *See, e.g., Martin v. Duffy*, 838 F.3d 239, 253 n.4 (4th Cir. 2017) (citing Fed. R. Evid. 201(d)).

promote the psychological wellbeing of *all* primates used in research. *See* Plaintiffs' Petition at 1, AR 4.

In addition to basing the Petition on the actions taken by NIH, Plaintiffs 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. *Id*. at 20–22, AR 23–25. They also documented the ways in which the current lack of clear and enforceable standards is extremely detrimental to these animals' psychological well-being, *id*. at 42–45, AR 45–48, and they provided detailed information about specific standards that would adequately accomplish this important objective. *Id*. at 22–32, AR 25–35.

Plaintiffs' Petition explained that the language of the current standard is "so vague that it lacks any enforceable definition of how to evaluate if such a plan is actually effectively designed or implemented in a way that *promotes* the primates psychological well-being." *Id*. at 3, AR 6 (emphasis in the original). It further noted that "[w]hile some additional guidance is provided . . . a lack of concrete, measurable, and enforceable definitions and criteria within the regulations has resulted in almost no meaningful regulation of the psychological well-being of primates used in research, and a lack of congruent application across facilities." *Id*.

Plaintiffs therefore urged that "[a]s a matter of consistency, and to promote harmonization of regulatory approaches to the same problems, NIH's newly accepted requirements for ethologically appropriate environments for chimpanzees provide standards that should be adopted by the USDA for chimpanzees and provide a baseline that should be adopted with appropriate modifications for *all* primates held in laboratories." *Id*. at 4, AR 7. For example, the Petition explained, citing to well-known primatologists, that macaques—one of the species

most commonly used in research— "have active minds; have inquisitive natures; are inventive; are sociable; have caring relationships; make and use tools; have a culture; have complex emotions; analyze past results . . . and have a sense of justice and fairness." *Id*. at 21, AR 24 (and authorities cited therein) (internal citations omitted). However, the Petition explained, these primates live in artificial environments, exposed to constant and unpredictable stressors, develop pathological behaviors and suffer severe stress due to their confinement, lack of access to social or mental enrichment, and lack of control over their environment. *Id*. at 5, AR 8. In response to this stress, primates in research facilities commonly engage in abnormal behaviors, including self-harm and mutilation. *Id*. at 35, AR 38. Accordingly, like chimpanzees, these primates also need to have their psychological needs met if they are to be afforded humane treatment. *Id*.; *see also id*. at 20–22, AR 23–25 (describing psychological needs of other primate species).

Plaintiffs' Petition further explained that Congress's determination 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 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." *Id*. at 5, AR 8. The Petition recounted—and documented with voluminous evidence—that:

> primates often develop pathological behaviors and suffer severe stress due to confinement, little or no social or mental enrichment, a complete lack of control over their environments, and living in an artificial environment where stressors are ever-present, unpredictable, and create learned helplessness given the animals' complete inability to deter, escape, or fight off harm or hardship.

Id.

Plaintiffs further explained—and thoroughly demonstrated with an exhaustive bibliography of scientific literature—that "[t]here is a wealth of information concerning the

psychological well-being of primates that was not available at the time the USDA regulations for psychological well-being were drafted in 1991." *Id.; see also id.* at 51–59; AR 54–62 (list of scientific literature relied on). Thus, they stressed "[t]he NIH's new recommendations for chimpanzee environments provide a valuable and readily available starting point for the USDA to amend Section 3.81 of the AWA regulations to upgrade the 'minimum requirements' for a 'physical environment adequate to promote the psychological well-being of primates.'" *Id.* at 5, AR 8 (citing 7 U.S.C. § 2143(a)(1)-(2)(B)).

In addition to requesting the agency to adopt the NIH requirements as a baseline for all primates used in research, "with species-specific modifications" for primates other than chimpanzees, Plaintiffs requested the USDA to "[a]dopt regulations for determining how and when chimpanzees and other primates exhibit psychological distress and what 'special attention' must be brought to bear to ameliorate these symptoms." *Id.* at 48, AR 51.

Finally, Plaintiffs demonstrated that the "severe stress that laboratory life imposes on primates[,] and the physiological responses to such psychological, cognitive, and social stress confounds research data and calls into serious question the validity of any research results." *Id.* at 46, AR 49. For this reason, also, Plaintiffs urged the USDA to grant their Petition. *Id.*

E. USDA's Initial Response to Plaintiffs' Petition

By letter dated May 20, 2014, the Deputy Administrator of APHIS's Animal Care division responded to Plaintiffs' Petition. AR 491. He stated that the agency "believe[s] that the issues raised in the petition are important and that many parties will have an interest in them." *Id.* Accordingly, he informed Plaintiffs that USDA would publish the Petition in the Federal Register to solicit public comment, and that "[o]nce we have analyzed all of the comments received, we will decide what action, if any, we should take in response to this request." *Id.*

APHIS published the Petition in the Federal Register for public comment on May 1, 2015, 80 Fed. Reg. 24,840, 24,841 (May 1, 2015), AR 491–92, and again on July 24, 2015, 80 Fed. Reg. 43,969 (July 24, 2015), AR 494. By the close of the second comment period, APHIS had received a total of 10,137 comments on Plaintiffs' Petition—the vast majority of which supported granting the Petition. *See, e.g.*, AR 495 (agency reported that 7232 comments (71%) were in favor of the Petition; 63 comments (1%) opposed granting the Petition; and 2842 comments (28%) did not address the Petition).

Many of the comments provided additional reasons for granting Plaintiffs' Petition. For example, the Laboratory Primate Advocacy Group ("LPAG"), a non-profit primate advocacy organization with decades of experience caring for primates in laboratories, zoos, and sanctuaries, stressed that the current regulation's requirement that the enrichment plan be based on "currently accepted professional standards" inevitably leads to ineffective standards because "'[p]rofessional standards' allow . . . laboratory industries to self-regulate." Comments of LPAG, Docket ID APHIS-2014-0098-10112 (Aug. 31, 2015), Pl. Ex. B.[4] As a result, LPAG explained, "[i]n the nearly 25 years since the promulgation of § 3.81, these industries *have not been incentivized to develop new professional standards or make innovative efforts to promote psychological well-being*." *Id*. (emphasis added). It further explained that, as a result, "*thousands of monkeys are traumatized each year because of [these] lax standards*." *Id*. (emphasis added).[5]

[4] The USDA has not placed all of these Comments in the Administrative Record, although it agrees they are part of that Record. Instead, it provides access to them through its website at https://www.regulations.gov/docket/APHIS-2014-0098/comments. *See also* ECF No. 28 (Status Report explaining that all such comments may be relied on by the parties).

[5] *See also* Comments of People for the Ethical Treatment of Animals (PETA), Pl. Ex. C ("nonhuman primates who are held in 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

Additionally, many commenters shared their opinions based on more than 20 years of personal experience working with primates used in research. For example, Gloria Grow, Founder and Director of the Fauna Foundation, a chimpanzee sanctuary that provides refuge for chimpanzees retired from laboratory settings stated that she supported granting Plaintiffs' Petition "based on what I have witnessed firsthand of the devastation animals sustain when their psychosocial needs have not been held as the highest of priorities by the labs and other facilities from which they came." Comments of Gloria Grow, Pl. Ex. D. Thus, she explained, "*[l]eaving the fate of animals in captivity in the individual hands of those to whom they serve without stringent oversight from regulatory agencies that clearly define what is expected in both physical and psychological wellbeing is negligent and a major contributor to unnecessary and prolonged suffering*." *Id*. (emphasis added).

> Similarly, Frances Burton, a primatologist at the University of Toronto, 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.

Comments of Frances Burton, Pl. Ex. E.[6]

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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"); *id*. (noting that "laboratories and their attending veterinarians have taken cover behind the nebulous language of Section 3.81, as it refers to 'currently accepted professional standards,' to allow for the widespread, but unacceptable, practice of singly housing primates in barren metal cages").

[6] *See also* Comments of Janine Perlman, a biomedical scientist, Pl. Ex. F ("These 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 . . . they should provide generous amounts of space in three dimensions, and must include sufficient, appropriate hiding places where animals can shelter."); Comments of

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.

Comments of Marc Bekoff, Pl. Ex. H (emphasis added).

F. <u>The USDA's Denial of Plaintiffs' Petition</u>

After Plaintiffs filed a case in this Court challenging the agency's unreasonable delay in responding to Plaintiffs' Petition, *New England Anti-Vivisection Society et al. v. Perdue,* Civ. No. 19-12276, they received a letter from the USDA denying Plaintiffs' Petition. AR 495. The agency gave several reasons for stating that no changes would be made to the 1991 regulation concerning the psychological well-being of primates. First, the agency stated that Plaintiffs could not be correct that the current standard was "too vague to be unenforceable," because between 2007-2015 the USDA had cited facilities for various violations of the regulation. *Id*. Second, the agency implied 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 [non-human 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 [Environmental Enrichment Plans]." AR 496.

Primatologist Dr. Jessica Ganas, Pl. Ex. G ("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.")

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

AR 496 (emphasis added).

Fourth, with respect to Plaintiffs' 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. AR 498-99.

G. Proceedings to Date

Plaintiffs filed this lawsuit on July 9, 2020. ECF No. 1. At the time they filed their Complaint, they suspected that the agency's statements in its Denial Letter that its inspectors "examine and document *all areas of care and treatment* that are covered under the AWA, including the plan," and that during such inspections "[t]he inspector also *observes the regulated animals; inspects the facilities,* including enclosure or housing materials space, and records," AR 496 (emphasis added), were not correct for the vast majority of research labs in this country. Plaintiffs suspected that, in fact, for all such labs accredited by the industry-dominated

Association for Assessment and Accreditation of Laboratory Animal Care ("AAALAC")[7] — which includes the vast majority of all major research laboratories in this country, *see* Justin R. Goodman et al., 18 J. Applied Animal Welfare Sci. 1, 2 (2014), AR 6197 —the agency does *not* conduct full inspections of each lab as required by the Animal Welfare Act, 7 U.S.C. § 2146(a), nor do the inspectors "observe[] the regulated animals." Instead, APHIS conducts only a *partial* inspection of such facilities that may not include observing *any* of the animals.

However, because Plaintiffs could not verify this actual practice when they filed their Complaint, they alleged this fact on information and belief, Complaint, ECF No. 1, ¶ 70, and submitted a request to the USDA under FOIA to obtain records that would demonstrate the actual inspection practices of the agency. When the agency did not respond to the FOIA request in a timely manner, Plaintiffs filed a related lawsuit in this Court to obtain access to those records. *New England Anti-Vivisection Society v. Animal Plant Health & Inspection Serv.*, Civ. No. 8:20-cv-03013 (D. Md. Oct. 16, 2020). As a result, the agency produced responsive records demonstrating that since 2019 the USDA has had in place an inspection policy –undisclosed to the public—whereby it no longer does a full annual inspection of all research facilities subject to the AWA for any lab that is accredited by AAALAC. *See* AR 3645–49, 3709.

In fact, as the documents released to Plaintiffs reveal, since February 2019, the USDA has instructed its inspectors that they are *prohibited* from conducting full inspections of such labs each year. Instead, they are required to inspect *only one of three facets of each such facility*—or a

[7] *See, also* AAALAC, Council on Accreditation (last visited July 1, 2022), https://www.aaalac.org/about/councl.cfm, AR 5993 (explaining that AAALAC's "Council on Accreditation" consists of representatives from universities with extensive animal-experimentation programs, contract testing laboratories, multinational pharmaceutical companies, and other entities that use or support the use of animals in research).

sampling thereof—when they do their annual inspection: *either* (1) the "animals" being maintained at the lab; (2) the "facilities;" *or* (3) the "paperwork" each facility is required to maintain, which would include each lab's "enrichment plan" for the psychological well-being of primates. USDA, Focused Inspections, Pl. Ex. I.[8] This means that pursuant to this "focused" inspection—which the agency also instructed its inspectors "*counts as the facility's annual inspection,*" AR 3645 (emphasis added)—*as many as four years may lapse before APHIS inspects a single animal that is the subject of the facility's research. See id.* Moreover, even if an inspector *does* choose to actually inspect the animals at the facility during one of these "focused" inspections, he or she may observe a mere "sampling" of those animals. *Id.*[9]

Meanwhile, on October 19, 2020, Defendants moved to dismiss this case on the grounds that Plaintiffs lacked Article III standing. Motion to Dismiss, ECF No. 7. In their supporting memorandum, Defendants contended that Plaintiffs could not demonstrate the requisite redressability, because, even if Plaintiffs prevailed, they could not show that any new standard would provide them with any information that is not already generated by the agency's current inspection regime—relying on the same incorrect statement about the scope of those inspections that was asserted in the agency's Denial Letter. Thus, the agency stated:

> as USDA explained in its response to Plaintiffs' petition for rulemaking, 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]." . . . Plaintiffs' complaint does not explain what *new* information would be submitted in future reports, given that current reports already discuss "*all* areas of care and treatment" covered by the Animal Welfare Act. *Id.*

[8] This document was inadvertently omitted from the Administrative Record; however, the government agrees that Plaintiffs may rely on it.

[9] Thus, under this inspection policy, in year one the inspector may only inspect paperwork; in year two, he may inspect the facility; in year three he may inspect a "sampling" of the paperwork or facilities; and in year four he may inspect *some* of the animals. USDA, Focused Inspections, Pl. Ex. I.

Memorandum in Support of Defendants' Motion to Dismiss, ECF No. 7-1, at 22 (emphasis in original).

However, after the USDA produced documents in the related FOIA case revealing the existence of its "focused" inspection approach to all labs accredited by AAALAC—under which the agency actually *prohibits* its inspectors from conducting full inspections of such research facilities each year—the agency filed with this Court a "Notice" to "correct" the above statement "to the extent it suggests that every agency inspection covers 'all areas' of the facility." ECF No. 19 at 2 (quoting Defendants' Memorandum in Support of its Motion to Dismiss). Rather, the agency explained that inspectors may conduct "focused inspections" which do *not* "examine and document all areas of care and treatment that are covered under the [Animal Welfare Act]." *Id*. The agency further informed the Court that "[i]n light of this clarification, USDA no longer intends to rely on the statements made in its motion to dismiss filings to the extent they suggest that each and every USDA inspection looks at all aspects of a regulated entity's care and handling of animals." However, although the agency had also relied heavily on this same rationale for denying Plaintiffs' Petition for Rulemaking, it did not seek a voluntary remand to correct this error as well.

On September 29, 2021, the Court denied Defendants' Motion to Dismiss, ECF No. 22; 2021 WL 4459217.

ARGUMENT

I. THE USDA'S DENIAL OF PLAINTIFFS' PETITION WAS ARBITRARY, CAPRICIOUS, AND AN ABUSE OF DISCRETION.

Summary judgment is warranted when there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *see also*,

Anderson v. Liberty Lobby, Inc., 477 U. S. 242, 248 (1986). Here, the sole question the Court must decide is whether the USDA's denial of Plaintiffs' Rulemaking Petition was arbitrary and capricious or an abuse of discretion within the meaning of the Administrative Procedure Act, 5 U.S.C. § 706(2); *see also American Horse Protection Assoc. Inc. v. Lyng*, 812 F.3d 1, 4 (D.C. Cir. 1987) (applying to the arbitrary and capricious standard of review to denials of rulemaking petitions). While the Court may not "substitute its judgment for that of the agency[,]" *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), "[its] inquiry must be 'searching and careful.'" *Ohio Valley Env't Coal., Inc. v. U.S. Army Corps of Eng'rs*, 828 F.3d 316, 321 (4th Cir. 2016) (quoting *N.C. Wildlife Fed'n v. N.C. Dept. of Transp.*, 677 F.3d 596, 601 (4th Cir. 2012)).

Therefore, in conducting this analysis, the Court must decide whether the agency has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made" and "must consider whether the decision was based on a consideration of the relevant factors." *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983). As the Supreme Court long ago explained, an agency's decision is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency . . ." *Id.*

Here, as demonstrated below, Plaintiffs easily satisfy these standards.

A. <u>Contrary to What the Agency Asserted in Its Denial of the Petition, Its Inspectors Do *Not* Conduct Full Inspections of All Research Labs.</u>

To begin with, particularly in light of the "Notice" filed by the agency to correct its misstatement in its motion to dismiss memorandum, ECF No. 19, the USDA has clearly "offered

an explanation . . . that runs counter to the evidence before" it. *State Farm*, 463 U.S. at 43. Thus, as explained, *supra*, at 18–19, in its Denial Letter, the agency asserted that there was no reason to improve the 1991 regulation for the psychological well-being of primates 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 [enrichment] 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.

Denial Letter at 2, AR 496 (emphasis added).

However, we now know that this statement is demonstrably incorrect – which is why the agency filed its "Notice" with the Court to "correct" this same statement. *See* ECF No. 19 at 2. Indeed, the records the agency provided to Plaintiffs after they filed their related FOIA case show that, with respect to research facilities that are accredited by the industry-dominated AAALAC—which includes the majority of research facilities in this country, Goodman et al., *Accreditation by AAALAC* at 2, AR 6197—the USDA *prohibits* its inspectors from conducting full inspections when they perform the annual inspections required by the statute, 7 U.S.C. § 2146(a). Instead, inspectors are instructed to only perform a partial inspection at that time of either (1) the animals; (2) the facilities; (3) the paperwork; or (4) a sampling of one or all of these categories. *See* USDA, Focused Inspections, Pl. Ex. I; see also AR 3645 (agency instructs its inspectors that this "focused" inspection constitutes the annual inspection required by statute).

Therefore, the record clearly shows that despite what the agency told Plaintiffs when it denied their Petition for Rulemaking, (1) the inspectors do *not* "examine and document all areas of care and treatment that are covered under the AWA; (2) the inspectors do *not* "observe[] the regulated animals" during each of these inspections; (3) the inspectors also do *not* always

"observe[]" "the facilities, including, enclosure or housing materials, space, and records; and (4) because they only do partial inspections each year, the inspectors have *no basis for determining whether "the facility is in full compliance with the AWA requirements*." AR 496 (emphasis added). Thus, the agency "offered an explanation for its decision that runs counter to the evidence before the agency"—a textbook example of arbitrary and capricious decision-making. *State Farm*, 463 U.S. at 43.

The significance of this patently incorrect rationale cannot be overstated. Because under the agency's own inspection policy, it may be years before an inspector ever looks at a single animal at any particular research facility, the inspector would have no way to observe whether, in fact, that facility's "enrichment plan" is actually promoting the psychological well-being of the primates, as required by the AWA. Indeed, even if the agency chose to actually examine animals in a given year as part of this "focused" inspection, it could fulfill its inspection obligations under the policy by observing only a "sampling" of the animals. USDA, Focused Inspections, Pl. Ex. I. Thus, under this inspection regime—which was kept secret from the public for years—there simply is no way that the USDA's inspectors are ensuring that these primates are receiving the environments and attention that they need and deserve, and that is *required* by the AWA.[10]

B. The USDA's Reliance on Non-Binding Suggestions Is Also Arbitrary and Capricious.

The USDA also denied Plaintiffs' Rulemaking Petition requesting concrete, enforceable standards on the ground that in 2017 it held a symposium entitled "Practical Solutions to Welfare Challenges," and because it has also issued several "Animal Care Aids" to "support . . . the

[10] Because this inspection policy is also clearly unlawful in violation of the plain language of the statute, Plaintiffs have brought an additional case challenging the policy. *Rise for Animals v. Vilsack,* Civ. No. 22-00810 (D. Md. Apr. 05, 2022).

development of compliant [environment enrichment plans]." Denial Letter at 2, AR 496. The agency stated that the purpose of these programs was to "continue to provide the regulated facilities and our inspectors *learning opportunities* regarding animal welfare." *Id*. at 4, AR 498 (emphasis added). However, the agency did not provide any evidence regarding which, or how many, research facilities attended that symposium—and there is nothing in the Administrative Record regarding that fact. Regardless, it is doubtful that this symposium was attended by all, or even a majority, of such entities. Moreover, the Animal Care Aids to which the agency refers do not even cite the USDA's primate regulation, and thus provide no proof whatsoever that the agency has informed the regulated facilities as to what is *required* to satisfy this standard. *See* AR 2998–3006.

Moreover, neither the discussion of "learning opportunities" that occurred at the 2017 symposium, nor the non-specific Animal Care Aids, are binding on any research facility. Therefore, this particular evidence of what the agency has done to "insure" that these primates are being treated humanely, 7 U.S.C. § 2131(1), and that their psychological needs are being met is underwhelming at best. Similarly, the mere fact that the agency has issued some citations between 2007 and 2015, *see* Denial Letter at 1, AR 496, hardly proves that the situation that the agency itself concluded existed in 1999—i.e., that the 1991 standard was "not useful" to judge whether facilities were providing adequate environments to promote the psychological well-being of primates, and that 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," 64 Fed. Reg. at 38,146, AR 702—has now been ameliorated. This is particularly true given the overwhelming evidence produced by the Plaintiffs—as well as the extensive public comments submitted to the agency—demonstrating that primates in labs *continue* to suffer

greatly under the current regulatory regime. *See* Petition at 10–18, AR 13–21; *see also, e.g., American Horse Protection Ass'n v. Lyng*, 812 F.2d at 6 (evidence of reduced findings of violations does not demonstrate the elimination of the problem in the face of evidence that the problem "continues to be widespread"); *id.* at 5 (noting that "[i]n considering a refusal to grant a rulemaking petition, the court must examine 'the petition for rulemaking, comments pro and con . . . and the agency's explanation of its decision to reject the petition.'") (citations omitted).

Indeed, although Plaintiffs relied heavily on the agency's own conclusions decades ago that the 1991 regulation was insufficient to meet the objective of the statutory requirement to promote the psychological well-being of these extremely intelligent and social animals, *see* Petition at 11–12, AR 14–15, in denying Plaintiffs' Petition the agency did not provide *any* evidence that the inspectors or the regulated industry now fully understand how to comply with this standard. For this reason also, the USDA's denial of Plaintiffs' Petition was arbitrary and capricious. *See, e.g., FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 557 (2009) ("An agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more that it can ignore inconvenient facts when it writes on a blank slate.").

C. <u>The Agency Ignored Decades of Scientific Evidence.</u>

In denying Plaintiffs' Petition, the agency also completely ignored the voluminous scientific evidence presented by Plaintiffs in their Petition—all of which has been generated since 1991 when the current standard was drafted. Hence, the agency also necessarily failed to base its decision on "the relevant factors." *State Farm*, 463 U.S. at 43 (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974)); *see also Lyng*, 812 F.2d at 5 ("a refusal to initiate a rulemaking naturally sets off a special alert when a petition has sought modification of a rule on the basis of a radical change in its factual premises."). Indeed, during

the 30 years since the primate regulations were first implemented in 1991, scientific knowledge about the abilities and needs of nonhuman primates has improved exponentially. This fact was heavily documented by Plaintiffs' Petition, public comments, and other documents the USDA included in the Administrative Record. *See generally* AR 707–2259; 2309–35; 2342–2407.

As Plaintiffs' Petition stressed, "[t]here is a wealth of information concerning the psychological well-being of primates that was not available at the time the USDA regulations for psychological well-being were drafted in 1991." Petition at 5, AR 8. The Petition goes on to summarize important discoveries in the field, including: that "[l]aboratory confinement and experimentation are well known to cause severe stress and abnormal mental states and behaviors in animals used for research," *id*. at 33, AR 36.[11]

The USDA also failed to consider the points raised by the over 7,000 comments that supported granting of Plaintiffs' Petition, despite acknowledging this support in its Denial Letter. Denial Letter at 1; *see also Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015) (finding that "an agency must consider and respond to significant comments received during the period for public comment"). For example, Dr. Marc Bekoff, a leading primatologist with a Ph.D. in Animal Behavior, who used to work in a primate research lab, stressed that "my own understanding from my decades of work [is] that any monkey who is displaying symptoms of

[11] *Citing* Brune, Brune-Cohrs, McGrew, & Preuschoft, 2006; Morgan & Tromborg, 2007); that "nonhuman primates live in constant fear and uncertainty about if and when they will be subjected to an experimental procedure," *id*. at 34, AR 37 (*citing* Sapolsky, 2004); and that "[n]onhuman primates in laboratories are known to develop self-injurious, stereotypic, and other abnormal behaviors . . . includ[ing] over-grooming or hair-pulling to the point of injury or permanent damage or scarring to skin or follicles, hitting and/or biting one's self, banging one's self against the cage, pacing, twirling, rocking, back-flipping, swaying, eye-covering, self-clasping, repetitive circling, and digitsucking," *id*. at 37, AR 40 (*citing* Bayne et al., 1991; Bourgeois, Vazquez, & Brasky, 2007; Brune et al., 2006; Goosen, 1981; Lutz et al., 2003, AR 724–36; Mallapur & Choudhury, 2003, AR 1450–57; Rommeck, Gottlieb, Strand, & McCowan, 2009, AR 1323–29; Roy, 1981; Declaration of Ned Buyukmihci, VMD at ¶ 4, Exhibit 5, AR 87).

severe stress must immediately be removed from the situation, provided remedial help, and, if his/her symptoms persist, be immediately retired from research and placed into sanctuary." Comments of Marc Bekoff, Pl. Ex. H.

Additional public comments also draw attention to crucial advancements in primatology and how evolving science should prompt improved regulations. For example, Friends of Animals explained that "[t]he growing body of literature on animal cognition and emotions demonstrates undeniably that animals have interests and points of view . . . They form close social relationships, cooperate with other individuals, and likely miss their friends when they are apart." *See* Comments of Friends of Animals, Pl. Ex. J, *citing* Fox and Bekoff, *Integrating Values and Ethics into Wildlife Policy and Management—Lessons from North America*, 1 Animals 126, 131 (2011). Veterinarian Nedim Buyukmihci, an Emeritus Professor of Veterinary Medicine at the University of California-Davis commented, "[I]t is axiomatic that the most important factor that will improve the welfare and psychological wellbeing of non-human primates used in research is *providing the opportunity for physical contact with members of their own or similar species . . . there is an extensive scientific literature supporting this conclusion*." Comments of Nedim C. Buyukmihci, V.M.D., Pl. Ex. K (emphasis included).

Nevertheless, the agency's Denial Letter makes no mention of the abundant scientific research that Plaintiffs and commenters provided depicting the vast improvements in primate science since the existing regulation was promulgated. The agency does not reference even one of the hundreds of scientific articles cited in Plaintiffs' Petition and the public comments, and does not explain why these advances do not necessitate improving the regulation. This omission is particularly glaring in light of the fact that the Animal Welfare Act itself explicitly reflects Congress' determination that expert advice and input be taken into account when promulgating

regulations to promote the psychological wellbeing of primates. *See* 7 USC § 2143(a)(5) ("[i]n promulgating and enforcing standards established pursuant to this section, the Secretary is . . . *directed* to consult experts") 7 U.S.C. § 2143(a)(5) (emphasis added); *see also Lyng*, 812 F.2d at 5 ("a refusal to initiate a rulemaking naturally sets off a special alert when a petition has sought modification of a rule on the basis of a radical change in its factual premises.").

D. <u>The USDA Did Not Address NIH's Conclusion that the Existing AWA Standard Is Inadequate.</u>

Finally, the agency's denial of Plaintiffs' Petition was also arbitrary and capricious because the USDA conspicuously failed to address the fact that NIH had necessarily determined that the AWA standard regarding the psychological well-being of primates was inadequate to ensure the psychological well-being of chimpanzees—the only primate species that agency addressed. Thus, the USDA "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

Indeed, as demonstrated *supra*, at 10, all research labs—including those that are federally funded—are required to abide by all of the USDA's AWA standards. *See* Pl. Ex. A ("Compliance with the USDA regulations is an *absolute requirement of this Policy*") (emphasis added). Therefore, when NIH decided to devise more specific requirements as to what is required to meet the psychological needs of chimpanzees, it necessarily believed that the existing USDA standard was inadequate for that purpose. Yet, in denying Plaintiffs' Petition, the USDA failed to say anything about this obviously troubling development—even though the AWA itself requires the agency to "consult . . . with other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used in research," 7 U.S.C. § 2145(a), and specifically provides that the USDA "*shall consult with the Secretary of Health and Human Services*"—the parent agency of NIH—with respect to the statutorily required standards. *Id*. (emphasis added).

Thus, by omitting any explanation of why the two agencies could reach such opposite conclusions about the degree of specificity required to ensure that these animals are treated humanely, which, in turn was the underlying premise of Plaintiffs' Rulemaking Petition, the USDA also "avoided the question"—another basis for finding its decision arbitrary and capricious. *Ohio River Valley Env't Coal., Inc. v. Kempthorne*, 473 F.3d 94, 103 (4th Cir. 2006); *see also* Petition at 3–4, AR 6–7 ("The new NIH recommendations are based on scientific evidence and expertise from some of the world's leading experts . . . ***we urge the USDA to adopt these same, species appropriate standards as the 'minimum requirements' for a 'physical environment adequate to promote the psychological well-being of all primates used in research***'") (emphasis in original) (citing 7 U.S.C. § 2143(a)(2)(B)).

Moreover, the agency's attempt to equate its 30-year old nebulous standard with the specific requirements now imposed by NIH for federally funded research on chimpanzees, falls extremely flat. Denial Letter at 3, AR 497. As just one example—and there are many—NIH Recommendation Number 6 provides that "[c]himpanzees must be provided with materials to construct new nests on a daily basis." AR 1933. The USDA states in its Denial Letter that this requirement is somehow already subsumed by its 1991 standard that requires "the primary enclosure to be enriched through the provision of non-injurious means of expressing species typical behavior." Denial Letter at 3, AR 497. However, the USDA's attempt at comparison only highlights why NIH obviously believed more specific requirements were necessary to ensure that chimpanzees are provided an environment that is actually "*consistent with the primate's natural instincts and habits,*" as Congress intended when it drafted the 1985 Amendment to the AWA. H.R. Conf. Rep. 99-147, *reprinted in* 1985 U.S.C.C.A.N. 2251, 2520, AR 512 (emphasis added). While the USDA's 30-year old "standard" is broad, vague, and difficult to enforce—as the

agency itself concluded many years ago, *see supra*, at 8–10—the NIH requirement is specific and completely verifiable, and hence also enforceable. Thus, by refusing to significantly improve this standard for the psychological well-being of primates, the agency is continuing to allow the "self-policing" of this industry that was the basis for Congress' original decision to enact the AWA in 1966. *See supra*, at 5–7.

* * *

For *all* of the above reasons, the USDA's decision is arbitrary and capricious. Indeed, as the en banc Court of Appeals for this Circuit recently stressed, "[i]t is the 'agency's responsibility' to offer an explanation why it made a certain decision, when '*every indication in the record points the other way*.'" *Mayor of City Council of Baltimore v. Azar,* 973 F.3d 258, 276 (4th Cir. 2020) (citations omitted) (emphasis added). Here, the USDA has failed to meet this basic requirement of Administrative Law.

II. PLAINTIFFS HAVE ARTICLE III STANDING.

This Court already ruled at the motion to dismiss stage that Plaintiffs had alleged sufficient standing in this case. ECF No. 22. As demonstrated below, Plaintiff have now proved that they have such standing.

To establish standing, Plaintiffs must demonstrate (1) that they suffer a concrete and particularized injury-in-fact; (2) that this injury is "fairly trace[able]" to the challenged action of the Defendants; and (3) that it is likely that the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560–61 (1992). Further, as in all standing inquiries, only one plaintiff need allege "a personal stake in the outcome of the controversy . . . to warrant . . . invocation of federal-court jurisdiction." *Horne v. Flores,* 557

U.S. 433, 445 (2009) (quoting *Summers v. Earth Island Institute*, 555 U.S. 488, 491–94 (2009)). As demonstrated below, Plaintiffs easily satisfy these requirements.

A. Plaintiffs Have Sufficient Injuries-In-Fact.

It is axiomatic that "[a]n organizational plaintiff may establish standing to bring suit on its own behalf when it seeks redress for an injury suffered by the organization itself." *White Tail Park, Inc. v. Stroube*, 413 F.3d 451, 458 (4th Cir. 2005) (citing *Warth v. Seldin*, 422 U.S. 490, 511 (1975)); *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378–79 (1982) (internal quotations and citations omitted). In *Havens*, the Supreme Court held that if the challenged action impairs an organization's activities, resulting in a diversion of the organization's resources, this is sufficient to establish the requisite injury-in-fact. *Id.* at 379. This Circuit recently held that "[a]n organization may suffer an injury in fact when a defendant's actions impede its efforts to carry out its mission." *People for the Ethical Treatment of Animals, Inc. v. Tri-State Zoological Park of W. Md., Inc.*, 843 F. App'x 493, 497 (4th Cir. 2021) (quoting *Lane v. Holder*, 703 F.3d, 668, 674–75 (4th Cir. 2012)). As demonstrated by the sworn declarations of each of the Plaintiff organizations, both organizations easily meet this test.

Rise suffers by being denied crucial information regarding the conditions under which primates are being maintained in laboratories, whether those primates are suffering psychological distress, and what measures are being taken to alleviate that distress—information that the USDA is failing to generate and provide to the public because it refuses to upgrade the 1991 standard. Declaration of Ed Butler, Pl. Ex. L ¶ 9; *see also People for the Ethical Treatment of Animals, Inc. v. USDA*, 797 F.3d 1087, 1095–96 (D.C. Cir. 2015) (organization has standing when it is deprived of information that the agency would necessarily generate if it had issued the standard requested).

Rise's mission is to protect animals in research facilities and prevent their suffering. Butler Decl. ¶ 3. One of its "primary purposes is to end the suffering of nonhuman primates used in research—an issue it has been working on for many decades." *Id*. Further, one of Rise's "most significant campaign[s] for nonhuman primates focuses on exposing, and educating the public about, the substantial inhumane treatment these animals endure in research laboratories." *Id*. at ¶ 8. To further this objective, Rise regularly submits FOIA requests to APHIS for "inspection records, annual reports," and other documents. *Id*. However, "because APHIS' current standards for primates are vague and unenforceable, *the information Rise obtains is of little value*." *Id*. (emphasis added). Therefore, "[h]ad APHIS granted Plaintiffs' Rulemaking Petition, APHIS would have promulgated concrete standards regarding the psychological well-being of nonhuman primates that in turn would have generated more detailed information regarding what those standards are, deviations from such standards, and what if any measures the USDA, as well as the regulated facilities, take to ameliorate the distress and suffering of these primates." *Id*. at ¶ 10. APHIS's denial of Plaintiffs' Rulemaking Petition frustrates and impairs Rise's mission because Rise has to "divert additional resources . . . to obtain information about the ways [nonhuman primates used in research] are treated and what is being done to minimize their suffering." *Id*. ¶ 6; *see also Humane Soc'y of the United States v. USDA*, No. 20-5291, 2022 WL 2898893, at *3 (D.C. Cir. July 22, 2022) (organization had standing because, as a result of the agency's withdrawal of the rule at issue, it had to "redirect its limited time and resources away from existing [animal protection] work to identify, investigate, publicize and counteract" the challenged practices).[12]

[12] The denial of this information is critical for Rise, as "one of its most important tools in pursuit of its advocacy for animals is its Animal Research Laboratory Overview (ARLO) database." *Id.* ¶ 11. Through ARLO, Rise "collect[s] and publicly disseminate[s] information about animal

Similarly, ALDF's mission is "to protect the lives and advance the interests of animals through the legal system." Declaration of Anthony Eliseuson, Pl. Ex. M, ¶ 3. In furtherance of this mission, it "engages in communication campaigns to educate the public, legislators, and others about the failure of research laboratories to provide proper care for primates." *Id*. ¶ 4. ALDF further explains that during this work it "often relies on information generated from public records requests to investigate problematic facilities," including "USDA inspection reports and other regulatory records," that are "crucial sources of information." *Id*. ¶ 6.

Defendants' denial of Plaintiffs' Rulemaking Petition frustrates ALDF's mission by preventing it from being able to "calibrate its advocacy to particular problematic facilities." *See id*. ¶¶ 5, 6. Instead, as a result of the denial, ALDF must "expend additional time and resources to obtain information through its own investigations to better understand the conditions under which primates are being maintained and treated at scrutinized facilities." *Id*. ¶ 7. This includes "submitting more public records request[s] and pursuing other means to obtain this information such as interviewing individuals with knowledge" of these conditions and practices. *Id*. Had APHIS imposed specific enrichment standards for primates that in turn provided the public with reports on non-compliance, ALDF "could rely on such information to educate the public, legislators, and others about these matters and to calibrate its advocacy on particular problematic facilities." *Id*. ¶ 6. Further, the denial of Plaintiffs' Rulemaking Petition requires ALDF to "divert significant resources to protect the psychological welfare of

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research facilities, including…whether the animals used in such research are treated humanely as required by the Act," *id.*, relying heavily "on the information contained in USDA inspection reports and annual reports." *Id.* Therefore, "without the information that would necessarily be generated had APHIS upgraded its primate psychological well-being standard as requested by Plaintiffs, Rise's ability to collect and disseminate such information is greatly adversely impacted, and Rise must now pursue alternative means to keep this database up to date." *Id.*

nonhuman primates that would not be necessary, or necessary to the same extent, had APHIS granted the Rulemaking Petition." *Id*. ¶ 8. Indeed, due to Defendants' denial of Plaintiffs' Petition, ALDF will likely receive, more complaints about primate facilities where animals are being neglected, and thus will have to expend "more resources investigating such facilities and working to ameliorate inadequacies." *Id*.; *see also id*. ¶ 10 (since the denial of the Petition, "investigations of research facilities that use primates involves the use of more resources to compensate for the lack of information available on USDA online inspection reports regarding how primates are currently treated in research facilities").

These organizational injuries are all soundly sufficient under the test for organizational injury articulated in *Havens* and recently summarized by the Fourth Circuit in *Tri-State Zoological Park*—i.e., APHIS's denial of Plaintiffs' Rulemaking Petition impairs the organizations' ability to carry out their longstanding animal protection missions, requiring these organizations to devote additional resources to obtain the information they need and to compensate for the agency's regulatory deficiencies.

B. Plaintiffs' Injuries Are Caused by the USDA's Denial of Their Rulemaking Petition.

Plaintiffs also easily demonstrate that their injuries are "fairly traceable" to the challenged action of Defendants. *See Simon v. E. Ky. Welfare Rights Org*., 426 U.S. 26, 41–42 (1976). Had APHIS granted [the] Rulemaking Petition, and, at an absolute minimum, adopted standards akin to those now required by NIH for the treatment of chimpanzees in federally funded laboratories, Plaintiffs "would no longer have to expend as many resources pursuing alternative ways to obtain [information on how primates are treated in research facilities] and advocating for improved standards for the psychological well-being of primates." *See* Butler Decl. ¶ 13; *see also* Eliseuson Decl. ¶ 12 (ALDF states that if Defendants had granted the

Rulemaking Petition, ALDF "would no longer have to expend as many resources to protect these animals."); *Pye v. United States*, 269 F.3d 459, 471 (4th Cir. 2001) (finding causation where agency breached its duty by failing to consider options raised by plaintiffs) (citing *Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 161–62 (1981)); *Nat'l Fed'n of the Blind v. U.S. Dep't of Educ.*, 407 F. Supp. 3d 524, 533 (D. Md. 2019) (plaintiff organization had successfully demonstrated an injury traceable to defendant agency because, "had [Defendant] not adopted the March 2018 Manual . . . Plaintiff would not have suffered this injury.").

C. Plaintiffs' Injuries Will Be Redressed If They Prevail in this Case.

Finally, Plaintiffs can also demonstrate sufficient redressability—i.e., that it is "'likely, as opposed to merely speculative, that [their injuries] will be redressed by a favorable decision.'" *Doe v. Va. Dep't of State Police*, 713 F.3d 745, 755 (4th Cir. 2013) (quoting *Friends of the Earth, Inc. v. Laidlaw Env't Services,* 528 U.S. 167, 181 (2000). To meet this test, "no explicit guarantee . . . is required to demonstrate a plaintiff's standing," nor must the injury be redressable in its entirety. *Equity in Athletics, Inc. v. Dep't of Educ.*, 639 F.3d 91, 100 (4th Cir. 2011); *see also Utah v. Evans*, 536 U.S. 452, 464 (2002) (holding that "a significant increase in the likelihood that the plaintiff would obtain relief" is sufficient to demonstrate redressability).

Here, both organizational Plaintiffs can demonstrate the requisite redressability because a favorable decision will require the USDA "to reconsider its denial of Plaintiffs' Rulemaking Petition," which in turn could lead to the promulgation of "heightened standards to promote the psychological well-being of all primates used in research." Butler Decl. ¶ 13; Eliseuson Decl. ¶ 12. This would necessarily generate the information Plaintiffs need to carry out their missions. Thus, the new standard would necessarily identify the actual measures that research labs would have to undertake to "promote the psychological well-being" of the primates in their care, shed

light on what the labs were actually doing to meet that standard, and allow Plaintiffs to monitor and report on the actions the agency is taking to enforce the new standard. *See Fed. Election Comm'n v. Akins*, 524 U.S. 11, 21 (1998) (explaining that to decide standing the reviewing court must accept the plaintiff's "view of the law"); *accord, Cooksey v. Futrell*, 721 F.3d 226, 239 (4th Cir. 2013); *see also PETA*, 797 F.3d at 1093, n.3 (finding that the USDA's failure to compile the information the organization needs to carry out its mission provides the requisite redressability); *see also FEC v. Akins*, 524 U.S. at 25 (noting that causation and redressability are both satisfied even though on remand the agency "might reach the same result exercising its discretionary powers lawfully"); *Massachusetts v. EPA*, 549 U.S. 497, 534– 35 (2007) (in ruling on the lawfulness of an agency's denial of a rulemaking petition the court need not find that on remand the agency will issue the regulation requested by the plaintiffs).

In fact, Congress has now mandated that USDA affirmatively disclose to the public *all* USDA inspection reports, annual reports submitted to the agency by research labs, "reports or other materials documenting any non-compliances observed by USDA officials," and various other USDA records concerning how the agency is implementing and enforcing the AWA. 7 U.S.C. § 2146(a). Therefore, if Plaintiffs prevail in this action and, as a result, the USDA issues the requested standard, a whole *slew of new information* about not only the *contents* of the new psychological well-being standard, but also how it is being implemented and enforced, will necessarily become available to the Plaintiffs as mandated by this new regulation. Accordingly, there can be no doubt that Plaintiffs have alleged sufficient redressability.

CONCLUSION

For all of the foregoing reasons, this Court should grant Plaintiffs' motion for summary judgment.

Respectfully submitted,

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