

UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND

NEW ENGLAND ANTI-VIVISECTION)
SOCIETY)
333 Washington Street)
Suite 850)
Boston, Massachusetts 02108)
(617) 523-6020,)

and)

ANIMAL LEGAL DEFENSE FUND)
525 East Cotati Avenue)
Cotati, CA 94931)
(707) 795-2533,)

Plaintiffs,)

Civ. No. 20-2004

v.)

ELIZABETH GOLDENTYER,)
Deputy Administrator)
Animal Care,)
Animal and Plant Health Inspection Service)
4700 River Road)
Riverdale, MD 20737 ,)

and)

SONNY PERDUE, Secretary)
United States Department of Agriculture)
1400 Independence Avenue, S.W.)
Washington, DC 20250,)

Defendants.)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This is a Complaint for declaratory and injunctive relief challenging a decision by the Animal Plant and Health Inspection Service (“APHIS”)—a division of the United States Department of Agriculture (“USDA”)— to refuse to upgrade the standards for the psychological

well-being of primates used in laboratory research. Those regulations were originally promulgated almost *thirty years ago* and are wholly inadequate to “insure the humane treatment” of these animals as required by the Animal Welfare Act (“AWA”), 7 U.S.C. § 2131. The agency’s decision not to upgrade these standards was issued in response to a Petition for Rulemaking by Plaintiffs that requested APHIS to follow the lead of its sister agency—the National Institutes of Health (“NIH”)—which in 2013 significantly upgraded the standards that apply to chimpanzees used in any federally funded research, including ensuring that these animals are housed in social groups instead of alone, have access to natural substrates and the outdoors, and are provided various opportunities for enrichment. 78 Fed. Reg. 39741 (July 2, 2013).

2. APHIS has known since 1999 that its own inspectors believe the 1991 standards are too vague to be enforceable and do not sufficiently “promote the psychological well-being of primates,” as required by the AWA, 7 U.S.C. § 2143(2)(B), and that better standards are “necessary” to accomplish this objective. 64 Fed. Reg. 38145 (July 15, 1999). Nevertheless, and although 99% of the public comments submitted to the agency in response to its notice of Plaintiffs’ Rulemaking Petition supported *granting* the Rulemaking Petition, APHIS has refused to upgrade these antiquated standards. In the meantime, tens of thousands of nonhuman primates suffer alone in laboratories without basic enrichment that decades of research demonstrate is critical to protect their psychological needs.

3. Promulgation of the requested regulations is necessary to provide all nonhuman primates used in research the environmental enrichment they need for their psychological well-being, and to establish clear, specific standards that can be uniformly implemented and enforced by the USDA across research institutions. Adoption of the requested standards would ensure that the USDA meets the AWA’s statutory mandate that the USDA “*shall* promulgate standards ...for a

physical environment *adequate* to promote the psychological well-being of primates.” 7 U.S.C. § 2143(2)(B) (emphasis added).

4. Plaintiffs seek a declaration that the agency’s denial of their Rulemaking Petition was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, within the meaning of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), and an order remanding this matter to APHIS for further consideration.

JURISDICTION

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1361, and 2201.

PARTIES

6. Plaintiff New England Anti-Vivisection Society (“NEAVS”) is a nonprofit, tax-exempt 501(c)(3) organization whose mission is to save animals from suffering. NEAVS seeks to end animal experimentation, to encourage the transfer of animals from laboratories to animal sanctuaries, and to reduce the suffering of laboratory animals by promoting their humane treatment. One of NEAVS’ primary purposes is to end the suffering of nonhuman primates used in research—an issue it has been working on for many decades. NEAVS also works to educate the public, lawmakers, and others about the needs of primates used in research, and the suffering they endure, as part of advocating that biomedical research transition from animal testing to non-animal alternatives.

7. APHIS’s denial of Plaintiffs’ Rulemaking Petition requesting that the agency promulgate specific, enforceable regulations to promote the psychological well-being of nonhuman primates used in research directly conflicts with, frustrates, and impairs NEAVS’ mission to protect these animals from inhumane treatment and to educate the public and policymakers about these matters. NEAVS has already spent considerable resources in an effort to convince APHIS to

upgrade these standards—resources that could have been spent on other matters. Now, as a result of the agency’s denial of its Rulemaking Petition, NEAVS will have to divert additional resources to alternative means of advocating for and protecting these animals, and to obtain information about the ways they are treated and what is being done to minimize their suffering.

8. Because of APHIS’ refusal to upgrade the standards for the psychological well-being of nonhuman primates used in research, NEAVS will have to expend additional resources educating the public, policymakers, and others about this issue, the need to improve the standards that apply to nonhuman primates used in research, and the importance of transitioning to non-animal research alternatives. NEAVS will also have to divert resources to develop training programs for APHIS inspectors regarding how to identify primate behaviors that indicate distress, stress, and suffering, and what actions must be taken to promote the psychological enrichment of these animals. This curriculum is necessary to fill the gap created by APHIS’ lack of specific, enforceable standards that have long since been required by the AWA. 7 U.S.C. § 2143(2)(B). Due to APHIS’ denial of the Rulemaking Petition, NEAVS is now developing a program to train USDA inspectors to identify psychological distress in nonhuman primates to assist them in enforcing the existing vague standards. The program includes consultation with expert primatologists who can train USDA inspectors to identify common behaviors evinced by nonhuman primates who are suffering psychological distress. If the Rulemaking Petition had been granted by the agency, APHIS would have initiated a rulemaking proceeding to significantly upgrade the standards governing the psychological well-being of primates used in laboratory research, including instructing inspectors how to identify and respond to primate distress and suffering, and NEAVS would not have to spend its own resources developing and implementing such training protocols.

9. As a result of APHIS' denial of Plaintiffs' Rulemaking Petition NEAVS also has to divert resources to developing modules of training for veterinary students at Tufts Veterinary School and other schools with a veterinary program. These modules will be used to educate future veterinarians who will be working with these primates in research labs or as employees of the USDA about how to identify common signs of psychological distress and suffering in nonhuman primates and how to ameliorate these conditions. If the USDA had granted Plaintiffs' Rulemaking Petition for Rulemaking, such training would not be necessary.

10. The Rulemaking Petition thoroughly detailed the voluminous scientific research—published since 1991 when the regulations were first promulgated—documenting the incontrovertible psychological needs of primates. Due to APHIS' refusal to upgrade the 1991 standards, NEAVS must further divert resources to engage in additional investigations and information gathering to educate the public, policymakers, and others about the emotional and psychological suffering of nonhuman primates in laboratories. NEAVS must also divert funds to invest in research to broaden the existing body of scientific evidence of the psychological suffering of nonhuman primates. All of these resources must be diverted from other activities in which NEAVS would otherwise engage to advocate for the protection and rescue of all animals used in research.

11. NEAVS's most significant campaign for nonhuman primates focuses on exposing, and educating the public about, the substantial inhumane treatment these animals endure in research laboratories. Toward that end, NEAVS regularly submits Freedom of Information Act ("FOIA") requests for APHIS inspection records, annual reports by research facilities, and reports by the facilities' Institutional Animal Care & Use Committees—the entities mandated by the AWA to oversee the treatment of animals used in research, 7 U.S.C § 2143(b). However, because APHIS' current standards for primates are vague and unenforceable, the information NEAVS obtains is

of little value. If the agency had granted Plaintiffs' Rulemaking Petition, the information that would be required to be generated, collected, and reported by research facilities would have been far more useful toward this end, and would allow NEAVS to effectively monitor how primates are treated in laboratories and whether APHIS is carrying out its statutory mandate to ensure their psychological well-being. APHIS' denial of the Rulemaking Petition deprives NEAVS of key information that it needs to educate the public about (a) the conditions under which primates are being maintained in laboratories; (b) whether they are suffering psychological distress; (c) if so, what measures are being taken to alleviate such suffering; and (d) whether APHIS is meeting its statutory obligation to "ensure" the humane treatment of these animals. 7 U.S.C. § 2131. This denial of information in turn impairs NEAVS' overall campaign to protect these animals and advocate for their placement in sanctuaries, and to advocate for a transition to non-animal alternative testing protocols. Had APHIS granted Plaintiffs' Rulemaking Petition, APHIS would have promulgated concrete standards regarding the psychological well-being of nonhuman primates that would have required the collection and generation of more detailed information regarding violations of such standards and what if any measures are being taken to ameliorate the distress and suffering of these primates.

12. NEAVS' aforementioned injuries are directly traceable to APHIS' denial of Plaintiffs' Rulemaking Petition and the agency's failure to meet its statutory obligation to promulgate standards to "promote the psychological well-being of primates." 7 U.S.C. § 2143(2)(B). Had APHIS granted that 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, NEAVS would not have to undertake all of these additional advocacy, educational, and information-gathering efforts.

13. All of these injuries would be redressed if Plaintiffs prevail in this action, as APHIS would be required to reconsider its denial of Plaintiffs' Rulemaking Petition and to promulgate heightened standards to promote the psychological well-being of all primates used in research.

14. Plaintiff Animal Legal Defense Fund (ALDF) is a nonprofit, tax-exempt 501(c)(3) membership organization that works to protect the lives and advance the interests of animals through the legal system. ALDF accomplishes this mission by engaging in litigation, providing legal assistance and training to prosecutors, supporting strong animal protection legislation, combating legislation harmful to animals, and providing resources and opportunities to law students and professionals to advance the emerging field of animal law.

15. ALDF has engaged in communication campaigns to highlight the failure of laboratories to provide proper care for primates, has filed comments with the NIH urging the agency to adopt a proposal to severely restrict research on captive chimpanzees, and has been involved in litigation to improve the welfare of primates used in the research field. ALDF often relies on information generated from public records requests to investigate problematic facilities. AWA inspection reports and other regulatory records are crucial sources of information in those circumstances. If APHIS had specific enrichment standards for primates that in turn provided the public with reports on non-compliance, ALDF would be able to calibrate its advocacy to particular problematic facilities. Instead, as a result of Defendants' denial of the Rulemaking Petition, in future advocacy for primates in research ALDF will need to conduct rigorous investigations to determine the inadequacy of primate enrichment at specific facilities.

16. APHIS' denial of Plaintiffs' Rulemaking Petition to promulgate specific, enforceable standards to promote the psychological well-being of all nonhuman primates used in research directly conflicts with, frustrates, and impairs ALDF's mission, and, as a result, the organization has been, and will be, forced to divert resources to compensate for this impairment of its mission.

17. Among other things, ALDF will now have to spend additional time and resources investigating inadequate enrichment opportunities for nonhuman primates through other means in addition to submitting FOIA requests, or forgo knowledge of that important information entirely. ALDF will also have to spend more time and resources ameliorating substandard welfare of nonhuman primates used in research through law enforcement requests, regulatory action, public communications, and other means.

18. ALDF will further have to divert significant resources to seek other means of protecting the psychological welfare of nonhuman primates that would not be necessary, or necessary to the same extent, had APHIS granted the Rulemaking Petition. For example, if primates are not receiving adequate enrichment at particular facilities, ALDF will likely receive more complaints about primate facilities where animals are being neglected, and thus will have to expend more resources investigating these research facilities and working to ameliorate these concerns.

19. These injuries to ALDF's mission are ongoing and injure ALDF by consuming organizational resources that could be spent on its other work to protect animals and gain greater legal protections for them.

20. ALDF's aforementioned injuries are directly traceable to Defendants' denial of Plaintiffs' Rulemaking Petition. If Defendants had granted the Rulemaking Petition, ALDF would not have to undertake these efforts and would not have had to expend these resources to the same extent.

21. These injuries to ALDF are actual and concrete, are presently being suffered, and will be redressed if Plaintiffs prevail in this action, because APHIS will need to reconsider its decision to deny the Rulemaking Petition to establish heightened, more enforceable standards to promote the psychological well-being of primates used in research.

22. Defendant Elizabeth Goldentyer is the Acting Deputy Administrator for Animal Care at APHIS and the official who signed the document denying Plaintiffs' Rulemaking Petition.

23. Defendant Sonny Perdue is the Secretary of the United States Department of Agriculture, which is the federal agency responsible for promulgating and enforcing federal regulations implementing the AWA. As such, Defendant Perdue is also responsible for denying Plaintiffs' Rulemaking Petition.

FACTS GIVING RISE TO PLAINTIFFS' CLAIMS FOR RELIEF

A. The Animal Welfare Act

24. The AWA was enacted to "insure that animals intended for use in research facilities...are provided humane care and treatment." 7 U.S.C. § 2131(1). The statute directs the Secretary of the 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).

25. In 1985, based on studies conducted by renowned primatologist Jane Goodall and others, Congress recognized that nonhuman primates have psychological and social needs that are critical to their well-being. They experience strong emotions like joy, sadness, fear, and despair, and exhibit remarkable intellectual abilities. They also maintain close, affectionate and supportive ties with their families and other members of their social groups, which they maintain throughout their lives

26. In response to these concerns, in 1985 Congress recognized the need for specific standards for "dealers, research facilities and exhibitors" to provide for the unique psychological needs of nonhuman primates. In finding that "[c]urrent standards leave too much room for shoddy care and inhumane treatment," 131 Cong. Rec. 22257 (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. Cong. & Ad. News 2251, 2520.

27. Thus, in 1985 Congress enacted the Improved Standards for Laboratory Animals Act, which amended the AWA by specifically requiring that the Secretary of the USDA promulgate “minimum requirements” to ensure that these facilities provide “a physical environment adequate to promote the psychological well-being of primates.” 7 U.S.C. § 2143(a)(2)(B). In enacting this legislation, Congress sought to require USDA to develop “uniform standards in order that we might have a consistent national policy to assure appropriate care and use of laboratory animals, while not jeopardizing research needs.” 131 Cong. Rec. S14,237 (daily ed. Oct. 28, 1985) (statement of Sen. Hatch).

28. Thus, in 1985, the AWA was amended to direct the Secretary of the USDA to promulgate standards that “shall include minimum requirements ... for a physical environment adequate to promote the psychological well-being of primates.” 7 U.S.C. § 2143(a)(2).

B. The USDA’s Implementation of the AWA’s Requirement

29. In 1991, the USDA promulgated regulations intended to implement the 1985 amendment. 9 C.F.R. § 3.81. However, those regulations allow the regulated entities, including research facilities, to develop and follow their own “enrichment plans” to provide “environment enhancement adequate to promote the psychological well-being of nonhuman primates.” *Id.* That plan must only “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.* Although the regulations require that each plan “include specific provisions to *address* the social needs of nonhuman primates of species known to exist in social groups in nature,” the regulations do not indicate what is necessary to “address” such needs, nor do they *mandate* that primate species that require social contact with members of their own species

actually be housed together. *Id.* (emphasis added). Additionally, while the regulations require that each plan provide a “physical environment” that is “enriched by providing means of expressing non-injurious species-typical activities,” 9 C.F.R. § 3.81(a)–(b), the regulations do not further clarify what is meant by this provision, nor specify which activities must be accommodated. Further, although the regulations acknowledge that particular categories of primates, including: (a) infants and young juveniles; (b) animals that show signs of psychological distress; (c) those housed alone; and (d) great apes of a certain size, “require[e] special considerations,” 9 C.F.R. § 3.81(c), no guidance is given as to what these considerations are, nor actually *mandate* any particular enrichment requirements for these animals.

30. There also is no requirement that each facility’s enrichment plan be pre-approved by the USDA, leaving facilities with unbridled discretion to determine what goes into each of their plans.

31. In addition, the USDA does not require each regulated facility to even submit its enrichment plan to the USDA, and hence there is no way for the public to monitor the adequacy of such plans under the Freedom of Information Act or otherwise.

32. In 1996, after five years of experience enforcing the new regulations, APHIS issued a report documenting that many of its inspectors found that “the primate environmental enrichment criteria [in Section 3.81] *were not useful*” to judge whether facilities were providing an environment adequate to promote primate psychological well-being, 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.*” 64 Fed. Reg. 38145, 38146 (July 15, 1999) (emphasis added). As a result, USDA concluded that inspectors and the regulated entities needed more specific guidance concerning the “critical” elements for such plans, including (a) social grouping; (b) social needs of infants; (c) structure and substrate; (d) foraging

opportunities; and (e) manipulanda—i.e., the kinds of instruments primates need to use their hands and feet. *Id.* at 38147.

33. In response to its own report, in 1999 APHIS concluded that “additional information on how to meet the standards of § 3.81 *is necessary.*” 64 Fed. Reg. at 38148 (emphasis added). Accordingly, 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 environmental enhancement to promote the psychological well-being of nonhuman primates.” *Id.* The Draft Policy specifically addressed the five elements that APHIS had identified as “the minimum” that must be addressed to comply with § 3.81—namely social grouping, the social needs of infants, structure and substrate, foraging opportunities, and manipulanda. *Id.* Each element was identified as “*critical* to environments that adequately promote the psychological well-being of nonhuman primates.” 64 Fed. Reg. at 38147 (emphasis added). APHIS published the Draft Policy in the Federal Register on July 15, 1999, explaining that it was “seeking public comment on the draft policy” before implementing it. *Id.* at 38145.

34. Prior to the development of APHIS’s Draft Policy, several animal protection organizations challenged the sufficiency of the 1991 regulations in federal court. *See, e.g., Animal Legal Def. Fund, Inc. v. Glickman*, 204 F.3d 229 (D.C. Cir. 2000). Although holding that the regulations were not arbitrary and capricious, the D.C. Circuit acknowledged that the regulations, as then currently drafted, “may prove difficult to enforce, or even difficult to augment through subsequent ‘interpretation.’” *Id.* at 235. However, the Court further noted that this concern was being ameliorated by the fact that APHIS was then in the process of finalizing the 1999 Draft Policy, which the Court stated would be “likely to assist both regulatees and enforcers” in determining the minimum steps that were actually required to promote the psychological well-being of primates as required by the 1985 Amendment. *Id.*

35. However, the Draft Policy was never finalized, and hence was never implemented. Rather, to date, no changes have been made to the primate regulations since they were first promulgated in 1991, despite the fact that over twenty years ago the USDA itself concluded that such changes were “necessary.” 64 Fed. Reg. at 38148.

C. Scientific Knowledge About the Psychological Needs of Primates Has Increased Exponentially Since the USDA Issued the 1991 Regulations.

36. Meanwhile, since the promulgation of the 1991 regulations nearly three decades ago, a substantial body of scientific evidence has been generated demonstrating the psychological capabilities and needs of primates, the ethical responsibilities of humans towards these animals, and the adverse impacts on scientifically valid research when the psychological well-being of primates is compromised.

37. As detailed in Plaintiffs’ Rulemaking Petition, nonhuman primate species have active minds and inquisitive natures; are inventive and sociable; develop caring relationships with others; make and use tools; develop rudimentary cultures; have complex emotions; analyze past results; imagine different outcomes; experience regret; appear to understand others’ perceptions, thoughts, and feelings; and have a sense of justice and fairness. Rulemaking Petition at 21.

38. Primates living in an artificial environment where stressors are ever present and unpredictable develop pathological behaviors and suffer severe stress due to confinement, little or no social or mental enrichment, and a complete lack of control over their environment. They also develop a condition called “learned helplessness” because of the animals’ complete inability to deter, escape, or fight off harm or hardship.

39. In response to such psychological stress, primates in research facilities commonly engage in abnormal behaviors—called stereotypic behaviors—such as rocking, swaying, repetitive circling, over-grooming to the point of permanent damage to their skin, biting

themselves, banging themselves against the cage, and other forms of self-harm and self-mutilation. Rulemaking Petition at 37. These behaviors are not natural for primates, and are the result of extreme and prolonged psychological distress. *Id.*

40. However, because the 1991 regulations remain in effect, laboratory primates continue to be housed in conditions that are extremely detrimental to their psychological well-being. Thus, in 2011, at the NIH-sponsored Symposium on Animal Welfare and Scientific Research, a participant lamented the heartbreaking truth—that “[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.” Proceedings of the Symposium on Animal Welfare and Scientific Research: 1985-2010, 2011.

D. The National Institutes of Health Upgrades Standards for Chimpanzees

41. In December 2010, at the request of the National Institutes of Health and in collaboration with the National Research Council, the National Academy of Medicine convened a Committee on the Use of Chimpanzees in Biomedical and Behavioral Research to consider the necessity of using chimpanzees in NIH-funded research. The Committee’s Report, completed in December of 2011, introduced the concept of the need for “ethologically appropriate physical and social environments” for such primates—“captive environments that do not simply allow but also, importantly, promote a full range of behaviors that are natural for chimpanzees.” 78 FR 39741, 39743. The Committee concluded that:

[i]t is generally accepted 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 the presence of conspecifics and sufficient space and environmental complexity to exhibit species-typical behavior. Therefore, to perform rigorous (replicable and reliable) biomedical and behavioral research, it is critical to minimize potential sources of stress on the chimpanzee.

Institute of Medicine, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity*, The National Academies Press (2011).

42. In response to this Report, the NIH Council of Councils (“CoC”) formed a Working Group on the Use of Chimpanzees in NIH-Supported Research. The Working Group spent several years analyzing the use of chimpanzees in research, and exploring the potential to create environments that not only allow, but affirmatively promote, natural behaviors and psychological well-being for chimpanzees used in research. The Working Group’s final recommendations, unanimously approved by the full CoC, concluded that any and all potential future use of chimpanzees must be subject to a strict independent oversight committee to assess whether that use is acceptable, necessary, and compliant with National Academy of Medicine guidelines, including housing the primates in an ethologically appropriate environment.

43. The CoC submitted its report to NIH, and, on June 26, 2013, after considering public comments, the NIH accepted nearly all of the CoC’s findings, including nine of ten recommendations regarding ethologically appropriate environments. These requirements provide concrete minimum standards for environments in which chimpanzees are held, including standards to address specific physical and social needs. NIH, *Announcement of Agency Decision: Recommendations on the Use of Chimpanzees in NIH-Supported Research*, June 26, 2013.

44. All federally funded laboratories were already required to follow all applicable AWA standards, including the USDA’s 1991 regulations regarding the psychological well-being of primates. *See* Public Health Service “Policy on Humane Care and Use of Laboratory Animals”, at 9 n.2 (“Compliance with the USDA regulations is an absolute requirement of this Policy”). Nevertheless, in 2013 NIH determined that *additional* requirements were required to meet the psychological needs of chimpanzees (the only primate species it specifically addressed).

45. Many of the NIH-adopted requirements correspond to the same elements that APHIS included in its 1999 Draft Policy as “critical” to promote the psychological well-being of *all* primates. 64 Fed. Reg. at 38147 (emphasis added). For example, the NIH requirements provide that chimpanzees must have the opportunity to live in social groupings; have access to the outdoors and natural substrates, such as grass, dirt, and mulch; have the opportunity to forage, and have varied diets; have the ability to climb and rest in elevated spaces; be provided the opportunity to build nests; and have the opportunity to make choices. *Id.* In addition, the NIH requirements provide that management staff must include experienced and trained behaviorists and enrichment specialists, and must receive training in core institutional values promoting psychological and behavioral well-being of chimpanzees in their care. *Id.*

46. As explained by former APHIS Deputy Administrator Dale Schwindaman, the USDA and NIH have a history of working “together to ensure harmonized animal welfare requirements by those two agencies.” Rulemaking Petition at 4. The AWA itself stresses the importance of this relationship by providing that the Secretary of Agriculture “shall consult with the Secretary of Health and Human Services” (NIH’s parent agency), prior to issuing regulations. 7 U.S.C. § 2145.

E. Plaintiffs’ Rulemaking Petition

47. On May 7, 2014, Plaintiffs submitted to the USDA a Petition for Rulemaking requesting that the USDA adopt the same minimum standards that NIH has adopted for chimpanzees used in federally-funded research for *all* nonhuman primates used in research, whether federally funded or not, as the “minimum requirements” for a “physical environment adequate to promote the psychological well-being” of such primates, pursuant to the mandate of the AWA. (7 U.S.C. § 2143(a)(2)(B)). As part of their Rulemaking Petition, Plaintiffs provided detailed expert information about how the NIH’s recommendations can be properly tailored and implemented

for each specific primate species commonly used in research, including macaques, marmosets, and baboons—tens of thousands of which are still being used in research in this country.

48. Plaintiffs' Rulemaking Petition also relied on the fact that, as far back as 1999, APHIS itself had already concluded that the current regulations cause "confusion among the regulated public concerning on what basis they will be judged by inspectors as meeting or not meeting the requirements," and that "additional information on how to meet the standards of § 3.81 is necessary." 64 Fed. Reg. at 38148.

49. The Rulemaking Petition further documented that the current lack of clear and enforceable standards is extremely detrimental to the psychological well-being of primates used in research, and provided examples of the prolonged and unnecessary suffering of specific primates due to inadequacies in the current regulatory scheme. For example, Plaintiffs documented that:

- A February 2012 inspection report for Virginia Commonwealth University notes, "Numerous animals in the primate colony participating in [laboratory testing] have areas of hair loss on their bodies, possibly due to over grooming. In nonhuman primates, over grooming can be an indicator of psychological distress. There is not sufficient evidence that personnel have fully recognized and addressed this problem."
- An August 2010 inspection report for Drug Research Laboratories in Pennsylvania states, "The environment enhancement plan for the facility states that the animals will receive some type of fresh fruit or vegetable daily. The plan is not being followed. According to the enrichment logs reviewed the 16 animals are only receiving fresh produce twice a week."
- A July 2010 inspection report for Boston University states, "[A specific laboratory protocol]... used Nonhuman Primates (NHPs) that were housed individually in isolation chambers which provided limited inter- and intra-species interaction with light cycle changes which for 3 month periods included constant dim light. Two animals were reported as having behaviors indicating psychological distress in their health records and behavioral assessments in the form of hair plucking (2/06 and 11/07) and various stereopathic displays (10/06-4/08). Based on the facility's Plan for Environmental Enrichment for NHPs these animals should have been put on special enrichment or removed from the study."

50. As the Rulemaking Petition discussed, adapting the NIH requirements to apply to all primate species used in research is essential “to promote the psychological well-being of primates,” in compliance with the USDA’s mandate under the AWA. 7 U.S.C. § 2143(a)(1). Plaintiffs explained in great detail that other species of primates have psychological needs similar to those of chimpanzees. Thus, according to Brian Hare, Ph.D., a nationally recognized primate expert at Duke University who testified before the National Academy of Medicine, “[m]ost of what you know about great apes is also true about monkeys.” *See*, Brandon Keim, “Medical experimentation on chimps is nearing an end. But what about monkeys?” *Wired Science* (2013).

51. Plaintiffs’ Rulemaking Petition also explained that adapting the NIH chimpanzee requirements to address the psychological needs of other primate species is entirely feasible. As preeminent animal scientist and primatologist Dr. Marc Bekoff explained in his comments in support of the Rulemaking Petition:

Since 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.

Docket No. APHIS-2014-0098-9944 (September 1, 2015).

52. Plaintiffs’ Rulemaking Petition also requested that the USDA promulgate regulations defining when primates experience psychological distress, and delineating what steps must be taken to address such distress. As the Rulemaking Petition explained, “[l]aboratory conditions and experiences involving diverse experimental procedures and frequent anesthetics commonly lead to acute and long-term mental and physical breakdown. As such, stress can result in both psychological damage as well as severe physiological consequences for an individual.”

Rulemaking Petition at 35.

53. Plaintiffs' Rulemaking Petition further documented that stress associated with living in laboratory conditions causes a wide array of harmful stereotypic behaviors in nonhuman primates, including "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 digit-sucking." Rulemaking Petition at 37. The Rulemaking Petition explained that "nonhuman primates live in constant fear and uncertainty about if and when they will be subjected to an experimental procedure"—a phenomenon known as an anticipatory stress response. Rulemaking Petition at 34. Thus, "[d]ue to prior adverse experiences, individual animals become hyper-vigilant, anticipating the recurrence of those experiences—much like adopted dogs that have suffered previous traumas flinch when approached by people." *Id.*

54. Plaintiffs' Rulemaking Petition requested the USDA to promulgate regulations designed to identify, address, and take steps to ameliorate these behaviors. Rulemaking Petition at 48.

55. The Rulemaking Petition provided examples of extreme psychological distress suffered by individual primates as a result of the current regulatory framework that fails to address the prevention and treatment of stereotypic behaviors, and provided evidence demonstrating that when these conditions are addressed, the primate's psychological condition can be dramatically improved. Rulemaking Petition at 36–37.

56. Plaintiffs' Rulemaking Petition further explained that psychological distress experienced by primates used in research can have negative impacts on the scientific validity of the results of such research. Rulemaking Petition at 46.

57. Plaintiffs' Rulemaking Petition demonstrated that the current USDA regulatory regime is insufficient to properly prevent psychological distress, 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.” Rulemaking Petition at 42. Plaintiffs’ Rulemaking Petition therefore urged the USDA to amend the current regulations to include criteria for determining when primates are experiencing psychological distress, as well as mandatory steps that must be taken to ameliorate such distress.

F. The USDA’s Initial Response to Plaintiffs’ Rulemaking Petition

58. By letter dated May 20, 2014, then Deputy Administrator for Animal Care Chester Gipson responded to Plaintiffs’ Rulemaking Petition by stating that, “[w]e believe that the issues raised in the petition are important and that many parties will have an interest in them.” Dr. Gipson further stated that “[a]ccordingly, we will publish the petition in a Federal Register notice in the near future 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.”

59. On May 1, 2015, APHIS published notice of the Rulemaking Petition in the Federal Register, stating that it was “making this petition available to the public and soliciting comments regarding the petition and any issues raised by the petition that we should take into account as we consider this petition.” 80 Fed. Reg. 24840, 24841 (May 1, 2015). On July 24, 2015, APHIS published a second notice reopening the comment period to give interested persons additional time to prepare and submit comments. 80 Fed. Reg. 43969 (July 24, 2015). That comment period ended on August 31, 2015.

60. APHIS received a total of 10,137 comments—the overwhelming majority of which supported adoption of Plaintiffs’ Rulemaking Petition. Docket No. APHIS-2014-0098. For example, Dr. Marc Bekoff urged the USDA to implement clear regulatory language in order to promote the psychological well-being of captive primates:

As cognitive beings capable of complex thinking and able to make decisions in the wild through which they protect themselves, provide for what they enjoy doing most, or help solidify bonds with other members of their group, providing for all these needs cannot be seen as a ‘regulatory burden’ to the research facility. Rather, laboratories must accept, if they continue to choose to conduct animal work over other forms of modern scientific investigation, that because they chose to work with a living being, there is, by definition, an added regulatory cost of doing business.

APHIS-2014-0098-9944 (September 1, 2015).

61. In the agency’s denial letter, APHIS provided data that 7,232 comments, representing 99% of the responsive comments received, were in favor of granting Plaintiffs’ Rulemaking Petition.

G. The USDA’s Recent Response to Plaintiffs’ Rulemaking Petition

62. Five and a half years later, by letter from Defendant Goldentyer dated October 10, 2019, APHIS denied Plaintiffs’ Rulemaking Petition, stating that no changes will be made to the existing 1991 regulations concerning the psychological well-being of primates.

63. The USDA’s denial letter states that, “our experience administering and enforcing the welfare standards related to environmental enhancement to promote psychological well-being demonstrated such standards are, in fact, enforceable.” However, as explained above, the agency itself acknowledged in both its 1996 Report and its 1999 Draft Policy that many of its 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, 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.” 64 Fed. Reg. at 38148.

64. The 1999 Draft Policy—upon which Plaintiffs heavily relied in support of their Rulemaking Petition, was not addressed, or even mentioned, in APHIS’ denial of Plaintiffs’ Rulemaking Petition.

65. The agency’s denial letter also did not point to any new evidence it had amassed since 1999 demonstrating that APHIS inspectors were no longer having difficulty determining whether a particular facility’s enrichment plan met the applicable psychological well-being standard, or that the regulated public was no longer confused about what was required to meet this standard.

66. Nor did the USDA’s denial letter address the fact that the USDA’s sister agency, NIH, had obviously concluded in 2013 that the USDA’s existing standards were not sufficient to promote the psychological well-being of chimpanzees used in federally-funded research, since NIH has now adopted much more stringent requirements—despite the fact that Plaintiffs also relied heavily on NIH’s conclusions in their Rulemaking Petition.

67. As explained above, Plaintiffs’ Rulemaking Petition also urged the USDA to promulgate regulations concerning the diagnosis and care of primates experiencing psychological distress, and asked the USDA to further consider “continuous and unresolved psychological distress of an animal in a lab as an indication of noncompliance” with the standards for psychological well-being. The agency responded to this request by stating that its inspectors “may” take such information into account in deciding whether a facility is failing to comply with the standards.

68. In its denial letter, APHIS states that it does not need to promulgate more detailed standards about what is required to promote the psychological well-being of primates because it held a symposium in 2017 entitled “Practical Solutions to Welfare Challenges,” and has also issued several “Animal Care Aids” to “support . . .the development of compliant [Environmental Enrichment Plans].”

69. On information and belief, the symposium on which APHIS relies in its denial letter was not attended by all, or even most, laboratories using primates in research. Further, the information imparted there, and in the agency's various Animal Care Aids, is completely non-binding. Hence, there is no requirement that any of the laboratories comply with any of those suggestions.

70. In its denial letter, APHIS also relied on the assertion that its inspectors can adequately determine whether a facility is in compliance with the psychological well-being standard. However, not only did the agency fail to point to any new evidence acquired since 1996 when it concluded that "many" inspectors found that the current regulations were not "useful" to judge compliance with the standard, but, on information and belief, APHIS also recently informed its inspectors of facilities accredited by the Association for Assessment and Accreditation of Laboratory Animal Care ("AAALAC") that they may *choose* which aspects of a particular facility they wish to inspect. This means that the inspectors are not even 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).

71. APHIS's denial of Plaintiffs' Rulemaking Petition fails to respond to *any* of the over 7,232 public comments it received in support of the Rulemaking Petition. Those 7,232 comments in favor of the Rulemaking Petition represent more than 99% of the 7,295 comments that addressed the petition issues.

72. As a result of the agency's denial of Plaintiffs' Rulemaking Petition, the inadequate primate psychological well-being standards that were issued in 1991 remain in place, without any modification.

PLAINTIFFS' CLAIMS FOR RELIEF

73. For all of the reasons cited in ¶¶62-72 above, Defendants' denial of Plaintiffs' Rulemaking Petition is arbitrary, capricious, and an abuse of discretion, within the meaning of the Administrative Procedure Act, 5 U.S.C. §706(2)(A).

74. In addition, because the agency failed to take into account the actions by NIH, all of the new evidence regarding the psychological needs of primates, the fact that the USDA itself had long ago concluded that the existing regulations were insufficient to promote the psychological well-being of primates, and the fact that the agency never finalized the 1999 Draft Policy that would have further specified the minimum requirements that are necessary to promote the psychological well-being of primates, Defendants' failure to grant Plaintiffs' Rulemaking Petition to revisit that standard also violates the 1985 mandate of the AWA that the agency "shall" promulgate a standard adequate to promote the psychological well-being of primates. Thus, its decision is also not in accordance with law within the meaning of the APA, 5 U.S.C. §706(2)(A).

75. Defendants' denial of Plaintiffs' Rulemaking Petition injures Plaintiffs as described herein.

WHEREFORE, Plaintiffs respectfully request that this Court issue an Order:

1. Declaring Defendants' denial of Plaintiffs' Rulemaking Petition to be arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, in violation of the APA, 5 U.S.C. § 706(2)(A);
2. Directing Defendants to set aside their denial of the Plaintiffs' Rulemaking Petition;
3. Directing Defendants to render a new decision on Plaintiffs' Rulemaking Petition consistent with the Court's opinion, by a Court-ordered deadline;
4. Retaining jurisdiction of this matter until Defendants have fulfilled all statutory

and Court-ordered obligations;

5. Awarding Plaintiffs their costs and reasonable attorneys' fees incurred in bringing this action; and

6. Granting such other relief as the Court may deem just and proper.

Respectfully submitted,

/s/ Katherine A. Meyer

Md. Bar No. 07823
Director, Animal Law & Policy Clinic
Harvard Law School
1585 Massachusetts Ave.
Cambridge, MA 02138
617-998-2450 (o)
202-257-5145 (c)
kmeyer@law.harvard.edu

Attorney for Plaintiffs

Date: July 8, 2020