

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITE COAT WASTE PROJECT, INC.,
7288 Hanover Green Drive,
Mechanicsville, VA 23111

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201

NATIONAL INSTITUTES OF HEALTH;
9000 Rockville Pike
Bethesda, MD 20892

Defendants.

Civil Action No. 1:22-cv-6

**Complaint for Declaratory and
Injunctive Relief**

Plaintiff White Coat Waste Project, Inc. (“WCW”) brings this action against the United States Department of Health and Human Services and National Institutes of Health (collectively, “NIH” or “Defendants”). Plaintiff, based on personal knowledge as to itself, on the investigation of its counsel, and on information and belief as to all other matters, alleges as follows:

NATURE OF ACTION

1. The federal government spends approximately \$20 billion in taxpayer money each year on grants, contracts, and additional funding to support experiments on dogs, cats, primates, and other animals, domestically and in foreign countries. Congress enacted federal legislation requiring that *each* entity receiving taxpayer funds to conduct animal research maintain an animal care committee to review, approve, and monitor animal experiments, and to ensure proper care for animals. 42 U.S.C.A. § 289d. Despite this clear mandate, NIH enacted a contradictory and binding

agency rule exempting foreign grant recipients of taxpayer money for animal experiments from maintaining an animal care committee (the “Foreign Animal Lab Loophole”).

2. As the Foreign Animal Lab Loophole contradicts the plain words of a federal statute, NIH acted beyond its delegated authority, rendering the Foreign Animal Lab Loophole invalid. This ultra vires agency action unlawfully imparts lesser animal-welfare standards, reduces oversight and transparency, and lowers costs for foreign recipients of taxpayer funds, as compared to domestic recipients of taxpayer funds. Pursuant to 5 U.S.C. § 706, Plaintiff seeks to hold unlawful and set aside the Foreign Animal Lab Loophole on the basis that it exceeds statutory bounds.

3. In the alternative, as the Foreign Animal Lab Loophole is substantive and legislative in nature, NIH unlawfully included it in agency requirements, in violation of notice-and-comment rulemaking under 5 U.S.C. § 553. Pursuant to 5 U.S.C. § 706, in the alternative, Plaintiff seeks to hold unlawful and set aside Defendants’ illegal regulation on the basis that it was issued without proper rulemaking pursuant to 5 U.S.C. § 553, and therefore, is arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law, and issued without observance of procedure required by law.

JURISDICTION AND VENUE

4. This Court has authority to review final agency actions under the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701–706, and has jurisdiction over this action seeking such review under 28 U.S.C. § 1331.

5. Venue is proper in this judicial district under 28 U.S.C. § 1391, as this civil action is brought against an agency of the United States residing in this district, and a substantial part of the events or omissions giving rise to the claim occurred in this district.

PARTIES

6. WCW is a bipartisan taxpayer watchdog organization pursuant to Section 501(c)(3) of the Internal Revenue Code, with its headquarters located at 7288 Hanover Green Drive, Mechanicsville, VA 23111. WCW's mission is to unite animal-lovers and liberty-lovers to find, expose, and defund wasteful and cruel taxpayer-funded animal experimentation. WCW's efforts to end wasteful expenditures and needless cruelty to animals are obstructed by Defendants' illegal conduct, as alleged herein.

7. WCW brings this action on its own behalf, and on behalf of its members, because the challenged conduct directly conflicts with, impairs, and frustrates its organizational mission and has required WCW to divert and redirect its limited resources to counteract and offset Defendants' unlawful actions and omissions. The diversion of WCW's resources to offset Defendants' unlawful conduct hinders the development of other organizational projects that would better advance WCW's mission and increase WCW's visibility, influence, and membership. Additionally, WCW suffers a significant and irreparable informational injury. The Foreign Animal Lab Loophole excuses foreign grant recipients from maintaining records related to its animal care committee, as well as reporting requirements involving violations that WCW would otherwise be able to obtain through the Freedom of Information Act, had the recipient been a domestic entity.

8. Defendant U.S. Department of Health and Human Services is a federal agency with the mission of enhancing the health and well-being of Americans.

9. Defendant National Institutes of Health is a subdivision of the Department of Health and Human Services. NIH describes itself as "the steward of medical and behavioral

research for the Nation.”¹ Part of this stewardship is the lawful administration of billions of dollars in taxpayer grants to animal experimenters each year.

FACTS

10. The federal government spends approximately \$20 billion in taxpayer money each year on grants, contracts, and additional funding to support experiments on dogs, cats, primates, and other animals, domestically and abroad.

11. A total of 1,117 U.S. animal laboratories are currently authorized by the NIH to receive taxpayer funding for animal experimentation, as are 353 animal laboratories in 57 foreign countries.²

12. Congress has spoken directly on this issue, and legislated specific requirements for *all* grant recipients of taxpayer funds used for animal experimentation.

Federal Law Expressly Requires *Each* Recipient of Taxpayer Funds to Maintain an Animal Care Committee to Ensure Proper Care of Animals in Experimentation

13. Federal law expressly provides that *every* entity receiving funds for biomedical and behavioral research maintain an animal care committee.

14. Animal care committees are also referred to as Institutional Animal Care and Use Committees, or IACUCs.³

15. Specifically, "Guidelines of the Secretary under subsection (a)(3) *shall require animal care committees at each entity* which conducts biomedical and behavioral research with funds provided under this chapter ..." 42 U.S.C. § 289d(b)(1) (emphasis added).

¹ *About the NIH*, nih.gov, <https://www.nih.gov/about-nih/what-we-do/nih-almanac/about-nih> (last visited Jan. 3, 2022).

² *Institutions with a PHS Approved Animal Welfare Assurance*, OLAW.NIH.GOV, <https://olaw.nih.gov/assured/app/index.html#ALL> (last visited Jan. 3 2022).

³ NIH, *NIH Grants Policy Statement*, Sec. 1.1 (April 2021).

16. Federal law articulates minimum duties of mandatory animal care committees to safeguard animal welfare and the appropriate use of taxpayer funds, ordering, among other things:

“Each animal care committee of a research entity shall—[¶] (A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semi-annually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment; [¶] (B) keep appropriate records of reviews conducted under subparagraph (A); and [¶] (C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.”

42 U.S.C. § 289d(b)(1)-(3) (emphasis added).

17. Animal care committees have the responsibility to review, approve, or withhold approval for proposed animal experiments; regularly inspect animal laboratories; address concerns about animal welfare; report deficiencies; and suspend noncompliant animal experiments.⁴

NIH Supplements Federal Law with Additional Binding Agency Requirements

18. NIH supplements federal law with its own binding agency requirements, the NIH Grants Policy Statement (NIHGPS).

19. The current version of the NIHGPS was published in April 2021.⁵

20. According to NIH, “The NIH Grants Policy Statement (NIHGPS) makes available, in a single document, the policy *requirements* that serve as the terms and conditions of NIH grant awards.” (emphasis added).⁶

⁴ *The Institutional Care and Use Committee*, OLAW.NIH.GOV, <https://olaw.nih.gov/resources/tutorial/iacuc.htm#5d> (last visited Jan. 3 2022).

⁵ *NIH Grants Policy Statement*, GRANTS.NIH.GOV, <https://grants.nih.gov/policy/nihgps/index.htm> (last visited Jan. 3 2022).

⁶ *Id.*

Binding NIH Rule Exempts Foreign Grant Recipients of Taxpayer Funds for Animal Experiments from Maintaining an Animal Care Committee, in Violation of Federal Law

21. Sec. 4.1.1.4 of NIHGPS, titled Foreign Recipients and Foreign Performance Sites, exempts foreign entities receiving taxpayer funds for animal experiments from maintaining an animal care committee.

22. Specifically, the Foreign Animal Lab Loophole states, “IACUC approval is *not* required of foreign recipients; however, OLAW *encourages* foreign recipients to use the standards in the Guide for the Care and Use of Laboratory Animals.” NIHGPS, Sec. 4.1.1.4 (emphasis added).

23. At the same time, NIHGPS does not offer this exemption to domestic recipients performing taxpayer-funded experimentation at a foreign site. *Id.*

24. According to NIHGPS, “When the recipient is a domestic institution and performance sites are foreign (i.e., domestic grant with a foreign component), PHS Policy requirements are applicable. Accordingly, the recipient remains responsible for animal activities conducted at the foreign site and must provide verification of IACUC approval” *Id.*

25. Because the NIHPGS states that foreign grant recipients are not required to maintain IACUC approval, the Foreign Animal Lab Loophole also, by extension, exempts foreign entities from obligations set forth by Congress under 42 U.S.C. § 289d(b)(1)-(3) related to records maintenance and reporting obligations of animal care committees, as well as assuring the “proper care of animals.”

**FIRST CLAIM FOR RELIEF:
Foreign Animal Lab Loophole is Ultra Vires and
Violates Administrative Procedure Act**

26. Plaintiff repeats and incorporates all allegations in each of the preceding paragraphs.

27. Publication of the NIHGPS, which sets forth the Foreign Animal Lab Loophole, is a final agency action.

28. The Foreign Animal Lab Loophole contradicts the plain words of a federal statute, 42 U.S.C. § 289d, as set forth above.

29. The Foreign Animal Lab Loophole has a present, binding effect; appears on its face to be binding; and is applied in a way that indicates it is binding.

30. The Foreign Animal Lab Loophole is in excess of NIH's statutory jurisdiction, authority, or limitations.

31. The plain text of 42 U.S.C. § 289d limits the NIH's ability to exempt foreign entities from statutorily-imposed and congressionally-mandated IACUC requirements.

32. The Foreign Animal Lab Loophole is, therefore, unlawful and should be invalidated and set aside under 5 U.S.C. § 706(2)(C).

33. The Foreign Animal Lab Loophole is a substantive and legislative rule that limits administrative discretion, effects a substantive change in existing law and policy, and is administered with binding effect.

34. The Foreign Animal Lab Loophole has a practical binding effect because foreign grant recipients of taxpayer money for animal experiments can rely on it as a norm or for safe harbor, allowing foreign recipients to reliably violate animal-welfare standards and procedures by which domestic grant recipients must abide, as well as evade appropriate oversight and public scrutiny.

35. The Foreign Animal Lab Loophole imparts substantive rights upon foreign grant recipients of taxpayer money for animal experiments, which they would not have had Defendants not issued the Foreign Animal Lab Loophole.

36. At a minimum, the Foreign Animal Lab Loophole holds foreign recipients of taxpayer funds to a lower standard of animal care than domestic recipients of taxpayer funds. This has a substantive and negative impact on the welfare of animals subject to experiments by foreign entities. Additionally, by exempting foreign entities from animal-welfare standards, the illegal rule allows foreign entities to compete for taxpayer funds at a discount, as compared to domestic entities.

37. The Foreign Animal Lab Loophole also reduces transparency, as foreign entities are not subject to the records maintenance and reporting requirements of 42 U.S.C. § 289d(b)(1)-(3). This denies WCW, its members, the public at large, and other stakeholders of pertinent information they might otherwise obtain through the Freedom of Information Act.

38. The Foreign Animal Lab Loophole also reduces oversight of taxpayer-funded animal experiments, as animal research at foreign entities is not subject to the animal care committee review, approval, and compliance monitoring requirements of 42 U.S.C. § 289d(b)(1)-(3), potentially leading to wasteful, unnecessary, unlawful, and even dangerous animal experimentation at taxpayers' expense.

39. As a result of Defendants' actions and omissions described herein, Plaintiff has suffered a concrete and particularized injury that is actual and/or imminent.

40. As a result of Defendants' actions and omissions described herein, Plaintiff has suffered an informational injury that is actual and/or imminent.

41. There is a causal relationship between Defendants' conduct as alleged herein, and Plaintiff's injury.

42. The offending conduct is likely to continue, and therefore, will continue to injure Plaintiff.

43. The relief requested by Plaintiff will redress Plaintiff's injuries.

**ALTERNATIVE CLAIM FOR RELIEF:
Foreign Animal Lab Loophole Issued without Notice and Comment and Violates
Administrative Procedure Act**

44. Plaintiff repeats and incorporates all allegations in each of the preceding paragraphs, and alleges the following in the alternative.

45. Promulgation of the Foreign Animal Lab Loophole described above constituted "rule making" within the meaning of the APA, 5 U.S.C. § 551(5), and was subject to the notice-and-comment requirements of 5 U.S.C. § 553.

46. The Foreign Animal Lab Loophole is a substantive and legislative rule that limits administrative discretion, effects a substantive change in existing law and policy, and is administered with binding effect.

47. The Foreign Animal Lab Loophole has a practical binding effect because foreign grant recipients of taxpayer money for animal experiments can rely on it as a norm or for safe harbor, allowing foreign recipients to reliably violate animal-welfare standards and procedures by which domestic grant recipients must abide, as well as evade appropriate oversight and public scrutiny.

48. The Foreign Animal Lab Loophole imparts substantive rights upon foreign grant recipients of taxpayer money for animal experiments, which they would not have had Defendants not issued the Foreign Animal Lab Loophole.

49. At a minimum, the Foreign Animal Lab Loophole holds foreign recipients of taxpayer funds to a lower standard of animal care than domestic recipients of taxpayer funds. This has a substantive and negative impact on the welfare of animals subject to experiments by foreign entities. Additionally, by exempting foreign entities from animal-welfare standards, the illegal rule

allows foreign entities to compete for taxpayer funds at a discount, as compared to domestic entities.

50. The Foreign Animal Lab Loophole also reduces transparency, as foreign entities are not subject to the records maintenance and reporting requirements of 42 U.S.C. § 289d(b)(1)-(3). This denies WCW, its members, the public at large, and other stakeholders of pertinent information they might otherwise obtain through the Freedom of Information Act.

51. The Foreign Animal Lab Loophole also reduces oversight of taxpayer-funded animal experiments, as animal research at foreign entities is not subject to the animal care committee review, approval, and compliance monitoring requirements of 42 U.S.C. § 289d(b)(1)-(3), potentially leading to wasteful, unnecessary, unlawful, and even dangerous animal experimentation at taxpayers' expense.

52. The Foreign Animal Lab Loophole is *not* an interpretative rule; general statement of policy; or rule of agency organization, procedure, or practice.

53. The Foreign Animal Lab Loophole is not based on specific statutory or regulatory provisions, nor does it interpret or clarify a specific statutory or regulatory provision.

54. In fact, the opposite, the Foreign Animal Lab Loophole contradicts a federal statute, 42 U.S.C. § 289d, as set forth above.

55. The Foreign Animal Lab Loophole has a present, binding effect; appears on its face to be binding; and is applied in a way that indicates it is binding.

56. The Foreign Animal Lab Loophole is sufficiently grave so that notice and comment are needed to safeguard the policies underlying the APA.

57. Defendants, however, did not provide notice or permit comment before issuing the Foreign Animal Lab Loophole.

58. The Foreign Animal Lab Loophole is, therefore, unlawful and should be set aside under 5 U.S.C. § 706(2)(D).

59. As a result of Defendants' actions and omissions described herein, Plaintiff has suffered a concrete and particularized injury that is actual and/or imminent.

60. As a result of Defendants' actions and omissions described herein, Plaintiff has suffered an informational injury that is actual and/or imminent.

61. There is a causal relationship between Defendants' conduct as alleged herein, and Plaintiff's injury.

62. The offending conduct is likely to continue, and therefore, will continue to injure Plaintiff.

63. The relief requested by Plaintiff will redress Plaintiff's injuries.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Enter a declaratory judgment that Defendants have violated the APA by exceeding their statutory authority or, alternatively, failing to notify the public and afford it an opportunity to comment on the Foreign Animal Lab Loophole;

B. Enter an order vacating and setting aside the Foreign Animal Lab Loophole, and enjoining Defendants from using the Foreign Animal Lab Loophole, or any substantive equivalent, or, alternatively, unless and until the provision has been properly adopted through notice-and-comment rulemaking;

C. Award Plaintiff its costs and expenses, including reasonable attorneys' fees pursuant to applicable statutes and/or rules; and

D. Grant such further and additional relief as this Court may deem just and proper.

Dated: January 4, 2022

Respectfully submitted,

/S/Vanessa Shakib

Vanessa Shakib (D.C. Bar No. 1753580)

Ryan Gordon

ADVANCING LAW FOR ANIMALS

409 N. Pacific Coast Highway, #267

Redondo Beach, CA 90277

Tel. (202) 996-8389

vshakib@advancinglawforanimals.org

rgordon@advancinglawforanimals.org

Attorneys for Plaintiff