In the United States Court of Appeals For the First Circuit

COMMONWEALTH OF MASSACHUSETTS; DANA NESSEL, on behalf of the people of the State of Michigan; STATE OF ILLINOIS; STATE OF ARIZONA; STATE OF CALIFORNIA; STATE OF CONNECTICUT; STATE OF COLORADO; STATE OF HAWAII; STATE OF MAINE; STATE OF MARYLAND; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF DELAWARE; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN,

Plaintiffs - Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, M.D., Ph.D. in their official capacity as Director of the National Institutes of Health; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS); ROBERT F. KENNEDY, JR., in their official capacity as Secretary of the U.S. Department of Health and Human Services,

On Appeal from the United States District Court
For the District of Massachusetts

(Counsel listed on next page)

BRIEF OF AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1(a), People for the Ethical Treatment of Animals, Inc. states that it has no parent corporation nor any stock and, therefore, no publicly held company owns ten percent or more of its stock.

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Cases
PETA v. Wildlife In Need & Wildlife In Deed, Inc., 476 F. Supp. 3d 765 (S.D. Ind. 2020)
PETA v. Wildlife In Need & Wildlife In Deed, Inc., No. 4:17-cv-00186-RLY-DML, 2018 WL 828461 (S.D. Ind. Feb. 12, 2018)
PETA v. Tri-State Zoological Park of W. Md., Inc., 424 F. Supp. 3d 404 (D. Md. 2019) 28, 29
United States v. Envigo RMS, LLC, 2022 WL 1607840 (W.D. Va. May 21, 2022)
United States v. Lowe, No. 20-cv-0423-JFH, 2021 WL 149838 (E.D. Okla. Jan. 15, 2021)
United States v. Mt. Hope Auction Co., No. 5:24CV1520, 2024 WL 4188303 (N.D. Ohio Sept. 13, 2024)
United States v. Weaver, No. 23-CV-0422-JFH, 2024 WL 324783 (E.D. Okla. Jan. 29, 2024)
Court Orders
Order on Mot. For Prelim. Inj., <i>P. Poe 5 and P. Poes 2-4 and 6-75 v. Univ. of Wash.</i> , No. 2:24-cv-00170-JHC, Doc. 90 (W.D. Wash. Apr. 10, 2025)
Legislation
FDA Modernization Act 2.0, S. 5002, 117th Cong. (2021-2022), https://perma.cc/U46J-W28C

Other Authorities

Alexandra C. Willcox et al., Detailed analysis of antibody responses to SARS-CoV-2 vaccination and infection in macaques, PLOS PATHOGENS 18(4): 1-22 (Apr. 11, 2022), https://perma.cc/A2GQ-4TKF
Alternatives to Animal Research, HARVARD MED. SCH., https://perma.cc/PFY3-FM456
Amanda Zhou, <i>UW ordered to pay PETA \$540k in lawsuit over primate research</i> , SEATTLE TIMES (last updated Oct. 14, 2022), https://perma.cc/74GG-APYN
Animals Die While University of Washington Experimenters Are Out to Lunch, PETA (last updated Nov. 30, 2022), https://perma.cc/HJ2T-SDNC11
April 7, 2025 Letter from Dr. Lisa Jones-Engel, Ph.D., to the National Institute of Health Center for Scientific Review, National Institute on Aging, and U.S. Department of Human & Health Services Office of Research Integrity, https://perma.cc/V3LG-8V9V
August 7, 2023 Letter from Robert M. Payne, DVM, to Washington Department of Health Veterinary Board of Governors, https://perma.cc/AVN7-5NMZ
August 15, 2024 IACUC Meeting Minutes, UNIV. OF WASH., https://perma.cc/8ZQ5-4Z4520
Case Summary: Armstead, William M., U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF RSCH. INTEGRITY, https://perma.cc/EH6H-3ECE25
Decl. of Kathy Guillermo, P. Poe 5 and P. Poes 2-4 and 6-75 v. Univ. of Wash., No. 2:24-cv-00170-JHC, Doc. 81 (W.D. Wash. Mar. 17, 2025) 17

Despina G. Contopoulos-Ioannidis et al., Translation of Highly Promising Basic Science Research into Clinical Applications, Am. J. MED. 114(6): 477-484 (Apr. 15, 2003), https://perma.cc/2WGV-YT6D
Eric Boodman & STAT, Researchers Rush to Test Coronavirus Vaccine in People, Sci. Am. (Mar. 12, 2020), https://perma.cc/XC9U-CVE3
February 15, 2022 – March 11, 2022 email correspondence between Jesse C. Day (Washington National Primate Research Center) and Jonathan Ting (Allen Institute), https://perma.cc/2HBK-L3VU
Francis S. Collins & Lawrence A. Tabak, <i>Policy: NIH plans to enhance reproducibility</i> , NATURE 505(7485): 612-613 (Jan. 27, 2014), https://perma.cc/7ZBK-SU6Q
Jon Cohen, 'It's sobering': A once-exciting HIV cure strategy fails its test in people, Sci. (July 25, 2018), https://perma.cc/LZ35-UGTD
Joseph M. Antony & Kelly S. MacDonald, <i>A critical analysis of the cynomolgus macaque</i> , Macaca fascicularis, <i>as a model to test HIV-1/SIV vaccine efficacy</i> , VACCINE 33(27): 3073-3083 (June 17, 2015), https://perma.cc/AWT8-4P9C
July 2, 2024 Letter from Dr. Lisa Jones-Engel, Ph.D., to U.S. Department of Agriculture Animal and Plant Health Inspection Service, https://perma.cc/LR7S-EG2D
Kathryn A. Guerriero et al., Recrudescence of Natural Coccidioidomycosis During Combination Antiretroviral Therapy in a Pigtail Macaque Experimentally Infected with Simian Immunodeficiency Virus, AIDS RES. & HUM. RETROVIRUSES 37(7): 505-509 (July 1, 2021), https://perma.cc/HXY2-9TJ8
Keith Brown, Profiles in Cowardice: WaNPRC Officials Who Hide the Ugly Truth, PETA (last updated Nov. 30, 2022), https://perma.cc/DC7G-5CDY

Kienan Briscoe, UW Primate Center destroys public records while investigated by Feds, Lynnwood Times (Feb. 4, 2022), https://perma.cc/X5LS-KVB3
Larry Carbone, <i>Euthanasia and Laboratory Animal Welfare</i> in LABORATORY ANIMAL WELFARE (Kathryn Bayne and Patricia V. Turner eds., 2014), https://perma.cc/MKW6-ED74
Marc Girard et al., New prospects for the development of a vaccine against human immunodeficiency virus type 1. An overview, COMPTES RENDUS DE L'ACADÉMIE DES SCIENCES - SERIES III - SCIENCES DE LA VIE 322(11): 3073-3083 (Nov. 1999), https://perma.cc/TUV2-7PSR
March 10, 2025 USDA Official Warning Notice of Alleged Violation, https://perma.cc/G5ZB-VY8Q
May 10, 2022 Letter from Dr. Lisa Jones-Engel, Ph.D., to U.S. Department of Agriculture Animal and Plant Health Inspection Service, https://perma.cc/NV7X-AV8L
NIH to prioritize human-based research technologies, NAT'L INSTS. OF HEALTH, https://perma.cc/KN5D-4725
PETA Statement: OHSU Monkey Dies After Experimental Brain Surgery, PETA (Jan. 20, 2021), https://perma.cc/PE5L-252P
PETA to NIH: Four Decades of Killing Monkeys in HIV Experiments Is Enough, PETA (last updated Jan. 26, 2023), https://perma.cc/WN3V-4GRJ
Rafick-Pierre Sekaly, <i>The failed HIV Merck vaccine study: a step back or a launching point for future vaccine development?</i> , J. of Experimental Med. 205(1): 7-12 (Jan. 21, 2008), https://perma.cc/RV52-6WQ8
Sara Oliver, Ivy League Scientist Pummeled Pigs' Brains and Likely Falsified Data, PETA (last updated Apr. 2 2024), https://perma.cc/XEV7-XL4M

September 19, 2024 IACUC Meeting Minutes, UNIV. OF WASH.,
https://perma.cc/5PLG-DH2P21
Study Finds Monkeys Don't Help Us Fight COVID-19: PETA Statement,
PETA (Dec. 10, 2021), https://perma.cc/T6JZ-22HU
Timothy K. Cooper et al., Research-Relevant Conditions and Pathology of
Laboratory Mice, Rats, Gerbils, Guinea Pigs, Hamsters, Naked Mole Rats,
and Rabbits, ILAR J. 62(1-2): 77-132 (May 12, 2021),
https://perma.cc/GF5A-J5HZ
1100ps://perma.ec/ 01 011 00112
UW Prof Burns, Sickens Monkey and Violates Regulation in Radiation
Experiment; PETA Demands Her Dismissal, PETA (Aug. 21, 2024),
- ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '
https://perma.cc/8TE2-CRDE
Victory! President Signs Groundbreaking FDA Modernization Act 2.0,
PETA (last updated Dec. 27, 2022), https://perma.cc/4NL4-Y8WQ 10

INTEREST OF AMICUS CURIAE¹

Amicus curiae is the country's largest animal protection organization, and as such, is also one of the country's leaders in the effort to modernize medical and scientific research. Amicus employs some of the foremost scientific experts in the field of research modernization, is dedicated to investigating and uncovering fraud, waste, and cruelty that is rampant in the animal experimentation industry, and is instrumental in moving government funding agencies and the scientific community toward a state-of-the-art approach that is beneficial to humanity and does not rely on animal more experimentation. Amicus seeks to correct certain information provided to, and relied on, by the District Court regarding the irreparable harm threatened absent injunctive relief so that the ultimate determination of this Court stands on unimpeachable facts and evidence. Amicus submits its motion and this brief pursuant to Federal Rule of Appellate Procedure 29(a)(2) and seeks leave of this Court to file its brief.

¹ No party's counsel authored this brief in whole or in part, and no person or entity other than *Amicus curiae*, its counsel, or its members made a monetary contribution intended to fund the brief's preparation or submission.

SUMMARY OF THE ARGUMENT

The District Court relied on outdated and incorrect information purporting to show that a reduction in federal funding would irreparably harm institutions experimenting on animals. The District Court's reliance on this erroneous information, supplied by the very institutions that stand to gain from continuing "business as usual" experiments on animals, undermines some of its ultimate conclusions with respect to injunctive relief.

Evidence shows that animals subject to experimentation endure conditions similar to or worse than conditions previously found by federal "irreparable harm." courts to constitute Moreover, animal experimentation is not necessary to achieve scientific advancement—nor has it been shown to be the most reliable methodology available to advance those interests. Animal experiments undertaken at these institutions can readily be replaced with advanced scientific models that do not use animals, and an enhanced understanding of the species-level differences between humans and non-human experimental "subjects" has revealed significant challenges and impossibility in reproduction of results and reliable translation of "findings" from one species to another.

These limitations have slowed and even prevented the development of treatments useful to human health.

By wasting resources on experiments focused on the living systems of biologically diverse non-human "subjects," the National Institutes of Health contravenes its own mission and delays the human health advancements that could be achieved by adopting state-of-the-art technologies that do not use and abuse animals. See Appellants' Br. at 10, 13, 55 (NIH's mission is to "seek fundamental knowledge about the nature and behavior of living systems in order to enhance health, lengthen life, and reduce illness and disability.") (internal quotations and citation omitted).

Should this Court uphold the District Court's order granting permanent injunctive relief, it should do so without relying on or affirming the District Court's findings suggesting that irreparable harms suffered by animals are only relevant to this case insofar as that suffering poses an inconvenience or obstacle to those institutions confining animals in their laboratories.

ARGUMENT

- I. The District Court's Analysis of Irreparable Harm Concerning Animals Used for Experimentation Undermines Some of Its Ultimate Conclusions.
 - A. The District Court relied on flawed premises advanced by self-interested institutions engaged in animal experimentation.

The District Court embraced flawed premises, supplied by those who stand to profit most from animal experimentation, when it focused its analysis of harms to "the lives of animals" only on these animals' purported significance to "research in advance of human trials" and other "biomedical advances." ADD. 61. As will be shown below, harms to animals themselves, including the suffering of animals bred and used for experimentation, can be sufficient to support injunctive relief, and the District Court had no need to instead evaluate the animals primarily as "significant capital investments in ... animal specimens." ADD. 60.

Likewise, in declarations submitted to and relied upon by the District Court, institutions interested in continued funding to support animal experimentation claimed that, without intervention, the animals they experiment on will have to be euthanized because they would not be able to sell them or relocate them to other facilities or sanctuaries. *See*

ADD. 61-62 (citing declarations). If it is a fact that these animals are not in a condition to be placed elsewhere, it is also a fact that, as explained below, these animals will in all likelihood be killed by the institutions holding them captive even without a cut in funding.

The District Court should not have credited these unsupported and easily contradicted assertions regarding the purported "value of lost research animals—representing years of study central to medical breakthrough—that will be euthanized." ADD. 68. Rather, the District Court's characterization of a reduction of funding used to keep animals used for experimentation in unnatural, dystopic conditions and continually subject them to inhumane (and difficult- or impossible-to-justify) procedures—such as removing infant animals from their mothers and isolating them, denying them comfort, frightening them with plastic snakes and spiders, conducting bizarre sex experiments, and forcing animals to inhale cocaine and ingest marijuana—as irreparable harm subverts the public interest and other important equities at issue.

Today, non-animal experimentation models—ranging from sophisticated tests using human cells and tissues (*in vitro* methods) and organs-on-chips to advanced artificial intelligence ("AI") and computer-

modeling techniques (*in silico* methods)—are superior and readily available to replace non-human animal "subjects." These alternatives, which are unhindered by the physiological and other species differences that make reliably translating "findings" from animal experiments to humans difficult or impossible, offer far more promise when it comes to delivering improved human health outcomes.

The limitations on translating animal experiments to human health are perhaps best exemplified by the United States' decades-long effort—and failure—to develop an HIV vaccine.³ Because non-human primates do not contract HIV and do not develop AIDS in the same way humans do, experimenters have instead infected non-human primate "subjects" with "simian immunodeficiency virus" (SIV), a virus that is unique to non-human primates, or a genetically-engineered SIV/HIV

² Alternatives to Animal Research, HARVARD MED. SCH., https://perma.cc/PFY3-FM45; see also NIH to prioritize human-based research technologies, NAT'L INSTS. OF HEALTH, https://perma.cc/KN5D-4725.

³ PETA to NIH: Four Decades of Killing Monkeys in HIV Experiments Is Enough, PETA (last updated Jan. 26, 2023), https://perma.cc/WN3V-4GRJ.

"hybrid" (SHIV) to study that virus and its immune response.⁴ Animal experimenters admit that "we still do not know how the SIV or SHIV model [used to infect primates] compares to HIV infection in humans," and "[e]xtrapolating from vaccine protection results in non-human primate studies to efficacy in man may be misleading."⁵

Nonetheless, the National Institutes of Health continues to fund these useless—and ultimately dangerous—experiments. In 2018, a highly-anticipated clinical trial of an HIV vaccine developed from years of costly and pointless animal experiments failed, and the vaccine did not deliver any results in humans.⁶ Exhibiting the dangers of relying on "findings" from animal experiments, a second clinical study testing an HIV vaccine developed from studies in non-human primates showed that,

⁴ Joseph M. Antony & Kelly S. MacDonald, *A critical analysis of the cynomolgus macaque*, Macaca fascicularis, *as a model to test HIV-1/SIV vaccine efficacy*, VACCINE 33(27): 3073-3083 (June 17, 2015), https://perma.cc/AWT8-4P9C; Marc Girard *et al.*, *New prospects for the development of a vaccine against human immunodeficiency virus type 1. An overview*, COMPTES RENDUS DE L'ACADÉMIE DES SCIENCES - SERIES III - SCIENCES DE LA VIE 322(11): 959-956 (Nov. 1999), https://perma.cc/TUV2-7PSR.

⁵ Girard et al., supra, note 4.

⁶ Jon Cohen, 'It's sobering': A once-exciting HIV cure strategy fails its test in people, SCI. (July 25, 2018), https://perma.cc/LZ35-UGTD.

in humans, the vaccine "alarmingly ... appeared to increase the rate of HIV infection[.]"⁷

Efforts to develop a vaccine in response to the COVID-19 pandemic likewise exemplify the waste associated with animal experimentation. Only after spending millions of dollars, killing countless monkeys, and wasting invaluable time did animal experimenters finally admit that the SARS CoV2 infection does not manifest in primates the same as in humans. Ultimately, the testing of COVID-19 vaccines did not require animal trials to be approved for human treatment, reinforcing the conclusion that animal experimentation is not only unnecessary, but can

⁷ Rafick-Pierre Sekaly, *The failed HIV Merck vaccine study: a step back or a launching point for future vaccine development?*, J. OF EXPERIMENTAL MED. 205(1): 7-12 (Jan. 21, 2008), https://perma.cc/RV52-6WQ8.

⁸ Alexandra C. Willcox et al., Detailed analysis of antibody responses to SARS-CoV-2 vaccination and infection in macaques, PLOS PATHOGENS 18(4): 1-22 (Apr. 11, 2022), https://perma.cc/A2GQ-4TKF; see also Study Finds Monkeys Don't Help Us Fight COVID-19: PETA Statement, PETA (Dec. 10, 2021), https://perma.cc/T6JZ-22HU (reporting on study showing that the SARS-CoV-2 virus behaves differently in humans than it does in non-human primates).

actually hinder the swift and economical development of life-saving medical treatments.⁹

Acknowledging this reality, two former directors at the National Institutes of Health admitted that "[p]reclinical research, especially work that uses animal models, seems to be the area that is currently most susceptible to reproducibility issues." Indeed, in one study designed to assess whether the promises of basic biomedical advancement were being fulfilled, researchers identified 101 articles published in the most prestigious medical journals in which the authors explicitly stated that their work would lead to a new application with real potential for a clinical breakthrough. A significant portion of the articles reviewed (sixty-four percent) described experiments on animals. Investigation into the conversion of experiments into clinical applications found that fewer

⁹ Eric Boodman & STAT, Researchers Rush to Test Coronavirus Vaccine in People, Sci. Am. (Mar. 12, 2020), https://perma.cc/XC9U-CVE3.

¹⁰ Francis S. Collins & Lawrence A. Tabak, *Policy: NIH plans to enhance reproducibility*, NATURE 505(7485): 612-613 (Jan. 27, 2014), https://perma.cc/7ZBK-SU6Q (emphasis added).

than ten percent of these self-proclaimed "highly promising" discoveries entered routine clinical use within twenty years.¹¹

Moving forward and signaling that the future of scientific advancement is in experimental models that do not involve animals, in 2022, the Food and Drug Administration ("FDA") Modernization Act¹² was signed into law, allowing the FDA to consider non-animal testing methods to establish a drug's safety and effectiveness and removing a mandate that required animal studies to introduce new human health products.¹³

However, not all institutions are ready to give up these outdated and wasteful animal experiments. Despite the abysmally low success rate of converting animal experiments to future human treatments, proponents continue to claim that animal experimentation is necessary when it is not. *See* ADD. 61 (citing Decl. of Mari Ostendorf, University of

¹¹ Despina G. Contopoulos-Ioannidis *et al.*, *Translation of Highly Promising Basic Science Research into Clinical Applications*, AM. J. MED. 114(6): 477-484 (Apr. 15, 2003), https://perma.cc/2WGV-YT6D.

 $^{^{12}}$ FDA Modernization Act 2.0, S. 5002, 117th Cong. (2021-2022), https://perma.cc/U46J-W28C.

¹³ Victory! President Signs Groundbreaking FDA Modernization Act 2.0, PETA (last updated Dec. 27, 2022), https://perma.cc/4NL4-Y8WQ.

Washington ("UW") (claiming that "pioneering biomedical advances that benefit human health ... will be crippled from loss of NIH funding")). Given how thoroughly discredited such assertions are, this Court should not affirm these institutions' misleading and conclusory claims that experimentation on animals is necessary, or even vital to, scientific advancement.

In addition to relying on Appellees' representations as to the necessity of continued animal experimentation without question, the District Court had no basis to credit these institutions' representations that animals in their custody and control would have to be euthanized absent continued funding. ADD. 61-62. These institutions failed to inform the District Court that, in reality, many animals in their facilities die from negligence, with federal inspectors finding, for example, that they were boiled alive in cage washers; starved to death after their heads or hands became trapped in cage bars, preventing them from reaching water or food; or were deprived of treatment for what became fatal

¹⁴ Animals Die While University of Washington Experimenters Are Out to Lunch, PETA (last updated Nov. 30, 2022), https://perma.cc/HJ2T-SDNC.

injuries or illnesses (such as when they suffered infections from improperly seated brain implants). 15

Nor did these institutions inform the District Court that almost all animals used for experimentation who do not die by "accident" are eventually killed after suffering through traumatizing, painful, and unnecessary procedures, or once they are no longer considered "useful" by animal experimenters. ¹⁶ Taking the statements of the institutions that experiment on animals at face value inevitably obscures the basic truth that animals suffer and die **because** they are being experimented on, not despite it.

The animal experimenters' representations not only lack this important context, but in some cases may also be false. For example, despite claiming that animals in its custody and control "cannot be sold or relocated to other [] facilities [or sanctuaries]," ADD. 61 (citing Decl.

¹⁵ PETA Statement: OHSU Monkey Dies After Experimental Brain Surgery, PETA (Jan. 20, 2021), https://perma.cc/PE5L-252P.

¹⁶ See Larry Carbone, Euthanasia and Laboratory Animal Welfare in LABORATORY ANIMAL WELFARE (Kathryn Bayne and Patricia V. Turner eds., 2014), https://perma.cc/MKW6-ED74 (acknowledging that the overwhelming majority of animals used for experimentation are killed in the laboratory).

of Mari Ostendorf, UW), UW's National Primate Research Center ("WaNPRC") has indeed offered non-human primates that have been experimented on in its facilities for sale to other animal experimenters at "discounted" prices.¹⁷

Ultimately, these institutions' attempt to characterize a reduction in federal funding to support animal experimentation as irreparable harm is built on incorrect and incomplete representations about both the necessity and worth of these experiments and the fate of these animals should experiments not continue pursuant to the status quo.

B. It is the institutions engaged in animal experimentation, not their lack of funding, which threaten the greatest irreparable harm.

The reduction or elimination of federal funding to support animal experimentation would considerably mitigate, not exacerbate, irreparable harm. Animal experimentation itself, as practiced by these institutions, perpetuates irreparable harms, including acute and long-

¹⁷ See, e.g., February 15, 2022 – March 11, 2022 email correspondence between Jesse C. Day (Washington National Primate Research Center) and Jonathan Ting (Allen Institute), https://perma.cc/2HBK-L3VU (responding to inquiry for "short term survival surgery eligible animals or other discounted animals" and processing "order" for primate).

term suffering inflicted on animals, negligence resulting in death, and damage to the integrity of medical and other scientific advancements.

1. Animal experimentation causes unconscionable irreparable harms to animals.

The irreparable harm to animals used for experimentation, and the unreliability of testimony from institutions invested in the continuation of animal experimentation, can be exemplified by one institution relied on heavily by the District Court: The University of Washington. ADD. 61, 67. In response to a public records request submitted to UW in 2021, PETA received 800 necropsy reports for primates held at UW's facilities across a period of four years. 18

These records revealed a pattern of failures by UW to adhere to established veterinary and animal care procedures, or to adequately investigate and address illness and infection in its macaque primate colonies. These conditions—which can ravage populations confined within small laboratory facilities—could easily impact the scientific

¹⁸ May 10, 2022 Letter from Dr. Lisa Jones-Engel, Ph.D., to U.S. Department of Agriculture Animal and Plant Health Inspection Service, at 1-2, https://perma.cc/NV7X-AV8L (hereinafter "May 2022 Letter"). ¹⁹ *Id*.

integrity of UW's experimental models and have broader repercussions for the health and well-being of those colonies.²⁰

And that is exactly what happened. Despite acknowledging the existence of rampant Coccidioidomycosis and other bacterial and fungal infections in UW's macaque colonies, the University made little effort to identify the etiological agents or environmental factors contributing to the high rates of illness, infection, and death observed in these contained monkey populations.²¹

Between May and August of 2021, six infant macaques died in UW facilities, and UW generically attributed a total of twenty five macaque infant deaths to "inanition" (starvation), "diarrhea," or "hypoglycemia from inadequate nursing"—with little or no investigation into the underlying causes of these conditions.²² Illness and infection likewise

²⁰ See, e.g., Kathryn A. Guerriero et al., Recrudescence of Natural Coccidioidomycosis During Combination Antiretroviral Therapy in a Pigtail Macaque Experimentally Infected with Simian Immunodeficiency Virus, AIDS Res. & Hum. Retroviruses 37(7): 505-509 (July 1, 2021), https://perma.cc/HXY2-9TJ8 (recommending that macaques with a history of Coccidioidomycosis be excluded from enrollment in HIV studies).

²¹ May 2022 Letter at 2-7.

²² *Id*.

afflicted UW's adult macaques, and in June 2021, two macaques who shared an enclosure died from severe bacterial infections, neither of which was definitively identified.²³

However, institutions like UW have an incentive to keep these incidents secret. In fact, *none* of the above-discussed macaque deaths were self-reported by UW, nor were they discussed at the University's Institutional Animal Care and Use Committee ("IACUC") meetings, at which attending veterinarians are required to report adverse events.²⁴ Fear to report is commonplace in institutions like UW, where whistleblowers who raise concerns about animal welfare face threats of retaliation or ostracization for this perceived betrayal.²⁵

Nevertheless, in May 2024, a whistleblower at UW came forward to report a 2023 incident where then-director of the University's National Primate Research Center, Michele Basso, failed to report post-operative

²³ *Id.* at 7.

²⁴ *Id.* at 14.

²⁵ July 2, 2024 Letter from Dr. Lisa Jones-Engel, Ph.D., to U.S. Department of Agriculture Animal and Plant Health Inspection Service, at 2-3, https://perma.cc/LR7S-EG2D (hereinafter "July 2024 Letter").

Basso omitted any reference to these clinical symptoms when she sought to amend lab protocol and conduct a second operation on the suffering macaque.²⁷ Based on the incomplete information provided by Basso, the IACUC approved the amendment and the macaque was cleared to endure a second surgery from which she never recovered.²⁸

UW's failure to adhere to established procedures of veterinary and animal care appears to be a pattern. Indeed, after a 2015 inspection, the United States Department of Agriculture ("USDA") called out UW's IACUC for essentially operating as a rubberstamping entity, flagging that the IACUC approved major surgeries on animals even though the experimenters had not provided crucial information in their proposed protocols.²⁹

²⁶ *Id.* at 1-2.

 $^{^{27}}$ *Id*.

 $^{^{28}}$ *Id.* at 2.

²⁹ See Decl. of Kathy Guillermo ¶ 6, P. Poe 5 and P. Poes 2-4 and 6-75 v. Univ. of Wash., No. 2:24-cv-00170-JHC, Doc. 81 (W.D. Wash. Mar. 17, 2025) (citing July 14, 2015 USDA inspection report).

More recently, in March 2025, the USDA issued UW a "warning" citing alleged violations of various Animal Welfare Regulations, including 9 C.F.R. § 2.31(e)(3), which requires that "[a] proposal to conduct an activity involving animals ... contain ... [a] complete description of the proposed use of the animals."³⁰ The USDA warning highlighted that, in 2024, "a male macaque underwent video fluoroscopy for more sessions than described in the approved protocol, and subsequently experienced radiation toxicity with clinical impacts."³¹

The USDA's warning flagged additional incidents involving macaques at UW as potential violations of Animal Welfare Regulations codified at 9 C.F.R. §§ 2.31, 2.32, and 2.33³²:

• In June 2023, an adult male macaque began to experience poor oxygenation during an operation, but the procedure space had inadequate emergency equipment to respond to the situation. A veterinarian was apparently not present at this time and had to be called when the macaque stopped breathing. The macaque

³⁰ April 7, 2025 Letter from Dr. Lisa Jones-Engel, Ph.D., to the National Institute of Health Center for Scientific Review, National Institute on Aging, and U.S. Department of Human & Health Services Office of Research Integrity, at 1-2, https://perma.cc/V3LG-8V9V (citing USDA Official Warning Notice of Alleged Violation, dated March 10, 2025).

 $^{^{31}}$ March 10, 2025 USDA Official Warning Notice of Alleged Violation, https://perma.cc/G5ZB-VY8Q (hereinafter "2025 USDA Warning"). 32 Id.

was relocated to another room and attached to a ventilator, which had not been properly tested and malfunctioned. The macaque died as a result of barotrauma, or tissue damage caused by the pressure changes which had developed rapidly in the malfunctioning tubing attached to the macaque.³³

- On two separate occasions in early 2024, UW failed to provide four macaques with post-operative analgesia following lymph node biopsies.³⁴
- In March 2024, the USDA identified a macaque who had not received the "appropriate analgesia" following a cerebrospinal fluid tap.³⁵
- That same month, two adult macaques escaped from their enclosure into the main room of the vivarium through an improperly secured panel and fought other macaques in the room. Four animals sustained injuries, three of whom required sedation for wound repair.³⁶

Not only do the animals at UW suffer from neglect or accidents, they also suffer by design. In May and June 2024, UW experimenter Fritzie Arce-McShane radiated a macaque three days in a row for over a month, despite her protocol requiring at least forty-eight hours of

³³ *Id.*; August 7, 2023 Letter from Robert M. Payne, DVM, to Washington Department of Health Veterinary Board of Governors, https://perma.cc/AVN7-5NMZ.

³⁴ 2025 USDA Warning.

 $^{^{35}}$ *Id*.

 $^{^{36}}$ *Id*.

recovery time between each session of radiation exposure.³⁷ The macaque exhibited clear signs of pain and radiation toxicity (including facial swelling, discharge from the eyes and nose, and red flaky skin), but experimenter Arce-McShane did not inform veterinary staff that she had violated her own protocol.³⁸ Only when the symptoms became more severe and the macaque's condition deteriorated did Arce-McShane admit to her transgressions.³⁹

In August and September 2024, the UW IACUC uncovered other incidents where Arce-McShane had violated experiment protocols, including failure to use anti-radiation goggles on a macaque during radiation exposure,⁴⁰ and three instances where Arce-McShane's laboratory administered an improper dose of a drug that likely would

³⁷ UW Prof Burns, Sickens Monkey and Violates Regulation in Radiation Experiment; PETA Demands Her Dismissal, PETA (Aug. 21, 2024), https://perma.cc/8TE2-CRDE.

 $^{^{38}}$ *Id*.

 $^{^{39}}$ *Id*.

⁴⁰ August 15, 2024 IACUC Meeting Minutes at 3-6, UNIV. OF WASH., https://perma.cc/8ZQ5-4Z45.

have lessened the macaque's pain and discomfort while he was subjected to these experiments.⁴¹

It is rare for these incidents to be made public or sanctioned in any way, as the institutions engaged in animal experimentation can be hyperprotective of their public reputations and are often de facto off-limits to the public and animal protection organizations. For example, a UW "No Photo" policy warns employees that the University's National Primate Research Center personnel are charged "with questioning any person carrying or using any type of camera equipment within [its] facilities." Employees of these institutions are encouraged to keep quiet for the sake of their own survival, and it most often falls to organizations like PETA to bring these incidents into the spotlight. 43

But even PETA's efforts can only expose so much. In 2022, a Washington court ordered UW to pay PETA more than $half\ a\ million$

⁴¹ September 19, 2024 IACUC Meeting Minutes at 4-5, UNIV. OF WASH., https://perma.cc/5PLG-DH2P.

⁴² Keith Brown, *Profiles in Cowardice: WaNPRC Officials Who Hide the Ugly Truth*, PETA (last updated Nov. 30, 2022), https://perma.cc/DC7G-5CDY.

⁴³ See, e.g., May 2022 Letter at 14 ("None of the 59 incidents included in this complaint have been self-reported to the USDA or OLAW.").

dollars in attorneys' fees and penalties after revelation of a UW policy of destroying photographs and videos from WaNPRC.⁴⁴ And just last month, members of the UW IACUC were denied a preliminary injunction in litigation brought by IACUC members to keep their identities hidden from the public after a Western District of Washington judge found, among other things, that testimony from the UW IACUC chair was not "consistent" with internal communications revealed in discovery. Order on Mot. For Prelim. Inj. at 14, P. Poe 5 and P. Poes 2-4 and 6-75 v. Univ. of Wash., No. 2:24-cv-00170-JHC, Doc. 90 (W.D. Wash. Apr. 10, 2025).

Given these repeated failures, UW is not a reliable source for the irreparable harms allegedly posed absent continued federal funding to support animal experimentation. Indeed, given how many of the above examples of irreparable harm to animals occurred at just one institution over a span of less than five years, the likely magnitude of the collective suffering of animals across this nation's institutions is unconscionable.

⁴⁴ Amanda Zhou, *UW ordered to pay PETA \$540k in lawsuit over primate research*, SEATTLE TIMES (last updated Oct. 14, 2022), https://perma.cc/74GG-APYN.

2. Animal experimentation irreparably harms the integrity of medical and other scientific advancement.

The irreparable harm caused by animal experimenters is not limited to the immense suffering the animals themselves endure, as reliance on animal experimentation also poses a threat to the integrity of scientific and medical advancement.

In addition to the low rate of inter-species conversion of data from animal experimentation into beneficial human applications, described above, ⁴⁵ animal experimentation frequently causes direct harm to scientific advancement. For example, in February 2022, UW found itself in the headlines after an investigation revealed that UW shipped primates infected with "valley fever" to other U.S. institutions, "potentially compromising tens of millions of dollars in research aimed at finding cures and vaccines for AIDS, HIV, hepatitis, Zika, Ebola and even COVID-19."

⁴⁵ Contopoulos-Ioannidis *et al.*, *supra*, note 11.

⁴⁶ Kienan Briscoe, *UW Primate Center destroys public records while investigated by Feds*, Lynnwood Times (Feb. 4, 2022), https://perma.cc/X5LS-KVB3.

Animal experimenters are well aware of the disastrous impact that unaddressed illness and infection can have on the integrity of their experimental models. A systematic review by the medical community of animal experimentation acknowledged that "[s]pontaneous conditions ... can be misrepresented as research-relevant effects of intended experimental interventions" and advised that experimenters consider the effects that "infectious conditions" in animals used for experimentation can have of the "research reproducibility and validity."⁴⁷ The same review revealed that "numerous viruses, bacteria, and parasites are still sporadically or regularly detected" in mice, the animal most frequently used for experimentation.⁴⁸

Animal experimenters have caused further irreparable harm to medical and scientific advancement by distorting and even falsifying "findings." A recent incident from the University of Pennsylvania ("UPenn") offers an example of the irreparable harm animal

⁴⁷ Timothy K. Cooper et al., Research-Relevant Conditions and Pathology of Laboratory Mice, Rats, Gerbils, Guinea Pigs, Hamsters, Naked Mole

Rats, and Rabbits, ILAR J. 62(1-2): 77-132 (May 12, 2021),

https://perma.cc/GF5A-J5HZ.

⁴⁸ *Id*.

experimentation poses both to animals and to scientific integrity. A UPenn experimenter, William Armstead, inflicted brain injuries on piglets by drilling into their heads and hammering cylinders into their brains.⁴⁹ In 2023, Armstead ultimately had to retract the findings resulting from these cruel experiments after the U.S. Department of Health and Human Services Office of Research Integrity found him to have engaged in "research misconduct" by intentionally falsifying and fabricating data.⁵⁰ This is far from an isolated incident.

This history and evidence show that experiments involving animal "subjects" are wasteful, inflict unnecessary pain and suffering on sentient beings, rarely translate to reliable data with the potential to better human health outcomes, and are actively harmful to the swift and economical development of life-saving medical treatments.

 $^{^{49}}$ Sara Oliver, $Ivy\ League\ Scientist\ Pummeled\ Pigs'\ Brains\ and\ Likely\ Falsified\ Data,$ PETA (last updated Apr. 2, 2024), https://perma.cc/XEV7-XL4M

⁵⁰ Case Summary: Armstead, William M., U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF RSCH. INTEGRITY, https://perma.cc/EH6H-3ECE.

The District Court's reliance on declarations from institutions interested in continuing to receive funds to support experimentation on animals to further conclude that these experiments "represent[] years of study central to medical breakthrough," ADD. 68, is based on incorrect and incomplete information about the irreparable harm posed absent continued federal funding, which ultimately undermines the Court's analysis.

II. Harm Threatened to Animals, Without More, is Sufficient to Constitute Irreparable Harm.

As demonstrated above, the District Court's reliance on the self-interested declarations of animal experimenters in its analysis and ultimate findings as to irreparable harm weakens its conclusions. The District Court would have been on stronger footing had it instead rejected this evidence or sought to balance the various alleged irreparable harms at issue against the harms continuously inflicted upon animals used for experimentation in laboratories.

Had the District Court considered the irreparable harms posed to the animals confined for experimentation, its analysis would have been consistent with irreparable harm analyses from courts across the country, who have correctly and consistently recognized that harm experienced by or threatened to animals is sufficient in and of itself to support a finding of irreparable harm.

For example, last year, the Northern District of Ohio granted a temporary restraining order based on the irreparable harm posed to the animals housed for auction at the defendant's facilities, some of whom had open, untreated wounds, were emaciated, and had experienced substantial hair loss. *United States v. Mt. Hope Auction Co.*, No. 5:24CV1520, 2024 WL 4188303, at *3 (N.D. Ohio Sept. 13, 2024). In support of this holding, the court invoked *United States v. Lowe, id.*, a 2021 decision in which the Eastern District of Oklahoma similarly granted injunctive relief based on the defendants' failure to provide adequate nutrition and veterinary care to animals in their care at a roadside zoo, resulting in unnecessary suffering and death. No. 20-cv-0423-JFH, 2021 WL 149838, at *14 (E.D. Okla. Jan. 15, 2021).

Irreparable harm to animals has likewise been recognized in cases involving animal experimentation. In *United States v. Envigo RMS, LLC*, the Western District of Virginia considered evidence that beagles bred for and used in animal experiments were living in "torturous conditions,"

enduring medical procedures without anesthesia, and being denied food or provided food infested with "live insects, worms, maggots, beetles, flies, ants, mold, and feces." 2022 WL 1607840, at *1, *9 (W.D. Va. May 21, 2022). Puppies at the facilities were "hosed down with cold water," causing at least sed five to die from cold exposure, while another 300+beagle puppies died from "unknown causes" over a seven-month period. *Id.* at *1. Finding "grave health risks" to the dogs remaining in the defendant's care, the court granted a temporary restraining order. *Id.* at *9.

These examples offer just a small sample of the cases recognizing irreparable harm sufficient to support injunctive relief based on harms threatened to animals, many of which were litigated by PETA. See also United States v. Weaver, No. 23-CV-0422-JFH, 2024 WL 324783 (E.D. Okla. Jan. 29, 2024) (finding "substantial risk" of irreparable harm where dogs held at a breeding facility lacked access to water and had untreated injuries and it was unclear how many dogs were still being housed in those same conditions); PETA v. Tri-State Zoological Park of W. Md., Inc., 424 F. Supp. 3d 404 (D. Md. 2019) (finding irreparable harm at a roadside zoo for animals living in "fetid and dystopic conditions," which led to the

deaths of multiple animals and was likely to lead to the deaths of the remaining animals absent injunctive relief); *PETA v. Wildlife In Need & Wildlife In Deed, Inc.*, No. 4:17-cv-00186-RLY-DML, 2018 WL 828461 (S.D. Ind. Feb. 12, 2018) (granting a preliminary injunction after finding threat of irreparable harm to big cats at a roadside zoo subjected to permanent declawing surgeries, premature maternal separation, and harmful public interaction); *PETA v. Wildlife In Need & Wildlife In Deed, Inc.*, 476 F. Supp. 3d 765 (S.D. Ind. 2020) (re-affirming earlier holding regarding irreparable harm to big cats and granting a permanent injunction).

Each of these decisions exemplifies the core principle that subjecting animals to deplorable conditions and inhumane treatment can, standing alone, constitute irreparable harm for purposes of granting injunctive relief.

In light of the foregoing, the District Court should have rejected one-sided evidence regarding the relevance of animal lives to its irreparable harm analysis, and its findings on this specific point should not be extended deference.

CONCLUSION

Should this Court uphold the District Court's grant of permanent injunctive relief, it should do so without relying on or affirming the Court's findings regarding irreparable harm that institutions carrying out animal experimentation unilaterally allege they would suffer.

Dated: June 5, 2025 Respectfully submitted,

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