



Animal Welfare Institute

900 PENNSYLVANIA AVENUE, SE, WASHINGTON, DC 20003 • 202-337-2332 • AWIONLINE.ORG

November 7, 2023

Honorable Patty Murray
Chair, Committee on Appropriations
Senate of the United States
Washington, D.C. 20510

Honorable Kay Granger
Chair, Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

Honorable Susan Collins
Vice Chair, Committee on Appropriations
Senate of the United States
Washington, D.C. 20510

Honorable Rosa DeLauro
Ranking Member, Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

Re: Dedicated Funding for Primate Research in Fiscal Year 2024 Appropriations

Dear Chair Murray, Vice Chair Collins, Chair Granger, and Ranking Member DeLauro:

As the House and Senate Appropriations Committees work to finalize the Fiscal Year 2024 (FY24) appropriations bills, the Animal Welfare Institute (AWI) feels it is important to address the provision in the Senate Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS) bill for \$30 million in National Institutes of Health (NIH) funding to “expand, remodel, renovate, or alter existing research facilities or construct new research facilities for nonhuman primate resource infrastructure” at the National Primate Research Centers (NPRCs) under 42 U.S.C. §283(k).

For the reasons outlined below, **rather than funding the renovation and expansion of nonhuman primate (NHP) resource infrastructure, AWI believes the public would be better served by using these funds to further develop modern research technologies that do not rely on animals. We do not believe that Congress should funnel additional taxpayer money into a fundamentally broken NPRC system that threatens both the safety of the animals and the integrity of the resulting research.**

NPRCs have a long and ongoing history of noncompliance with the Animal Welfare Act (AWA). The Animal Welfare Institute is deeply concerned about NPRCs’ ability and motivation to comply with the AWA’s minimum requirements and safeguard the welfare of NHPs. Within the past year, six of the seven NPRCs (either the centers themselves, or the universities that operate them) have had critical citations; and since 2014, all seven have had *multiple* critical citations. Critical citations are those that “had a *serious or severe adverse effect on the health and well-being of the animal*” (*emphasis added*) and direct citations are those that are “**currently (at the time of the inspection) having a serious or severe adverse effect on the health and well-**

being of the animal.”¹ (*emphasis in original*) In the 8-year period between 2015 and 2022, the Texas Biomedical Research Institute (operating the Southwest NPRC) “racked up 30 violations” and the University of California, Davis (operating the California NPRC) had 13 “critical” or “direct” citations.² Five of the seven NPRCs have paid *multiple* USDA fines. The two largest USDA-stipulated penalties paid in the past four years for any type of regulated entity—breeder, dealer, research, exhibitor, transporter—have been by NPRCs: the University of Wisconsin-Madison (UW-Madison; operating the Wisconsin NPRC) and Oregon Health & Science University (OHSU; operating the Oregon NPRC). UW-Madison was fined \$74,000 for 28 citations occurring between 2015 and 2019,³ and has continued to be cited for critical citations since.⁴ OHSU was fined almost \$38,000 for citations between 2018 and 2021,⁵ with 31 citations between 2014 and 2022, 15 of which were “critical” or “direct” citations.⁶ Indeed, OHSU leads the nation in number of citations.⁷ Moreover, the University of Washington (UW) (operating the Washington NPRC) was investigated recently after diseased monkeys were allegedly sent across the country, “potentially compromising tens of millions of dollars in research.”⁸ The UW has a “history of negligence,”⁹ leading to a \$20,000 fine in 1995,¹⁰ a \$10,893 fine in 2011, a \$20,000 fine in 2008,¹¹ and a \$3,750 fine in 2022.¹² Despite these fines, and merely ten months after the most recent one, the UW received yet another critical citation in September involving a monkey death due to negligence, and was also cited for a preventable brain injury suffered by another monkey.¹³

Indeed, many of the USDA citations referenced herein involve injuries or deaths due to negligence at NPRCs.

Apart from the threat to research integrity from using injured, ill or diseased monkeys or distributing them to study sites, other aspects of NPRC use of NHPs also impact the validity of the science underlying these studies. The September USDA inspection at UW also uncovered multiple research oversight issues, including lack of training.¹⁴ Moreover, the findings regarding inadequate oversight or training from this egregious September inspection are not an isolated incident among the NPRCs. For example, a 2021 inspection of OHSU found that the “root cause” of horrific monkey deaths and injuries was “insufficient training and/or supervision.”¹⁵ Further underscoring the broken nature of the NPRC system, last year the director of the Southwest NPRC admitted to faking research data related to a monkey study; that study was later retracted.¹⁶ Despite the Office of Research Integrity finding him guilty of “intentionally, knowingly, and/or recklessly falsifying and fabricating” data, he did not immediately lose his job, leading to “shock and dismay” among researchers.¹⁷

It is clear that fines have not alleviated animal welfare noncompliance, as “violators consider them merely a ‘cost of doing business.’”¹⁸ Additional funding for infrastructure would not address many of these problems. Continuing to use taxpayer funds for NHP research under such conditions is deeply troubling. **Indeed, the continued citations issued to NPRCs indicate that *withholding* funding from these facilities may be the only way to enforce compliance with the law.** Congress did this with the Agricultural Research Service (ARS) in the wake of the scandalous conditions documented at the ARS’s Meat Animal Research Center.¹⁹ **Given the paltry amounts of USDA fines, we believe that Congress’s proactively withholding money may be the only way to ensure compliance at the NPRCs.**

Indeed, rather than funneling \$30 million in additional NIH funding to NPRCs that cannot or will not comply with the minimum requirements of the AWA, we believe that Congress should direct these funds toward modernizing our approach to research. Indeed, a National Academies of

Sciences, Engineering and Medicine (NASEM) committee, which was convened in response to a request from Congress, has recently expressed in its final report that "continued development and validation of new approach methodologies (in vitro and in silico model systems) is critically important to support further advances in biomedical research."²⁰ Congress has also shown a longstanding interest in the development of non-animal models; the 1993 NIH Revitalization Act (in which Congress "directed the National Institutes of Health (NIH) to support research to replace, reduce, and refine animal use in biomedical research, and to develop and validate alternatives to animal use") shows that such methods were already being sought by Congress 30 years ago.²¹ The FY24 LHHS report itself states that "NIH is also encouraged to continue the development and validation of new approach methodologies that reduce the need for, enhance the utility of, and mitigate shortages and costs of NHP models in the future," which indicates that the Committee is aware of the need for change.

Without pressure and support from Congress, it is unlikely that alternatives will be developed, because major financial incentives for using live monkeys are at play in the NHP research industry as a whole. In 2021, according to data from the USDA, "more than 42 percent of labs that used or held NHPs were for-profit entities."²² Inotiv, a for-profit company that advertises itself as the world's largest and most trusted supplier of NHPs, and which has faced allegations of abuse,²³ listed \$140 million in sales in 2022—a quarter of all company revenue—from the sale of Cambodian monkeys alone.²⁴ A stock analyst recently estimated that a pause on monkey shipments from Cambodia could cost the for-profit company Charles River Laboratories (CRL)—by far the largest user of monkeys for experimentation in the U.S. (as well as a dealer)—between \$80 million and \$160 million in sales.²⁵ These financial incentives have come into even sharper relief in the wake of the landmark indictment brought by the U.S. Department of Justice against employees of a Hong Kong-based primate supplier alleging that thousands of "laundered" monkeys from Cambodia had been illegally smuggled into the U.S. for experimentation. Tellingly, the alleged motive was "financial gain."²⁶ (Inotiv has reported to the SEC that its "principal supplier" of monkeys is this Hong Kong-based company.)²⁷

With significant profits to be made from the use of NHPs in research, there is little incentive for researchers to focus on improving and expanding new approach methodologies (NAMs) unless the government creates pressure to do so. For example, CRL has also faced criticism for its use of horseshoe crabs for bacterial endotoxin tests, from which it profits handsomely, yet it has been a vocal opponent of non-animal alternatives to horseshoe crab testing.²⁸ In 2020, endotoxin tests numbered 70 million annually and it is estimated that the relevant market will be worth \$1 billion annually by 2024.²⁹ The European Pharmacopeia has recognized the non-animal test as a standard method since January 1, 2021.³⁰ The NASEM report expressed support for NAMs, but failed to address financial incentives—which can stifle the development of NAMs.³¹ **Funding is one of the best levers the government has to encourage such change. Channeling government funding away from NHP research infrastructure—within a broken NPRC system—and toward alternatives is an ideal way to address multiple concerns in one bill.**

The financial incentives described above make significant development and improvement of non-animal models unlikely without pressure from the government. The \$30 million earmarked for NHP resource infrastructure would make a significant contribution to efforts to improve alternatives and signal Congress's commitment to moving toward modern and more sustainable research methods.

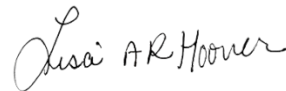
As a final point: The FY24 LHHS report also notes that the Committee “is alarmed that NIH has no central data management or reporting structure for tracking the number of NHPs required to meet current and future research needs” and therefore “directs NIH to develop a strategic management plan for NHP research resources to bolster cooperative efforts, data sharing, purposeful planning, and data-driven care and management methods.”³² The Animal Welfare Institute shares the Committee’s alarm at the lack of data management and reporting in this area, and **we support the call for a strategic management plan to address planning, data sharing and management to expand the effectiveness of use of any primates that must be used in research as alternatives are developed.** We would also ask that, as part of that process, the NIH use any new guidelines or methodological requirements as an opportunity to continue the encouragement of the use of the ARRIVE Guidelines suggested in February with Notice #NOT-OD-23-057.³³

Thank you in advance for your attention to these important issues.

Sincerely,



Joanna Makowska, PhD
Director & Senior Scientist, Applied Animal Behavior
Animals in Laboratories Program



Lisa Hoover, JD, MA, MLA
Senior Policy Advisor
Animals in Laboratories Program

¹ See USDA Animal Welfare Inspection Guide. Retrieved from

https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf

² Oregon Public Broadcasting. (2023) Primate research center in Oregon leads nation in violations. *OPB*.

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³ See USDA Citation & Notification of Penalty. Retrieved from

<https://www.aphis.usda.gov/enforcement/university-wisconsin-madison.pdf>

⁴ See USDA Inspection Reports: <https://aphis.my.site.com/PublicSearchTool/s/inspection-reports>

⁵ Portland Tribune. (2022) OHSU fined nearly \$38,000 over animal welfare violations. Retrieved from

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⁷ Ibid.

⁸ Briscoe, K. (2022) UW Primate Center destroys public records while investigated by Feds. *Lynnwood Times*.

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⁹ Ibid.

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¹¹ Seattle Times staff. (2011) UW fined in primate death. *The Seattle Times*. Retrieved from

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¹² PETA. (2022) Following PETA’s complain, University of Washington Fine \$3,750. Retrieved from

<https://www.peta.org/media/news-releases/following-petas-complaint-university-of-washington-fined-3750/>

¹³ See USDA Inspection Reports: <https://aphis.my.site.com/PublicSearchTool/s/inspection-reports>

¹⁴ See USDA Inspection Report Certificate #91-R-0001, September 12, 2023:

<https://aphis.my.site.com/PublicSearchTool/s/inspection-reports>

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- ¹⁵ See Oregon Health & Science University Inspection Report Jan. 25, 2021, Certificate # 92-R-0001: <https://aphis.my.site.com/PublicSearchTool/s/inspection-reports>
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