



July 25, 2023

The NABR Update is a news summary of federal and state government affairs, animal rights activities, and other issues related to animal research that may have a direct effect on your organization or its constituents. It's an exclusive service available for NABR members only. If your organization is interested in joining NABR or if you have any questions or suggestions, please email us at info@nabr.org.

Senate Health, Education, Labor and Pensions (HELP) Committee Addresses NHP Crisis

On July 19, 2023, Sen. Cassidy, MD, (R-LA), ranking member on the Senate HELP Committee, sent a letter to President Biden urging the administration to take immediate action on the NHP supply chain issue.

In the letter, Sen. Cassidy raised concerns that the shortage of monkeys will delay the development of drugs, reduce access to essential medications, and result in rising costs for American patients. He also expressed concerns that manufacturers will turn to other countries, like China, to conduct time-sensitive research on drugs to make up for the United States' monkey shortage.

Senator Cassidy wrote, *"While our country seeks to reduce the need for animal testing over the long term, such testing is still critical to ensuring that patients have safe, effective drugs. We cannot cede global leadership in biomedical*

research to China by allowing China to establish a near-monopoly on non-human primate research. It is imperative that the White House ensure that all relevant agencies are coordinating to solve this problem, and that these agencies are transparent with Congress about their efforts.”

NABR applauds these efforts and will continue working with stakeholders and Congress to find solutions to the NHP crisis impacting life-saving biomedical research.

The letter can be accessed [here](#).

BACKGROUND: Following a decision by U.S. Fish and Wildlife Service (FWS) to deny permits for non-human primates (NHPs) used for essential research, NABR began working with stakeholders to educate members of Congress and highlight the gravity of the situation.

Without continued access to NHPs for research, the United States biopharmaceutical pipeline will slow down significantly and impair research and scientific advancements. There are estimated to be 17,752 individual products currently in the U.S. R&D pharmaceutical pipeline, accounting for 47% of the global R&D pipeline. Of these, it is estimated that 56% have used or will require the use of NHPs during their development.

If NHPs are no longer available, these preclinical drug projects may grind to a halt- this includes drugs for cancer, diabetes, and neurodegenerative diseases, as well as vaccines.

FEDERAL

House Rules Committee Set to Mark Up Two Appropriations Bills

This week, the House Rules Committee plans to approve two spending measures with amendments. The Military Construction, Veterans Affairs, and

Related Agencies Appropriations Act, 2024 and Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2024 will then go to the House floor for consideration.

Both spending bills are accompanied with report language directing the agencies on how Congress intends the funds to be used. Below is a breakdown of report language impacting animal research.

[Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2024](#)

Research Using Animals.—The Department is directed to include in any report to Congress describing animal research approved under Section 247 in Division J of the Consolidated Appropriations Act, 2023 (P.L. 117–328), submitted after the date of filing of this report, details on the specific alternatives to animals that were considered, why those alternatives were not chosen, and an explanation for why these animal subjects were the only viable option for this research. Also, the Committee looks forward to the Department fully implementing its plan to eliminate or reduce the research conducted using canines, felines, or non-human primates in 2024, as directed in Public Law 116–94.

[Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2024](#)

Animal Research- The Committee directs ARS to ensure that each of its facilities housing animals is adhering to the Animal Welfare Act at all times and to submit quarterly reports that include both all violations found by APHIS

during that quarter and the specific actions that will be taken to prevent their recurrence.

Animal Welfare Act- The Committee supports a collaborative approach between APHIS and licensees involving education, training, and outreach to improve the care of animals. The Committee directs APHIS to initiate a scientific evaluation of the impact of “teachable moments” on animal welfare within 90 days of enactment of this Act.

Emergency Preparedness and Response- The Committee continues to provide funding for the Animal Care Program to coordinate with the Federal Emergency Management Agency on the National Response Plan and to support State and local governments’ efforts to plan for protection of people with animals and incorporate lessons learned from previous disasters. The Committee maintains the 2023 funding levels to support hazard preparedness and response for zoos and aquariums, and implementation of emergency contingency plans for all facilities regulated under AWA.

New Alternative Methods- The Committee directs FDA to efficiently and expeditiously utilize existing funds to reduce animal testing and advance alternative methods in a measurable and impactful way. The Committee requests a report within 90 days of enactment of this Act which provides details on the status of forming the New Alternative Methods Program in the Commissioner’s office. Such report should include, but is not limited to, a description of program goals and staffing levels by position classification; FDA’s priority areas for reducing animal use and advancing alternatives, including goals, timelines, and funding associated with each of these identified priorities; the metrics the agency will use to measure impact; and how the agency will communicate information regarding acceptance of alternative methods to the

regulated community. The agency should, where applicable, minimize funding to carry out new animal testing, including in comparing the use of animals to alternative methods, but instead use existing animal data and alternative methods that will reduce animal use in research.

Cease Animal Research Grants Overseas (CARGO) Act Introduced in Congress

On July 19, 2023, Congresswoman Titus (D-NV-1) introduced the CARGO Act, which amends the Public Health Service Act to prohibit the National Institutes of Health from awarding any support for an activity or program that involves live animals in research unless the research occurs in the United States.

Congresswoman Titus said in a statement, "By onshoring these experiments and instituting more stringent regulations of the NIH's experimental contractors, we can stop funding cruelty to innocent animals and restore integrity to this critical component of our national scientific research."

The bill is lobbied and supported by the People for the Ethical Treatment of Animals (PETA).

More information is available [here](#).

Senators Introduce the Worldwide Animal Testing Compliance and Harmonization (WATCH) Act of 2023

On July 24, 2023, Sen. Schmitt (R-MO) and Sen Merkley (D-OR) introduced the WATCH Act to amend section 495 of the Public Health Service Act to require inspections of foreign laboratories conducting biomedical and behavioral research to ensure compliance with applicable animal welfare requirements.

The WATCH Act:

- Requires foreign laboratories to meet the same animal welfare requirements as domestic laboratories to qualify for NIH funds.
- Foreign labs must submit to quarterly site inspections to ensure their continued compliance with animal welfare requirements.
- The NIH provides \$220 million per year in grants to foreign organizations for research projects involving animals.
- Unchecked animal testing in foreign nations often contributes to the formation and propagation of new diseases.
- U.S. labs conducting research involving live animal subjects require proper care for animal subjects, clean cages, and on-site veterinarians. There are no such requirements for foreign labs.

More information is available [here](#).

Senate Appropriations Committee Scheduled to Markup Labor, Health and Human Services Bill

The full Senate Appropriations Committee is scheduled to markup its version of the FY24 Labor, Health and Human Services, Education, and Related Agencies Appropriations Act on Thursday, July 27, at 10:30am. This appropriations bill funds the Department of Health and Human Services and likely contains report language on animal research.

More information and a link to view the markup can be found [here](#).

NIH Seeks Input on Challenges and Opportunities for the Further Development and Use of Novel Alternative Methods

As previously reported the National Institutes of Health (NIH) is [seeking public input](#) on challenges and opportunities for the further development and use of novel alternative methods (NAMs) in biomedical research. Input received from

this request will inform the NIH and the development of the Advisory Committee to the NIH Director (ACD)'s recommendations on high-priority areas for future investment in NAMs.

The NIH is requesting information in three specific areas:

- The use of novel alternative methods to study human biology, circuits, systems, and disease states.
- Approaches for catalyzing the development and validation of novel alternative method technologies.
- Strategies for maximizing the research of novel alternative method technologies.

Comments on the Request for Information must be submitted by Aug. 16, 2023, through the online comment portal found [here](#). The ACD Working Group on Novel Alternative Methods will also be hosting an expert workshop on Aug. 21, 2023. The agenda for this meeting along with videocast information will be posted to the OSP website later this summer.

For additional context on the NAMs issue, please see the latest *Under the Poliscope* blog [here](#).

Questions may be sent to SciencePolicy@od.nih.gov.

NABR encourages those with specific knowledge in these three areas or other areas involving the use of NAMS in biomedical research to provide feedback to the ACD working group.

A recently submitted comment by Dr. Ed Levin, Professor of Psychiatry and Behavioral Sciences at Duke University Medical Center, highlights the continued need for animal models to advance biologic research for improving human health.

Dr. Levin's comments can be viewed [here](#).

APHIS Announces New Animal Care Deputy Administrator and Program Review

On July 18, 2023, the USDA's Animal and Plant Health Inspection Service (APHIS) announced that Dr. Roxanne Mullaney will be APHIS Animal Care's new deputy administrator effective immediately. She's been acting in this position since May 2023, when the previous deputy administrator, Dr. Betty Goldentyer, retired. Prior to that, Dr. Mullaney served as Animal Care's associate deputy administrator.

Dr. Mike Watson, acting APHIS administrator, shared the following statement on Dr. Mullaney's new role. "We are excited about this review and know that many of you have thoughts and ideas about enforcement of the Animal Welfare Act and the Horse Protection Act. We look forward to exploring possible opportunities to have you, our stakeholders and partners, as a part of this process. Until then, please join me in welcoming Dr. Mullaney to this new role."

The full announcement is available [here](#).

OLAW Fall Webinar to be Held on September 14, 2023

OLAW will be hosting a fall webinar to explore the [NC3Rs Experimental Design Assistant](#) (EDA).

The EDA helps users build a diagram representing an experimental plan, provides customized feedback, and can make suggestions on statistical methods, randomization, blinding, sample sizes, and other critical design aspects. Dr. Esther Pearl, NC3Rs Program Manager for Experimental Design, will discuss how the EDA can assist research staff, how it can simplify protocol review for IACUCs, and will demonstrate features of this free resource.

This webinar will be held on Sept. 14, 2023, from 1-2 p.m.

More information and registration for the webinar can be found [here](#).

ANNOUNCEMENTS

Lasker Foundation Announces Winners of the 2023 Young Scientist Essay Contest - Addressing Ethics in Biomedical Research

The Lasker Foundation recently chose five winners of its 2023 essay contest on addressing ethics in biomedical research. The winning submissions were selected from hundreds of essays written by biomedical graduate students and health profession trainees from 25 countries. The winning students explored unanticipated ethical issues encountered during their training and strategies used to address them.

The 2023 Lasker Foundation Essay Contest Winners include:

- **Allison Chen / Cornell University**, “Training in an AI World” – asks whether AI will boost productivity or quash the ability of young scientists to complete fundamental tasks on their own.
 - **Louise O. Downs / University of Oxford**, “Is a Test Better Than No Test When There Is No Treatment?” – weighs the pros and cons of searching for a diagnosis when there is no possibility of treatment.
 - **Ayush Kumar / University of Massachusetts Chan Medical School**, “Using HG1222; A Perspective into the Ethics of Collecting Biospecimens” – shares the story of how a patient encounter challenged his understanding of patient consent for research.
 - **Salman E. Qasim / Icahn School of Medicine at Mount Sinai**, “The Human Brain: The Final Frontier, and the Wild West” – wonders if researchers are using the best methods to recruit patient volunteers for their studies.
 - **Sneha Rath / Harvard Medical School / Mass General Hospital/ Broad Institute of MIT and Harvard**, “Cementing the Bricks” – grapples with how scientists can ensure that results are reproducible and how best to proceed when findings are not what they seem.
-

As part of a recently announced three-year partnership with The Journal of Clinical Investigations (JCI), the winning essays will be published by JCI and Lasker in tandem, allowing for expanded visibility within the broad, international biomedical research community.

This year, the Foundation selected five winners from 280 submissions. Each winner will receive a \$5,000 stipend to offset educational expenses. Topics included the use of artificial intelligence (AI) in biomedical research, scientific reproducibility, appropriate use of diagnostic testing and issues of patient recruitment and consent.

Each year the Essay Contest invites young scientists – medical, biomedical, and other health profession trainees to discuss big questions in biomedical research and policy. The 2023 contest was open to medical school students, interns, residents, and fellows; doctoral students and postdoctoral fellows in biomedical sciences; and graduate students in public health or other health professions programs from around the world.

The winning essays are available on the [Lasker Foundation website](#) and within [JCI's July 17 issue](#).
