

August 07, 2024

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.

NHP Update

NABR President Matthew Bailey Represents Biomedical Research at the 33rd CITES Animals Committee Meeting

The 33rd CITES Animals Committee Meeting was held in Geneva, Switzerland July 12-19, where the Long-Tailed Macaque (LTMs) was a topic of discussion. NABR President Matt Bailey made parties to the convention aware of NABR's recent challenge to the International Union for the Conservation of Nature's (IUCN) Red-List claiming the species is "endangered" and highlighted the fact that the organization has now issued a reassessment of the species in response to NABR's concerns. A review of trade with LTMs in range states has been ongoing for numerous years now. Having supplied the Animals Committee with sufficient scientific data on the species, Indonesia was voted to be removed from the review process, signaling no concerns about the species in that country. Meanwhile, a trade embargo remains in place for Laos relative to the LTM and many other species. However, delegates from the U.S., Canada, and Europe requested that LTMs remain under review for the countries of Vietnam, Philippines and Cambodia. U.S. delegates expressed concerns about the high number of LTMs produced by Cambodia during the COVID crisis, to which Cambodia rebutted on the floor and agreed to submit a written explanation to the committee. According to the chair of the Animals Committee, once Cambodia provides their explanation it is possible the country could be removed from the review process at the CITES Standing Committee meeting in February of 2025.

FEDERAL

House Lawmakers Send Letter to the Dept. of Defense on Dog Testing

On July 26, 2024, Congresswoman Young Kim (D-CA-40) and Congressman Don Davis (D-NC-01) led a bipartisan letter to Department of Defense (DOD) Secretary Lloyd Austin requesting information on animal research with dogs and cats at the DOD. This letter, signed by 25 members of Congress, is part of a campaign backed by animal rights group White Coat Waste Project (WCW) to end research with dogs and cats at various federal agencies.

In the letter, lawmakers question the need for continued studies with dogs and cats for research and push for the use of alternative models. Specifically, the letter asks the secretary to provide Congress with the following information.

1. Dog testing details:

- Is the beagle testing ordered under contract number HT94252310580 still underway? If so, when is it scheduled to be completed? If not, when did it end?
- How many beagles have been used in this testing to date? How many more beagles are planned to be used for the completion of this project?
- How many beagles were euthanized? What kind of euthanasia methods were used (Please list all methods)?
- Were the dogs used in this testing debarked?

• What USDA pain category is this testing classified in?

2. **Dog testing justification**: The FDA states that it does not mandate dog testing for human drugs. Did the FDA specifically request that the DoD conduct this 13-week dog test? Did the DoD explore alternatives? Please provide written documentation.

3. **Other DOD dog and cat testing**: Please list all current grants, contracts and other spending for the use of dogs and cats in testing and research and well as those over the past 5 years.

4. **Dog and cat testing alternatives**: Is the DoD allowing animal testing alternatives? If so, please describe any current DoD efforts to promote and adopt animal testing alternatives.

Congresswoman Kim's press release can be seen here.

The full letter is available here.

Update: FY25 Appropriations Bills

The Senate returned to Washington, D.C. last week to continue consideration of fiscal year 2025 appropriations bills to fund the federal government. On August 1, 2024, the Senate Appropriations Committee passed four appropriations bills including its version of the Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS) Appropriations bill. The Labor-HHS bill provides funding for NIH and contains language pertaining to biomedical research.

The following appropriations bills are accompanied by report language that contains more detailed guidance for federal departments and agencies to spend the congressionally directed funds. Although report language does not have the binding effect of law, it is generally followed by agencies who depend on funding from Congress. Below is an update on the report language impacting animal research in the Senate's pending FY25 appropriations bills.

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Animal Research—The Committee directs ARS to provide a report on steps the agency can take to transition away from animal research.

Animal Care—The agency conducts regulatory activities that ensure the humane care and treatment of animals and horses as required by the Animal Welfare Act (Public Law 89–544) and Horse Protection Acts (Public Law 91–540). These activities include inspection of certain establishments that handle animals intended for research, exhibition, and as pets, and monitoring certain horse shows.

Animal Welfare—The Committee is concerned about APHIS's Animal Care program and the steep decline in enforcement related to violations of the Animal Welfare Act and provides an increase of \$3,000,000 to address these concerns. The Committee urges the agency to reform its current licensing and enforcement scheme. While the agency took steps towards this goal over the last year, the Committee believes more progress can be made. This includes, but is not limited to: ensuring consistent, thorough, unannounced inspections on a regular basis; ensuring each failure to allow access for inspection and each violation or failure to comply with animal welfare standards is documented on an inspection report; and, requiring that inspection reports which identify violations or failures of compliance be shared with relevant local, State, and Federal agencies.

The Committee continues to encourage APHIS to use its full enforcement capabilities under the AWA against chronic violators of the AWA. The Committee directs the agency to update the Committee within 60 days of enactment of the Act on AWA enforcement activities, including the number of cases referred to the Office of the General Counsel, the Department of Justice, or both, when ap propriate. The Secretary of Agriculture shall continue the March 2024 memorandum of understanding with the U.S. Attorney General to encourage greater collaboration on Animal Welfare Act enforcement and ensure that the Department of Justice has access to evidence needed to initiate cases.

Inspection of Research Facilities—The Committee is aware that Veterinary Medical Officers [VMOs] and Improved Training for Institutional Animal Care and Use Committees [IACUC] members play a significant role in the administration of animal protection programs at research facilities. Therefore, proper training of such 51 personnel is essential. The Committee directs APHIS to provide on- demand, publicly available training for IACUC members and VMOs on how to perform adequate inspections of research facilities. The training should inform VMOs and IACUC members, as relevant to their respective roles in providing oversight of research facilities, how to review, monitor, and approve research facilities' protocols; verify the accuracy of annual reports submitted by research facilities to confirm the correct number of animals used in every experiment and that animals are reported in the correct pain category; and review and monitor experiments performed on animals by research facilities to ensure the humane care and use of animals in compliance with the AWA and IACUC-approved protocols.

National Animal Health Laboratory Network—The Committee provides no less than the fiscal year 2024 level for the National Animal Health Laboratory Network.

Animal Testing—The Committee directs FDA to efficiently and expeditiously utilize existing funds to replace, reduce, and refine animal testing and advance new alternative methods [NAMs] in a measurable and impactful way. The

Committee encourages FDA to support NAM's. This program is responsible for furthering the development, qualification, and implementation of alternative methods for regulatory purposes. The agency is further directed to provide to the Committee within 90 days of enactment a report on the status of work within the NAM's Program in the Commissioner's office, including a description of program goals and staffing levels by position classification. To encourage the use of NAMs by industry, the Committee directs FDA to determine whether any changes to its regulations may be warranted to make clear to the extent such studies are not scientifically necessary that animal tests are not required to support clinical testing in humans. The Committee strongly recommends prioritizing the acceptance of alternative methods in developing and evaluating drugs and biological products wherever appropriate and scientifically feasible. The agency should, where applicable, minimize funding to carry out new animal testing, including to compare the use of animals to alternative methods, and use existing animal data and alternative methods that will reduce animal use in research when human data is not available.

Predictive Toxicology Roadmap Guideline Studies—The Committee supports activities to implement goals set in the Predictive Toxicology Roadmap. However, the Committee is concerned that funding intended to advance New Approach Methodologies [NAMs] and reduce animal testing for product development will be used to conduct new animal tests for comparative guideline studies. While it is important to ensure that novel methods can be relied upon for product development and regulatory decision-making, the Committee encourages FDA to first consider the use of human data or existing animal study data in this comparative assessment, when feasible, to remain aligned with the intentions of the roadmap and animal testing reduction, refinement, and replacement goals. The Committee directs NCTR to prioritize use of existing human data, or existing data from animal tests conducted prior to enactment of this act when scientifically appropriate, when collaborating with other FDA Centers and the National Toxicology Program data if appropriate.

Commerce and Justice, Science and Related Agencies

Animal Welfare Act Enforcement—The Committee supports the Memorandum of Understanding issued on March 8, 2024, between DOJ and the U.S. Department of Agriculture [USDA] and their joint commitment to enforcing the Animal Welfare Act [AWA]. The Department is directed to continue coordinating and collaborating with USDA on AWA enforcement cases to ensure the DOJ receives necessary information regarding AWA violators, who have multiple citations for conduct that seriously or adversely affects the health or well-being of an animal, in a timely manner. The Department shall report to the Committee, within 90 days of enactment of this act, on its AWA enforcement actions.

Interior, Environment, and Related Agencies

Wildlife Trafficking—The Service plays a critical role in the ongoing effort to combat the global crisis of wildlife poaching and trafficking, which escalates the risk of animal-to-human disease transmission and is driven by demand for highvalue illegal wildlife products, facilitated by sophisticated criminal networks profiting from this multi-billion dollar black market industry. Poaching of rhinoceros, pangolin, loris, and elephants has reached unprecedented levels, and illegal trade is undermining the conservation of scores of other species. The Committee continues to support government-wide efforts to combat wildlife trafficking. The bill maintains resources that will support the Service in continuing to strengthen its forensic capabilities to disrupt smuggling networks; improve collaboration with other Federal, State, local, and foreign governments; and promote international wildlife conservation. The Committee remains concerned about the global health risk from wildlife to human disease transmission, particularly in light of recent national health emergencies.

Labor, Health and Human Services, and Education, and Related Agencies

Research with Non-Human Primates [NHP]—The Committee recognizes the critical role of NHP research in virtually all areas of biomedical research. Research with unique animal models makes irreplaceable contributions to understanding the biological processes that cause disease, which is necessary for the development, safety and efficacy testing of new therapeutics before clinical trials. NHP research will be vital to studying both the underlying mechanisms and potential cures for existing and emergent diseases. NHP research remains critical to understand the causes of degenerative and brain diseases and to improve the effectiveness of new compounds and nonpharmaceutical treatments such as deep brain 153 stimulation and neuromodulation. The Committee urges NIH to award funding to meritorious research proposals to study these neurodegenerative disorders, including studies that utilize NHPs. NIH is also encouraged to continue the development and validation of new approach methodologies as promising technological advancements that enhance the utility of NHP models and may reduce the need for models in the future.

Primate Research Centers—The Committee includes \$30,000,000 in funding to remodel, renovate, or alter existing research facilities or construct new research facilities for non-human primate re source infrastructure, as authorized under 42 U.S.C. section 283k.

Novel Alternative Methods—The Committee is aware that ARPA–H's programs, many of which encompass a wide range of biomedical research,

utilize both animal and non-animal research methodologies. Each program is led by a Program Manager [PM] who oversees multiple groups of performers who aim to solve the same problem through unique approaches. Acknowledging ARPA– H's operational model, the Committee urges ARPA–H to require performers to specify expected use of animals and novel alternative methods [NAMs] in their proposals, if known. ARPA–H shall aggregate this data for anticipated awards and information from the Vertebrate Animal Section submissions (required by the Office of Laboratory Animal Welfare) into a comprehensive annual report that reflects the methodologies used across their programs, including descriptions and rationale for animal models and NAMs used. This report shall be submitted to the Committee and made publicly available within 90 days following the conclusion of each project year. This activity will ensure accountability and transparency across ARPA–H, fostering ethical research practices while advancing biomedical innovation.

New Approach Methodologies—The Committee supports the NIH Common Fund's Complement Animal Research In Experimentation [Complement-ARIE] Program, intended to spur the development, standardization and use of new approach methodologies [NAMs] in tend to more accurately model human biology. The Committee also encourages NIH, in new Announcements and other indications of funding opportunities, to continue consideration of NAMs as an option for areas of preclinical research when it is not appropriate to use human participants and where the use of NAMs has been demonstrated to support biomedical discoveries. The Committee further encourages NIH to collect and make publicly available a report that outlines how the use of vertebrate animal models in agency research contributes to the mission of NIH as well as efforts by the agency to encourage the use of new approach methods or strategies. This report should include examples of how other methods have been used in NIH research to reduce, replace, and refine the number of animals used in research.

Cephalopod Research—The Committee recognizes that there are no federally required welfare standards for the use of cephalopods in federally-funded research because all invertebrate animals are excluded from the Public Health Service [PHS] Policy on the Hu mane Care and Use of Laboratory Animals, which provides certain welfare standards for vertebrate animals. The Committee recognizes that implementing and complying with the PHS Policy re quires reference to guidelines in the Guide for the Care and Use of Laboratory Animals (the Guide), which does not currently include cephalopod-specific welfare guidelines, and updates to which are overseen by the National Academies of Sciences, Engineering, and Medicine [NASEM]. The Committee appreciates NIH's efforts to consolidate resources and possibly develop guidance for the hu mane care and use of laboratory cephalopods; however, this guidance will not be a sufficient substitution for the PHS Policy in establishing welfare standards for cephalopods and will be temporary until cephalopod quidelines are included in the Guide and until the PHS Policy definition of "animal" is updated to include cephalopods. The Committee urges NIH to continue working with NASEM on this issue and urges NIH to consider expanding the definition of "animal" in the PHS Policy to include cephalopods if the Guide is updated and permanent guidelines are in place.

Military Construction, the Department of Veterans Affairs, and Related Agencies

Sunset Provision in Bill Text: (g) The Department shall implement a plan under which the Secretary will eliminate the research conducted using canines, felines, or non-human primates by not later than 2 years after the date of enactment of this Act. More information is available here.

ANIMAL RIGHTS NEWS

Financial Update: Animal Rights Groups Raise Big Money

Each year, tax-exempt organizations are required by law to submit a Form 990 to the IRS. This form provides the public with information about a nonprofit organization and is used by government agencies to prevent organizations from abusing their tax-exempt status. NABR recently examined the latest available Form 990s for top animal rights organizations. The amount of funding these groups raise is shocking. These funds are often used to target animal research and move toward the goal of ending animal use across many industries. The breakdown of annual revenue and total assets by each organization are as follows.

Total Top Players' Annual Revenue: More than \$830,200,000

- American Society for the Prevention of Cruelty to Animals (\$389M)
- Humane Society of the United States (\$259.5M)
- People for the Ethical Treatment of Animals (\$68.2M)
- Humane Society International (\$23M)
- Foundation to Support Animal Protection (\$22.9M)
- Physicians Committee for Responsible Medicine (\$16.3M)
- Animal Legal Defense Fund (\$15.1M)
- Humane Society Legislative Fund (\$14.3M)
- Animal Welfare Institute (\$7.4M)
- National Anti-Vivisection Society (\$3.5M)
- White Coat Waste Project (\$3.1M)
- Beagle Freedom Project (\$2.6M)
- Nonhuman Rights Project (\$1.6M)
- American Anti-Vivisection Society (\$1.4M)
- Animal Wellness Action (\$1.2M)
- Direct Action Everywhere (\$0.6M)
- International Foundation for Ethical Research (\$0.3M)
- Stop Animal Exploitation Now! (\$0.2M)

Total Top Players' Assets: More than \$1.1 Billion

- American Society for the Prevention of Cruelty to Animals (\$508M)
- Humane Society of the United States (\$418.7M)
- Foundation to Support Animal Protection (\$34.1M)
- American Anti-Vivisection Society (\$33.8M)
- People for the Ethical Treatment of Animals (\$25.1M)
- Animal Welfare Institute (\$19.5M)
- Animal Legal Defense Fund (\$16.8M)
- Physicians Committee for Responsible Medicine (\$11M)
- National Anti-Vivisection Society (\$10.8M)
- Humane Society Legislative Fund (\$10.5M)
- Beagle Freedom Project (\$3.5M)
- Nonhuman Rights Project (\$3.1M)
- White Coat Waste Project (\$2.2M)
- Humane Society International (\$1.8M)
- Stop Animal Exploitation Now! (\$1.3M)
- Animal Wellness Action (\$1M)
- International Foundation for Ethical Research (\$.8M)
- Direct Action Everywhere (\$0.3M)

ANNOUNCEMENTS

NABR Webinar: "Current and Future Challenges Facing Biomedical Research"

Please join us on Tuesday, Oct. 8, at 12:30 p.m. EST for the 61st NABR webinar when Matt Bailey, President of NABR and FBR; Brandon Morton, NABR's Director of Government Affairs; and Taylor Bennett, NABR's Senior Scientific Advisor, sit down to discuss the "Current and Future Challenges Facing Biomedical Research." NABR is the only national nonprofit organization dedicated solely to advocating for sound public policy that recognizes the vital role animals play in biomedical research. In that role, NABR provides the unified voice for the scientific community on legislative and regulatory matters affecting laboratory animal research at the federal level. FBR provides valuable communication expertise promoting public understanding and support for biomedical research to address the challenges and variety of tactics used by those opposed to animals in biomedical research. These tactics include calling into question the validity of animal models, the money spent to support that research, an increased number of legislative efforts at the federal, state and local level and targeted campaigns against specific areas of research. In addition, these groups have effectively weaponized the use of FOIA and state open records acts to target institutions and individuals. In this webinar, recent legislative and regulatory issues will be reviewed, and animal rights campaigns will be highlighted to share lessons learned for addressing the challenges facing the research community.

Registration is available here.

Lasker Foundation Announces Winners of 2024 Essay Contest

On July 25, 2024, the Lasker Foundation announced five winners of its annual essay contest. These essays were submitted by biomedical graduate students and health profession trainees. The topic of the essay contest was to identify a specific unmet need in biomedical knowledge or a scientific question that is insufficiently addressed in biomedical research today.

The 2024 Lasker Foundation Essay Contest Winners:

- Kevin S. Blake / Washington University School of Medicine in St. Louis, "Missing Microbiomes: Global Underrepresentation Restricts Who Research Benefits" – calls for diversification of populations surveyed in microbiome research.
- Catherine M. Bridges / Medical University of South Carolina; Lexington Medical Center, West Columbia, "Illuminating Maternal Sepsis: A Call for Improved Recognition and Prevention" – argues for increased research on maternal sepsis, the third-leading direct cause of maternal mortality.
- Andrea M. Maxwell / University of Minnesota Medical School, "What Happens to the Brain During Pregnancy?" advocates for more neuroscience research about brain function during pregnancy.
- Subashan Vadibeler / University of Leeds; University of Oxford, United Kingdom, "The (Unresolved) Antibody Paradox" – calls for deepened understanding of antibody-dependent enhancement, as antibody-based therapies become more prevalent treatments against existing and emerging infections.
- Sarah Voss / Johns Hopkins Medical Institute, "The Enemy of My Enemy Is My Friend" – imagines a future in which bacteriophages are used as therapeutics against antibiotic-resistant infections.

More information is available here.

IACUC Administrators Association Best Practice Meeting- In Person

The IACUC Administrators Association (IAA) is announcing open registration for a face-to-face, immersive one-and-a-half-day professional development opportunity designed specifically for Animal Care and Use Program (ACUP) professionals. The "IACUC Administrators Best Practice Meeting: The Essentials" will focus on the core requirements and best practices for using vertebrate animals in research, instruction, and testing activities. This program will cover key regulatory frameworks, ethical considerations, and administrative responsibilities to ensure compliance and promote excellence in animal care and use programs. Participants will engage in interactive discussions and networking opportunities to enhance their understanding and the implementation of regulations governing the care and use of vertebrate animals in research, teaching and instruction. Attendance will be limited to approximately 35 individuals.

Aug. 15-16, 2024 | Cincinnati, OH | In-person

Attendees are encouraged to identify specific topics that they would like to discuss during the registration process (or send Bill Greer an email at (wggreer@umich.edu).

Registration is available here.

11th Annual 3Rs Symposium: Practical Approaches to Each of the 3Rs

This symposium will focus on reduction, refinement, and replacement methods to improve laboratory animal welfare while maintaining or improving scientific results. Sessions will discuss opportunities to do more with less, refinement techniques for research involving pain and distress, and how to use the 3Rs to improve efficiency and rigor. The goal of the symposium is to bring together experts and practitioners to share information and discuss new and practical approaches to the 3Rs.

Sept. 4-5 and 11-12 | 10:00 a.m. – 1:30 p.m. ET | Virtual

The symposium will take place over four days and is jointly organized by:

- The Center for Alternatives to Animal Testing, Johns Hopkins University Bloomberg School of Public Health
- The Department of Molecular and Comparative Pathobiology, Johns Hopkins University School of Medicine
- The USDA's Animal Welfare Information Center (AWIC) at the National Agricultural Library
- The Office of Laboratory Animal Welfare (OLAW), National Institutes of Health.

Registration is available <u>here</u>.

Register Now for the Winter 2024 SCAW Annual Winter Conference

Registration is open for the Scientists Center for Animal Welfare (SCAW) winter conference. SCAW two-day conferences provide key findings and advances in research animal welfare, explore policy and management issues related to IACUCs and develop awareness of humane care and use of agricultural animals in research. Topics to be discussed include:

- New Approach Methodologies (NAMs): Beyond the Buzz Applications and Impact
- Can Virtual Technology Lessen the IACUC Burden
- Legal Tips for Internal Compliance and External Reporting to Federal Agencies: What to Do and What Not to Do
- Are You Up to Date with OLAW, APHIS and AAALAC International: Q & A for You and Me
- Extrinsic Factors: Can We Talk About the People Problem
- Lights, Vibration, and More: How Extrinsic Factor Affect the Animals in the Research Facility
- The Intersection of Non-Compliance and Research Misconduct: Going From Bad to Worse
- Sound Public Policy

Dec. 9-10, 2024 | San Antonio, TX | In-Person

Early registration ends Oct. 15, 2024. The hotel deadline is Nov. 15, 2024. Registration is available <u>here</u>.

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