



July 12, 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.

NABR Files Petition Challenging the Listing of Long-Tailed Macaque by IUCN

Working with recognized, independent scientists, the National Association for Biomedical Research (NABR) filed a petition with the International Union for Conservation of Nature (IUCN) challenging the recent designation of the long-tailed macaque (*Cynomolgus macaque*) as endangered under IUCN listing criteria. This designation is a result of improperly used data that do not support species listing as endangered. NABR calls for an immediate review.

National Association for Biomedical Research President Matthew R. Bailey said:

“Nonhuman primates make up less than 0.5% of all animals in research, yet they play a critical role in developing new drugs, devices, and vaccines for people and for pets. Tens of thousands of drugs and therapeutics may never make it through the research and development pipeline without long-tailed macaques in research. The listing of long-tailed macaques and any ensuing importation restrictions must be based on the best available scientific evidence. Arbitrary restrictions imposed on the importation of long-tailed macaques could jeopardize millions of human lives and threaten global public health.”

“The listing of the long-tailed macaque as endangered by the IUCN sets a dangerous precedent because this determination is not based on peer-reviewed scientific information. This is particularly troubling because arbitrary actions like this make life-saving medical research even more difficult to conduct in the U.S. and other countries.”

The IUCN assessment completed in 2022 fails to present scientific evidence supporting the reclassification of the long-tailed macaque from vulnerable to endangered. The IUCN assessment contains numerous errors and misstatements and does not provide actual evidence of species declines compared to past evaluations.

Nonhuman primates are currently irreplaceable in neuroscience, neurodegenerative disorders, infectious diseases, immunotherapy, reproduction, aging, chronic inflammatory disease, and other areas of science. Since nonhuman primates and humans share between 93% and 98% of the same DNA, have similar brain anatomies, and share similar body systems, they are a key to biomedical research discoveries that yield new drugs, vaccines and biologics. The overwhelming majority

of drugs on the market today relied on safety and efficacy data from multiple animal models before being allowed to move to human clinical trials as demonstrated by the Foundation for Biomedical Research's top 25 drugs and animal models study.

BACKGROUND

Long-tailed macaques are used extensively in medical research to develop drugs in the United States. The National Academies report on Nonhuman Primate Models in Biomedical Research: State of the Science and Future Needs (2023) emphasizes that animal testing followed by human clinical trials currently remains the best way to examine complex physiological, neuroanatomical, reproductive, developmental, and cognitive effects of drugs to determine if they are safe and effective for market approval. The major regulatory agencies across the world, including the U.S. Food and Drug Administration and the European Medicines Agency, require most new drugs and biologics to be evaluated for measures of safety and efficacy with rodent and non-rodent animal models, including nonhuman primates before human clinical trials can safely begin.

On March 7, 2022, the IUCN determined that the long-tailed macaque should be considered "endangered" under IUCN criteria. The basis for this determination is outlined in an assessment completed by M.F. Hansen and other contributors (Hansen et al. 2022).

On June 15, 2023, NABR filed a petition with the IUCN challenging the change in listing status. Scientists involved in drafting the petition note the lack of data to support the recent status determination. In its review of Hansen et al. (2022), the petition notes that the scientific literature referenced is often misinterpreted

and such information does not demonstrate that the long-tailed macaque has declined.

The filing of this petition by NABR triggers a scientific review by the IUCN. During this review, scientists will review the best available scientific information to determine the status of the long-tailed macaque under IUCN criteria. At the conclusion of this process, the IUCN will announce its findings and any changes in listing status.

FEDERAL

President Biden Taps Dr. Mandy Cohen to be the Next CDC Director

On June 16, 2023, President Biden announced that Dr. Mandy Cohen will be the next director of the Centers for Disease Control and Prevention.

During his announcement, President Biden stated, “Dr. Cohen is one of the nation’s top physicians and health leaders with experience leading large and complex organizations, and a proven track record protecting Americans’ health and safety.”

Dr. Cohen will replace outgoing CDC Director Dr. Rochelle Walensky at the beginning of July.

The White House press release is available [here](#).

Additional information on Dr. Cohen can be found [here](#).

Senate Appropriations Committee Begins Marking Up Funding Bills for FY24

On June 22, 2023, the full Senate Committee on Appropriations began marking up bills to fund the federal government through fiscal year 2024. The business meeting included allocating funding for all 12 appropriations subcommittees, along with advancing the Military Construction, Veterans Affairs, and Related Agencies and Agriculture, Rural Development, Food and Drug Administration, and Related Agencies funding bills.

The Senate Appropriations Committee will hold the next business [meeting](#) on July 13 at 11 am to markup the Legislative Branch Appropriations Act, Commerce, Justice, Science, and Related Agencies Appropriations Act, and the Financial Services and General Government Appropriations Act.

A summary of the Ag/FDA bill is available [here](#).

A summary of the MilCon/VA bill is available [here](#).

New Updates to the OLAW Guidance Disclaimer

OLAW is seeking feedback from the public on a proposed revision to its [current guidance disclaimer](#). OLAW's review of the disclaimer was one of the action items identified by the research community and described in the 21st Century Cures Act final report, [Reducing Administrative Burden for Researchers: Animal Care and Use in Research](#). The proposed revision is now available for public comment through a [Request for Information \(RFI\)](#). The final text will be published once comments have been considered.

Comments will be accepted from July 11, 2023, to October 22, 2023. Click [here](#) to submit comments.

More information is available [here](#).

OLAW Seeks Feedback on Proposed Guidance for Streamlining Protocol Reviews

As part of the 21st Century Cures Act, OLAW committed to reviewing and revising the guidance for streamlining protocol reviews and significant changes to reduce administrative burden. The proposed revisions are now available for public comment through a [Request for Information \(RFI\)](#). The final guidance will be published along with a new webpage once comments have been considered.

Comments will be accepted from July 11, 2023, to October 11, 2023. Click [here](#) to submit comments.

More information is available [here](#).

STATE

Pennsylvania Bill Introduced to Create an Animal Welfare Board

On June 14, 2023, Pennsylvania state Sen. Gene Yaw reintroduced the Animal Welfare Board Act, a bill to establish an Animal Welfare Board in the Commonwealth of Pennsylvania.

Specifically, this legislation would create an 18-person Animal Welfare Board to review laws and regulations in the state relating to animal welfare. The board would be made up of Pennsylvania residents from each of the following:

- i. The University of Pennsylvania School of Veterinary Medicine
- ii. The College of Agricultural Sciences of the Pennsylvania State University
- iii. The American Kennel Club
- iv. The Federated Humane Societies of Pennsylvania
- v. The Northeast Beagle Gundog Federation
- vi. The Pennsylvania Society for the Prevention of Cruelty to Animals

- vii. The Pennsylvania Farm Bureau
- viii. PennAg Industries Association
- ix. The Pennsylvania State Grange
- x. The Insurance Federation of Pennsylvania
- xi. The Office of Attorney General
- xii. The Pennsylvania State Police
- xiii. The Pet Advocacy Network
- xiv. The Pennsylvania Federation of Dog Clubs, at least one of whom represents a licensed kennel.
- xv. The Pennsylvania Veterinary Medical Association

This legislation was referred to the Agricultural and Rural Affairs Committee and awaits further action.

Bill text is available [here](#).

Michigan Reporting and Adoption Bills Pass Senate

On June 28, a package of two bills known as Teddy's Law, were passed by the Michigan State Senate by a vote of 27-10. Details of the bills are as follows.

[SB148](#): This bill requires research facilities that use dogs or cats to submit an annual report to the Michigan Department of Agriculture with the following information.

- The total number of dogs and cats owned by the research facility.
- The total number of dogs and cats that are used for laboratory research conducted at the research facility.
- The total number of dogs and cats released by the research facility.

Facilities that do not comply would be required to pay fines that will go into a laboratory animal fund created within the state treasury.

This bill is now awaiting further action in the Michigan State House of Representatives.

[SB149](#): This bill would:

- license and regulate dealers that deliver, transport, board, buy, or sell dogs or cats for laboratory research purposes.
- regulate research facilities that use dogs or cats for laboratory research.
- require research facilities to offer laboratory animals no longer needed for laboratory research to certain animal protection shelters for adoption before euthanizing.
- require research facilities to submit annual reports.
- provide immunity from civil liability under certain conditions.

This bill is now awaiting further action in the Michigan State House of Representatives.

Oregon Legislature Passes Bill Requiring Additional Reporting on Primates in Research

On June 21, the Oregon State Senate passed HB2904, a bill that requires an institution or research facility that performs research, testing, or studies involving nonhuman primates to annually report certain information to the state veterinarian. This legislation also provides penalties for non-compliance.

Specifically, this bill requires the Oregon Health and Science University to report the number of nonhuman primates, listed by species, that, in the previous year were:

1. used in research at the university.
2. used in breeding at the university.
3. born at the university.
4. purchased or sold by the university.
5. injured, or died, in a manner that resulted in an animal welfare citation by the United States Department of Agriculture.

Legislation requiring these types of reporting requirements has been introduced and supported in several other states by animal rights groups. Implications of this legislation include the likelihood of increased targeting of research institutions and researchers by animal rights groups.

The bill is now awaiting a signature from Oregon Gov. Tina Kotek to become law.

Bill text is available [here](#).

More information can be found [here](#).

LEGAL

SCOTUS Decision Regarding Online Threats Raises the Bar for Proving the True Threats Exception to the First Amendment

In a case decided on June 27, 2023, the Supreme Court of the United States held that to prove speech is a true threat unprotected by the First Amendment, one must show the speaker understood his or her statements were threatening under a recklessness standard. *Counterman v. Colorado*, 600 U.S. ___, No. 22-138, slip op. at 3–4 (June 27, 2023). This case arose after Counterman, defendant, made several Facebook profiles from which he sent C.W., a local musician, hundreds of messages that described danger to her. *Id.* at 1–2. For example, in one message, Counterman told C.W. to “die.” *Id.* at 2. The State of Colorado charged Counterman under a Colorado criminal statute that criminalizes “repeatedly mak[ing] any form of communication with another person in a manner that would cause a reasonable person to suffer serious emotional distress” *Id.* The trial court found Counterman’s statements constituted true threats and were consequently not protected by the First Amendment, and the jury found Counterman guilty of violating the Colorado criminal statute *Id.* at 3. The Supreme Court was faced with two questions: By evaluating Counterman’s speech under an objective standard to determine whether it constituted an unprotected true threat, did Colorado violate the First Amendment, and if so, meaning a subjective evaluation is required, what standard of review is proper? *Id.* at 3–4. The Court held that to show speech is

a true threat unprotected by the First Amendment, one must prove the speaker understood his or her statements were threatening under a recklessness standard. *Id.* at 4–5. In other words, for a state to justify prosecuting a defendant for issuing true threats, the state must show “a speaker is aware that others could regard his statements as threatening violence and delivers them anyway.” *Id.* at 11. Therefore, since Colorado prosecuted Counterman under an objective rather than subjective standard, the Court vacated and remanded the case. *Id.* at 14.

This case could be impactful for NABR members, many of whom have been victims of online threats, because, as the dissent points out, the holding “unjustifiably grants true threats preferential treatment.” *Id.* (Barrett, J., dissenting). While “nearly every other category of unprotected speech may be restricted using an objective standard,” the Court here chose to adopt a subjective standard, which is more difficult to meet. *Id.* Therefore, NABR members should be aware of this heightened standard, especially if their states, like Colorado, use an objective rather than a subjective standard to determine whether speech constitutes an unprotected true threat.

Disclaimer

This case summary is presented for reference and informational purposes only. Every effort has been made to ensure the accuracy of this summary. Nothing in this document should be construed as legal advice. Any legal questions should be submitted to a licensed attorney in the respective state. The National Association for Biomedical Research makes no warranty, express or implied, regarding the accuracy of this document.

ANNOUNCEMENTS

Q&A With the USDA - The 11th Edition

NABR is once again pleased to announce the return of one of its most requested webinars, the Eleventh Edition of "Q&A with the USDA." Join USDA-

APHIS Animal Care's Dr. Elizabeth Theodorson, Assistant Deputy Administrator, Animal Welfare Operations, for "Q&A with the USDA: The Eleventh Edition on Tuesday, July 25 at 12:30 p.m. EDT.

As in the past, this [webinar](#) will provide NABR members with a unique opportunity to ask questions directly of the leadership of Animal Care's Animal Welfare Operations. A lot has changed in the last year. The final rule on Standards for Birds Not Bred for Use in Research Under the Animal Welfare Act was released, an advance notice of proposed rulemaking that includes establishing standards for environmental enrichment of all regulated animals was released for comment and the deputy administrator who participated in this annual event on numerous occasions retired.

You should take advantage of this unique opportunity provided to NABR members to better understand what impact these and other ongoing changes may have on your institution concerning compliance with Animal Welfare Regulations. **Questions should be submitted in advance to info@nabr.org.** They will be reviewed and formatted to prevent duplication and will be answered in the order they are received, so please submit them as soon as possible. As in the past, we will schedule the session for an hour but will continue the webinar until all questions have been addressed.

A registration link for the webinar is available [here](#).

Scientists Center for Animal Welfare (SCAW) In-person IACUC Training Workshop

In December, SCAW will hold an in-person IACUC training workshop titled "Advancing Animal Welfare and Science: Processes and Principals". Details can be found below.

December 4-5, 2023 | Menger Hotel, San Antonio, TX

Early registration ends October 15, 2023

Hotel cutoff November 11, 2023

Some topics to be discussed:

- One Health and Animal Research: The Opportunities, Pitfalls, and Perils
- What Makes a Great Protocol?
- The CUSP Sharing Site – A Collaborative Community Database
- Are You Up to Date with OLAW, APHIS, and AAALAC International: Q & A for You and Me
- The 3Rs Collaborative: Better Science – for Both People and Animal
- Results of the 2022 VCRACW Guide Revision Priority Survey and Discussion
- IACUC Centric Zebra Fish
- Sound Public Policy

Non-member registration and discounted registration for SCAW Institutional Members (if you are unsure of your membership status, please contact SCAW at info@scaw.com)

Program and registration are available at:

<http://go.pardot.com/e/858023/annual-winter-conference-html/zpktt/1008616710?h=HV-RjOqKDEzkZ0b-ry3YAJnrizm2XST4Md1DPEjHrR0>

NABR | 1909 K Street, NW, Suite 300 | Washington, DC 20006 |

Tel 202.857.0540 | Fax 202.659.1902 | info@nabr.org

This email was sent to jhoward@parthenonmgmt.com

[Manage your email preferences](#)

5034 Thoroughbred Lane