June 24, 2022

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.

Mother Jones Publishes Honest Look at State of Primate Research in the U.S.

NABR strongly recommends you read this article about primate research published in Mother Jones yesterday. In development for months, it provides a remarkably detailed and balanced story about the challenges of NHP research in the U.S. NABR President Matthew Bailey spoke with journalist Jackie Flynn Mogensen as she explored the complex policy landscape for nonhuman primate research for her story. Her article offers a retrospective on biomedical research with nonhuman primates going all the way back to the early 20th century and

highlighting challenges faced by the nonhuman primate research community over the years. These include fear of reprisal from animal rights activists, difficulties in finding airlines that will transport animals destined for research, a community that has trouble communicating with the public to advocate for itself, and a shortage of monkeys for necessary research in a time of COVID.

Mogensen stated, "Believe me, I wish biomedical research had a better substitute for testing on our closest animal relatives. And one day, it might. **But no matter how you or I feel about it, it's clear the practice has saved—and is saving—human lives.** If you received a shot of the Covid vaccine, for instance, you have monkeys to thank for it; before their vaccines were released to the masses, Pfizer, Moderna, and Johnson & Johnson trialed them in monkeys first. The same is true for Covid treatments like monoclonal antibodies or the antiviral remdesivir. Monkeys were also instrumental in testing vaccines that can protect against monkeypox.

And so the monkey shortage is putting human lives at risk. Scientists say vital medical and scientific studies have been delayed or prevented entirely, leaving us ill-prepared to keep fighting this pandemic, not to mention future ones."

Bailey highlighted the importance of educating the public about the vital role of animal research for medical discoveries, stating, "I think raising awareness about the nonhuman primate shortage increases the odds that support will gather for providing either funding or other policy solutions to address the problem."

If someone you know is either opposed or unsure about primate research (including your elected representatives), we can think of no better article to send

them. http://go.pardot.com/e/858023/ypox-future-pandemic-vaccines-/mr3xj/532695300?h=etYCH1VlBp1JhYx0T8e0aEHxSs8ppieb_e3-rhFwWmE

FEDERAL

Senate Health, Education, Labor and Pensions (HELP) Committee Advances FDA Legislation; Includes Alternatives Language

Last week, the Senate HELP Committee advanced the FDA user fee reauthorization package to the Senate floor by a vote of 13-9.

The FDA user fee agreement is reauthorized every five years to enable the FDA to collect fees from brand drug, generic drug, biosimilar and medical device manufacturers to allow the agency to hire additional review staff and expeditiously review product applications.

This must-pass legislative package contains many provisions to "*hold the FDA accountable with stricter deadlines on future negotiations with the medical industry, overhauling diagnostic regulation, dietary supplements and cosmetics reform, formula shortages, opioids, and animal studies*."

The animal studies provision includes similar language to the House version pulled from the FDA Modernization Act of 2021. This language "*allows an applicant for market approval for a new drug to use methods other than animal testing to establish the drug's safety and effectiveness. Under this bill, these alternative methods may include cell-based assays, organ chips and micro physiological systems, sophisticated computer modeling, and other human biology-based test methods*."

The House passed its version of the FDA reauthorization package on June 8. After the Senate passes its version, the two chambers will reconcile their bills

in conference, vote on final passage, and send the legislation to the president's desk to be signed into law before the current agreement expires at the end of September.

More information is available here.

Congress Begins Marking Up FY2023 Funding Bills

On Thursday, June 23, the House Appropriations Committee marked up funding bills for the 2023 fiscal year. This markup included the FY 2023 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, and Military Construction, Veterans Affairs, and Related Agencies Appropriations Bills.

These bills provide funding for government agencies and contain report language that instructs the agencies as to how Congress would like to see the funds implemented. Biomedical research is largely impacted by these appropriations bills as the Department of Agriculture, and the Food and Drug Administration rely on this funding to continue to conduct lifesaving research. Each year animal rights groups lobby Congress to include report language to hinder biomedical research funding for animal research. NABR and other scientific organizations work to oppose this language by educating lawmakers about the need for ethical, lifesaving biomedical research.

Problematic Report Language in House Ag/FDA Appropriations:

Animal Care Program—*The Committee is concerned about APHIS's Animal Care program and the steep decline in enforcement related to violations of the Animal Welfare Act. The Committee has included some of the reforms below in bill language, along with a funding increase to ensure compliance with both the*

bill and report language. The Committee has also provided an increase for the Office of General Counsel to address its workload on animal issues.

The Committee will continue to discuss the poor state of the program with USDA and may seek further changes in the final 2023 bill.

The Committee directs the agency to reform its current licensing and enforcement scheme immediately. This includes, but is not limited to, the following:

- *ensure consistent, thorough, unannounced inspections on a regular basis;*
- *act swiftly when facilities fail to comply with any of the Act's requirements;*
- *ensure each interference with, and/or failure to allow access for inspection, as well as each violation or failure to comply with animal welfare standards, is documented on an inspection report, and assess penalties as deemed appropriate in each such case;*
- *ensure that there is no use of teachable moments or any similar program that obscures findings during inspections; and*
- *require that inspection reports that identify violations or failures of compliance be shared with relevant local, state, and federal agencies.*

The Committee is also concerned about the lack of enforcement of online dog dealers, which has allowed many online operations to continue selling puppies without the necessary USDA licensing under the Animal Welfare Act.

The Secretary is directed to make a priority of the enforcement of the 2013 rule that requires that dealers who are selling animals sight-unseen to consumers must have the necessary license to do so. If necessary, the Secretary of Agriculture shall enter into a memorandum of understanding with the 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.

Non-Human Primates—*The Committee continues to encourage the FDA to reduce primate testing, prioritize alternative research methods to relocate primates to sanctuaries and requests that a progress report continue to be included in the FDA's annual budget justification.*

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.*

APHIS Inspections of ARS Facilities—*The funding provided for the Animal Welfare program includes funding to support the agreement between APHIS and ARS, under which APHIS conducts compliance inspections of ARS facilities to ensure compliance with the regulations and standards of the Animal Welfare Act. The Committee directs APHIS to conduct inspections of all such ARS facilities and to post the resulting inspection reports online in their entirety without redactions except signatures. The Committee continues to direct APHIS to transmit to the Committees all inspection reports involving ARS facilities, including pre-compliance inspections. These facilities involve federal funds over which this Committee has oversight responsibilities. APHIS is directed to include every violation its inspectors find and never to frustrate the Committee's oversight activities by using so-called ''teachable moments'' or other means of not reporting ARS facility violations.*

Problematic Report Language in House Mil-Con/VA Appropriations:

Animal Research—The Committee has included bill language to prohibit painful research on dogs and cats beginning in fiscal year 2023. Additionally, the Department is directed to include in any report to Congress describing

animal research approved under Section 247 of the Consolidated Appropriations Act, 2022 (P.L. 117– 103), submitted after the date of filing of this report, detail on what specific alternatives to animals were considered, why those alternatives were not chosen, and therefore supporting why these animal subjects are the only viable option for this research.

- This is included in the Medical and Prosthetic Research Section, with a recommended FY23 budget of $926 million
- There are 14 other programs included in this budget; including Cannabis Research and NICoE collaboration

The full committee markup of the FY 2023 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, and Military Construction, Veterans Affairs, and Related Agencies Bills can be seen here.

STATE

CA Toxicology Bill SB879 Passes Assembly Judiciary Committee

A bill to end toxicological testing on dogs and cats has passed California's General Assembly's Judiciary Committee. This bill, which was reintroduced in January and passed the Senate in May, would ban toxicological testing on dogs and cats for the development of new drugs and treatments unless the experiment is conducted for specified purposes. Although the bill contains an exemption for biomedical research, the language can easily be amended to exclude this life saving work.

NABR will continue to report attempts by animal research opponents to pass local and state legislation in hopes of ultimately influencing federal legislation.

Bill text can be found here.

More information is available here.

LEGAL

New Jersey Supreme Court Rules on Legal Personhood Issue

On June 13, the New Jersey Supreme Court reconfirmed that the state's rescue doctrine only applies to humans. The appeal heard at the court required the Justices to determine whether to expand the common law rescue doctrine to permit plaintiffs to recover damages for injuries sustained as a proximate result of attempting to rescue the defendants' dog.

In the end the New Jersey Supreme Court "*declined to consider property, in whatever form, to be equally entitled to the unique value and protection bestowed on a human life. The Court nevertheless expands the rescue doctrine to include acts that appear to be intended to protect property but are in fact reasonable measures ultimately intended to protect a human life.*

A full copy of the opinion and explanation of the rescue doctrine can be found here.

Additional information is available here.

ICYMI: VICTORY: New York Supreme Court Reaffirms the Obvious: An Elephant is not a Human

On June 14, the New York State Court of Appeals (the highest court in the state of New York) ruled 5-2 that Happy the elephant is not a human being with constitutional rights. The decision comes after a hearing in May where the Nonhuman Rights Project challenged the Bronx Zoo's confinement of "Happy" the elephant. The group had argued that keeping Happy at the zoo was

considered “cruel confinement” and that because elephants are intelligent beings, the animal’s habeas corpus rights against illegal imprisonment should be recognized.

In the end, New York’s top court disagreed, and Chief Justice Janet DiFiore explained by stating “nothing in our precedent or, in fact, that of any other state or federal court, provides support for the notion that the writ of habeas corpus is or should be applicable to nonhuman animals.” The Chief Justice, who authored the decision, expressly mentioned NABR’s brief during the oral arguments. NABR applauds the court’s decision on the grounds that creating legal standing, or “personhood,” for animals in the courts would ultimately lead to an abolishment of animal research.

NABR President Matthew Bailey said, “The Nonhuman Rights Project’s continued attempts to find a venue willing to grant legal personhood to animals is literally turning our justice system into a kangaroo court. Most people agree that humans bear great responsibility for the welfare of animals but opening the door for animal rights groups to sue on behalf of any animal at any time will ultimately spell the end of medical advancement in the United States. We are very pleased common sense prevailed in this case and will remain vigilant regarding future attempts to end humane research with animals.”

BACKGROUND: Last year, the Nonhuman Rights Project (NhRP) filed habeas corpus litigation against the Bronx Zoo on behalf of “Happy” the elephant. An appellate court dismissed NhRP’s petitions in December 2020, asserting that “the writ of habeas corpus is limited to human beings.” However, Judge Eugene M. Fahey, associate judge of the New York Court of Appeals, wrote in support of the NhRP’s position. The New York Court of Appeals later agreed to hear an

appeal of the case. “Happy” is the first elephant in the United States to have a habeas corpus hearing, according to the NhRP.

In a recent article, Associated Press reported that “The National Association for Biomedical Research said authorizing such petitions on behalf of animals could drive up the costs of conducting critical research. State and national associations representing veterinarians filed a brief saying NRP’s lawsuit promote animals’ personhood rights above animals’ welfare.”

Due to the dangerous legal precedent, that could be set against research institutions working with animal models, NABR filed an amicus brief to the New York Court of Appeals explaining that the court “should hold that the privilege of the writ of habeas corpus may not be invoked on behalf of an elephant.”

NABR’s amicus brief can be found here.

A full copy of the opinion, with dissents, is available here.

More information can be found here.

ANNOUNCEMENTS

AALAC Council Releases Guidance to Clarify Expectations for Managing and Reporting Adverse Events

The AALAAC International’s Council on Accreditation released an updated FAQs guidance to help clarify “Managing and reporting adverse events” and “What are the reporting requirements for maintaining accreditation?”

Per AAALAC International's Rules of Accreditation (Section 2.g.), any accredited unit should notify AAALAC International "of significant adverse events relating to the animal care and use program." In the updated version, institutions are now asked to "activate an established adverse event assessment and reporting plan that provides guidance on what should be investigated, the time of reporting, and who should receive reports, as well as steps to prevent or mitigate recurrence."

Read the FAQs on **"Managing and reporting adverse events."**

Read the FAQs on **"What are the reporting requirements for maintaining accreditation?"**

Q&A With the USDA- The Tenth Edition

The National Association for Biomedical Research (NABR) is pleased to invite your institution to join us on July 19, 2022 at 12:30 p.m. EDT for "**Q&A with the USDA: The Tenth Edition**," with guest speakers USDA-APHIS Animal Care's **Drs. Elizabeth Goldentyer,** Deputy Administrator, and **Lemnique Wafer,** Assistant Director of Animal Welfare Operations.

Under an active institutional membership, NABR members have the opportunity to partake in these exclusive webinars that provide vital information for the scientific community on legislative, regulatory and legal matters affecting responsible, humane, and ethical research with laboratory animals. Member institutions benefit from NABR's expertise and up-to-date analysis on policies regarding humane animal research. By understanding these policies and committing to the safety and welfare of laboratory animals, your institution can continue to develop discoveries and solutions to improve the quality of life for both animals and people.

As in the past, this webinar will provide NABR members with a unique opportunity to ask questions directly of the leadership of APHIS Animal Care. A lot has changed in the last year as the restrictions imposed by the pandemic impacting the inspection process have been lifted and the final rules on AWA Research Facility Registration Updates, Reviews, and Reports and Handling of Animals have been issued. Contingency plans have also been released, as was the proposed rule on Standards for Birds Not Bred for Use in Research Under the Animal Welfare Act.

So please join us for what promises to be a very interesting and informative presentation to better understand what impact these and other ongoing changes may have on your institution concerning compliance with the 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.

Click here to register: http://go.pardot.com/e/858023/register-7277265465224845579/mr3yx/532695300?h=etYCH1VlBp1JhYx0T8e0aEHxSs8ppieb_e3-rhFwWmE

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