August 17, 2021

FEDERAL

Senate Appropriations Committee Approves Three Spending Bills for Fiscal Year 2022

This month, the Senate Appropriations Committee began marking up its versions of spending bills for the fiscal year 2022. The committee advanced the Agriculture-FDA, Energy and Water, and Military Construction and Veterans Affairs fiscal year 2022 appropriations bills with strong bipartisan support.

Information including bill text, report language, and summaries of the bills can be found here.

The Senate Appropriations Committee will continue consideration of the remaining nine appropriations bills after the summer recess.

Congress has until Sept. 30 to pass funding bills and avert a government shutdown.

NABR continues to monitor the appropriations process as Congress considers spending bills for the fiscal year 2022.

Animal Research-Related Report Language in the Senate FY2022 Spending Bills
FY2022 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies:

**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. 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 is also concerned about online dog dealers that are continuing to sell animals without the necessary USDA licenses pursuant to the Animal Welfare Act (Public Law 89–544). The Committee encourages APHIS to continue to conduct robust oversight and enforcement of this statute and the 2013 rule requiring online dealers who are selling animals to consumers sight-unseen to have the necessary license.

**Livestock Genetic Research**—The Committee is aware of the promise that genetic engineering holds for addressing livestock animal diseases, welfare, and production. However, the inability to consistently produce genetically engineered “founder animals” in significant numbers represents the major bottleneck for many promising animal biotechnologies. While the National Institutes of Health [NIH] have invested in such facilities for human biomedical research activities that produced needed mice, rats, and pigs, the USDA has not supported similar scale efforts. As such, the Committee provides an additional $3,000,000 to partner with a major university where genetic engineering expertise is already available and to contract for such services for
swine models. The Committee encourages USDA to leverage existing investments in this area made by the NIH.

**ISTAND**—The Committee supports the assessment of non-animal approaches for qualification within the Innovative Science and Technology Approaches for New Drugs [ISTAND] pilot program. The Committee is pleased that ISTAND provides a pathway for regulatory acceptance of innovative non-animal methods that may better protect public health, improve the safety and efficacy of drug development, and reduce animal testing.

**Imported Dogs**—The Committee is aware that the USDA issued a report that showed that over one million dogs are imported into the United States each year. Of that number, however, less than 1 percent are subject to thorough health screenings to show that they are healthy, vaccinated and free of disease prior to entering the country. The limited health requirements and inspection has resulted in the importation of animals that arrive in poor health, as well as the importation of animals carrying various diseases from rabies to canine influenza to leptospirosis, among others. Diseases such as canine rabies have cost millions of dollars to eradicate in the United States and unscreened animal imports threaten to undo that progress while threatening public health. Therefore, the Committee directs APHIS to strengthen its oversight of imported dogs, including stronger interagency coordination to better protect animal and public health.

**FY2022 Military, Construction, Veterans Affairs:**

**SEC. 247** The Committee includes a provision prohibiting the use of canines in VA research unless: the scientific objectives of the study can only be met by using canines; the study has been directly approved by the Secretary; and the study is consistent with the revised VA canine research policy document released in December, 2017.
NABR Comments on USDA’s Contingency Planning Proposed Rule

Below is the link to NABR’s comments to the United States Department of Agriculture’s notice of proposed rulemaking and request for comments to lift the stay and make minor revisions to the Animal Welfare Act regulations governing handling of animals: contingency plans.

NABR’s full response can be viewed here:
http://go.pardot.com/e/858023/download-file-507-0/9pgvt/261861558?h=DzuHoJVGVC8XprC8SMF6evfUL4GmncTDvx5sNhQnQQ

NABR members are always welcome to use NABR’s comments as a guide when submitting their own.

White Coat Waste Project Targets Biomedical Research with Claims of Unethical Research on Canines at the National Institutes of Health

White Coat Waste Project continues its campaign to hinder lifesaving biomedical research at our nation’s leading research institutes. The group has targeted Drs. Anthony Fauci and Francis Collins by promoting anti-research propaganda and stories of unethical testing. Their latest petition claims that these public health officials spent over $424,000 of taxpayer money on “unnecessary” experiments involving canines at the NIH. This is another attempt by one of many anti-animal research groups seeking to cut all taxpayer funding for biomedical research in the name of animal rights. NABR continues to monitor these groups for misinformation aimed at ending lifesaving, ethical and essential laboratory animal research.

ANNOUNCEMENTS
FDA Requests Comments on Eligibility for the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

“The Food and Drug Administration (FDA, we, or the Agency) is soliciting comments on our current policy on eligibility for indexing. Indexing is the process of adding an unapproved drug for a minor species to our index of legally marketed unapproved new animal drugs for minor species (the Index). Except for in some early non-food life stages, members of a food-producing minor species are not eligible for indexing, even if a subset of animals within a food-producing minor species is not intended to be consumed by humans or food-producing animals. Specifically, we are requesting comment on this policy.”

As a result of this policy a “drug for use in laboratory rabbits is ineligible for indexing even though a rabbit raised for use in research is not intended to be consumed by humans or other food-producing animals.” The FDA has received input from stakeholders asking the agency “to allow indexing of drugs for use in certain populations of animals that would be considered food-producing under current indexing policy. Instead of considering any member of a food-producing minor species ineligible for indexing, they have requested that we establish criteria that, if met, could determine that a subset of animals within a food-producing minor species is eligible for indexing because they are not consumed by humans or by food-producing animals.” There are several species used in biomedical research besides rabbits that could be impacted should this change be made.

Comments are due by Sept. 22, and NABR is developing its comments and will make them available to the membership.

Register for OLAW’s Upcoming Webinar on AAALAC International
The National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) will host a live webinar called “What Every IACUC Should Know about AAALAC International” on Sept. 9. Dr. Jane Na, director of the Division of Assurances at OLAW, will discuss how institutions can use sections of the AAALAC Program Description to reduce administrative burden when preparing a Domestic Animal Welfare Assurance (NOT-OD-21-130). Dr. Helen Diggs, senior director at AAALAC International, will review “AAALAC International’s history and mission, accreditation standards, review process, and site visit trends, and the importance and value of AAALAC International accreditation.”

The webinar will be held from 1-2 p.m. EDT and is tailored to “IACUC staff, IACUC members, IOs, veterinarians, investigators, compliance personnel, animal care staff, and others involved in animal programs.” Click here for more information and registration access.

**Funding Opportunities: DoD FY21 Funding Opportunities Includes TBI and Transplantation Research**

The Department of Defense (DOD) programs, managed by the office of Congressionally Directed Medical Research Programs (CDMRP), released its fiscal year 2021 (FY21) funding opportunities. The following are the opportunities:

**Reconstructive Transplant Research Program (RTRP)**
- Advanced Technology Development Award
- Investigator-Initiated Research Award

**Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP)**
- Clinical Research Development Award
Clinical Trial Award
Focused Program Award
Idea Development Award
Investigator-Initiated Research Award
Translational Research Award

**Scleroderma Research Program (SRP) - New Pre-Application and Application Deadlines!!!**

Idea Development Award
Idea Development Award – New Investigator Collaboration Option
Translational Research Partnership Award

For more information on the programs, visit
http://go.pardot.com/e/858023/2021-08-17/9pgw5/261861558?h=DzuHoJVG9euXprC8SMF6evfUL4GmncTDvx5sNhQnQQ.

For more info on application strategies, visit
http://go.pardot.com/e/858023/pubs-Webinars-webinar-series/9pgw7/261861558?h=DzuHoJVG9euXprC8SMF6evfUL4GmncTDvx5sNhQnQQ.

For general submission instructions and other announcements, visit
http://go.pardot.com/e/858023/2021-08-17/9pgw9/261861558?h=DzuHoJVG9euXprC8SMF6evfUL4GmncTDvx5sNhQnQQ.