

August 03, 2021

FEDERAL

House Passes Nine Funding Bills for Fiscal Year 2022

Last week the House of Representatives passed nine of the twelve appropriations bills to fund the federal government through fiscal year 2022. These bills include Labor, Health and Human Services, Education, Agriculture, Rural Development, Energy and Water Development, Financial Services and General Government, Interior, Environment, Military Construction, Veterans Affairs, State-Foreign Operations, Legislative Branch, Transportation, and Housing and Urban Development Appropriations Act, 2022. The House plans to vote on the last three spending bills after the August recess. These include Defense, Homeland Security, and Commerce and Justice.

Information including bill text, report language, and summaries of the bills can be found [here](#).

The Senate will begin marking up its own versions of three spending bills this week. These include Agriculture-FDA, Energy and Water, and Military Construction-VA.

NABR continues to monitor the appropriations process as both Chambers consider spending bills for fiscal year 2022. Below is a breakdown of the House spending bills

Animal Research-Related Report Language in the House FY2022 Spending Bills

FY2022 Labor, Health and Human Services:

National Primate Research Centers—The Committee **does not include funding** directed towards expanding non-human primate resource infrastructure. The president’s budget request included \$50,000,000 for this activity.

Center for Alternatives to Animals in Research and Testing—The Committee directs NIH to submit a plan not later than 180 days after enactment of the Act for the **establishment of a Center for Alternatives to Animals in Research and Testing within NIH**, for the purposes of (1) developing, promoting, and funding alternatives to animal research and testing, and (2) developing a plan for reducing the number of animals used in Federally funded research and testing.

Collection and Reporting of Animal Research Numbers and Agency Funding—The Committee recognizes that Congress has long expressed an interest **in reducing the use of nonhuman animals in NIH-funded research** and replacing animals with valid, reliable alternatives. In the National Institutes of Health Revitalization Act of 1993, Congress first requested that the agency create a plan for doing so. The Committee also recognizes the scientific community’s Stated commitment to the “three Rs” of replacement, reduction, and refinement. Integral to that commitment are the accurate counting of animals used in research and testing and the accurate reporting of NIH funding dedicated to projects involving animals.

The Committee recognizes that it has been NIH's policy since 1985 to collect an "average daily inventory" of vertebrate animals housed in research facilities that wish to receive agency funding. The Committee understands that domestic facilities are required to file such documentation every four years as part of an Animal Welfare Assurance and that copies of the documents are available to the public only through Freedom of Information Act requests. The Committee requests a report from NIH within 120 days of enactment of this Act outlining a plan for increasing the accuracy and transparency of collecting and publicly disseminating research animal numbers. The plan should explain how NIH will collect the information annually and include a draft form that requires the total number of animals per species bred and used in the previous year and assigns all animals to a pain and distress category. The plan should also include details on how NIH will create a publicly accessible online database for dissemination of this information. Secondly, the Committee requests that NIH include in its report a plan for implementing a system that tracks which agency-funded projects involve the use of animals and makes the information publicly accessible. The Committee recognizes that NIH currently collects such information with every grant application using the Research & Related Other Project Information form, which asks applicants to answer "Yes" or "No" to the question "Are Vertebrate Animals Used?" NIH's plan should ensure that the answer to that question for each funded project is searchable via the Expenditures and Results module of NIH's Research Portfolio Online Reporting Tools website as many other categories of information are.

Humane Research Alternatives—Recognizing that humane, cost effective, and scientifically suitable **non-animal methods** are available but underutilized, the Committee requests that NIH assemble a panel to investigate and make recommendations regarding incentives for more quickly and effectively moving NIH intramural and external research away

from methods that rely on animals to methods that rely on non-animal methods including epidemiological and clinical studies, cell-based methods, computer modeling and simulation, and human tissue studies. The panel should review and recommend means of encouraging greater reliance on human-relevant non-animal methods/approaches. Panel membership should include individuals with proven knowledge of/experience with non-animal research methods; with expertise in evaluating the adequacy of searches for non-animal methods/approaches described in research proposals; and with knowledge of the welfare concerns and scientific limitations of animal-based studies. The Committee asks that NIH provide a report of the panel's findings within 60 days of enactment of this Act.

Maintenance of Chimpanzees on U.S. Air Force Bases—*The Committee remains concerned about NIH's intention to retain government-owned chimpanzees at the Alamogordo Primate Facility (APF), a laboratory facility, instead of retiring them to the national chimpanzee sanctuary, Chimp Haven. While NIH cites the health condition of the chimpanzees as a reason to warehouse them at APF, the health condition of the chimpanzees and their long history of laboratory use makes it urgent that they be provided an opportunity to live the remainder of their lives in sanctuary, even if for a short period. The Committee directs the NIH to resume transport of government-owned and supported chimpanzees beginning with chimpanzees at APF. Movement of chimpanzees from Southwest National Primate Research Center (SNPRC) and Keeling Center for Comparative Medicine and Research (KCCMR) should follow transport of the APF chimpanzees to Chimp Haven. The Committee also directs the NIH to provide a written report to the Committee every 180 days, beginning no later than December 31, 2021, that shall include: (1) the number of chimpanzees transported to the national sanctuary over the last quarter; (2) a census of all government-owned and supported chimpanzees remaining, if any, at APF, SNPRC or KCCMR; (3) a list of any chimpanzee deaths that have*

occurred at any time after January 1, 2020, at either APF, SNPRC, KCCMR, or the national sanctuary system, and (4) the plan, including the timeline, for transferring the chimpanzees from APF, SNPRC, and KCCMR to Chimp Haven.

Brain Cancer—The Committee recognizes that certain types of brain cancers are associated with high mortality and morbidity rates. Primary brain tumors, such as glioblastoma multiforme, have a five-year survival rate of five percent in adults and less than 20 percent in children. Certain brain tumors that occur in humans also occur spontaneously and naturally in **dogs**. These brain cancers in dogs share many of the same molecular underpinnings of their human counterparts. There is great potential for developing treatments for brain cancers that will benefit dogs and humans and provide an intermediate step to evaluate human treatments in a more meaningful and related species. The Committee encourages NIH to continue to support research that brings together researchers and clinicians from pediatrics, adult oncology, veterinary medicine, and biomedical engineering to leverage the linkage between brain cancers in dogs and humans in order to evaluate and develop treatments and safe delivery systems to benefit both species.

Emerging Diseases—The Committee supports the work of NIAID in researching emerging coronaviruses, and urges NIAID to fund basic science on a host of deadly viruses, including SARS-CoV-2, Ebola, Marburg, and Nipah viruses. The Committee notes the importance of using high containment BSL-3 and BSL-4 labs in this effort. The Committee is aware of the success of **non-animal approaches** to identify how viral proteins interact with host proteins and their pathways. The Committee notes the success of these approaches with SARS-CoV-2 to identify new therapeutic approaches. The Committee encourages NIAID to support research into

viruses, including Ebola, Marburg, and Nipah viruses, to help identify small molecule drugs to block infection by a host of deadly viruses.

Vascular Dementia—A growing number of Americans are developing severe forms of vascular dementia, conditions resulting from many years of living with chronic diseases such as hypertension and cardiovascular disease. This prevalence is especially high in areas with high rates of hypertension, obesity, and lack of access to regular health care. Epidemiological studies and human pathology studies have demonstrated association of vascular risk factors, vascular diseases, and pathology with dementia. **Research in animal models** could further investigate causal relationships, understand mechanisms, and test novel interventions (including repurposing existing drugs). Study of the mechanisms of vascular dementia can help researchers to understand causation, develop new treatment therapies and study how to repurpose existing drugs to delay or halt disease progression. The Committee encourages NHLBI to continue its support for investigating potential relationship between vascular disease and risk factors for vascular dementia, leveraging the work of well-established longitudinal cohort studies of dementia and cardiovascular disease and experimental models well characterized phenotypes and mechanisms. The Committee encourages NHLBI to coordinate this research with NIA and NINDS to ensure that the continuum of research from basic science to observational cohort to clinical trial to implementation is maintained.

Live Animal Imports—The Committee is aware that **importation of live animals**, particularly **dogs**, has increased substantially during the COVID-19 pandemic and is concerned by instances in which live animals have been held at ports of entry for hours or days. The Committee emphasizes the importance of prioritizing inspection of live cargo by CDC personnel to ensure that all due standards of animal welfare are maintained and urges CDC to adopt policies limiting the maximum amount of time between the

arrival of cargo containing live animals and inspection to the shortest practicable period.

FY2022 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies:

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 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 directs the agency to reform its current licensing and enforcement scheme. 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 the Act's requirements; ensure 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 consider assessing penalties 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 concerned about the lack of enforcement of online dog dealers, which has allowed many operations to continue selling dogs without the necessary USDA licensing pursuant to Animal Welfare Act. The Committee directs the Secretary to prioritize enforcement of the 2013 rule that requires dealers who are selling animals sight-unseen to consumers to have a license to do so. The Committee also urges the Secretary to enter into a 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

Live Animal Imports—The Committee is aware that **importation of live animals**, particularly **dogs**, has increased substantially during the COVID–19 pandemic. The Committee is concerned about differences in the APHIS licensing and registration processes that may lead to a lack of oversight of registrants and/ or repeated failures to maintain basic standards of animal care. The Committee is concerned that while the Agency can deny an initial license or terminate an existing license for dealers or exhibitors that handle live animals for failure to comply with Animal Welfare Act requirements, the process of registration with the Agency for the purposes of serving as a carrier or intermediate handler of live animals, or as a research facility, does not require demonstration of compliance with Animal Welfare Act requirements or other similar Agency regulations. The Committee directs APHIS to take all available administrative actions to address this issue and to send to Congress recommendations for additional legislative steps, if needed, not later than 120 days after enactment of this Act

Searchable databases—The Committee directs APHIS to ensure that the searchable animal welfare database is searchable at least to the same extent that they were on January 30, 2017 in terms of both function and content.

Alternative Testing—As expressed in H. Rpt. 116–446, the Committee is encouraged by the FDA’s efforts to reduce testing on **dogs and other animals**. The Committee commends the agency for the formation of its Alternative Methods Working Group to foster the advancement and regulatory acceptance of new research technologies that can improve the efficiency and effectiveness of the development of drugs and other FDA-regulated products and reduce and replace testing on dogs and other animals. A number of these initiatives were outlined in the January 2021

FDA report 'Advancing New Alternative Methodologies at FDA'. However, the Committee is concerned about a lack of performance goals and metrics to measure FDA's progress in this area, as outlined in the 2019 GAO report entitled 'Animal Use in Research: Federal Agencies Should Assess and Report on Their Efforts to Develop and Promote Alternatives'. The Committee directs the FDA to deliver a report on FDA's acceptance of alternatives to animal tests for regulatory purposes. The report shall include the following: (1) a review of existing laws, policies and regulations allowing FDA acceptance of non-animal test data; (2) a review of non-animal test methods that the FDA has allowed to be used in place of animal tests for regulatory purposes; (3) a review of existing performance goals and metrics used by FDA to monitor progress and measure the success of its efforts to accept alternative tests methods and reduce animal use; and (4) recommendations to improve objective assessment of the impact of FDA programs to reduce animal use and advance alternative methods in the future. The Committee directs FDA to deliver a report to the Committees within one year of enactment of this Act.

FY2022 Military, Construction, Veterans Affairs:

SEC. 245. *(a) Except as provided by subsection (b), none of the funds made available by this Act may be used by the Secretary of Veterans Affairs to purchase, breed, transport, house, feed, maintain, dispose of, or experiment on, **dogs or cats** as part of the conduct of any study including an assignment of pain category D or E, as defined by the Pain and Distress Categories of the Department of Agriculture (or such successor categories developed pursuant to section of the Animal Welfare Act (7 U.S.C. 17 2143)).*

(b) Subsection (a) shall not apply to training programs or studies of service dogs described in section 1714 20 of title 38, United States Code, or section 17.148 of title 21 38, Code of Federal Regulations.

House Hearing on “The Path Forward: Advancing Treatments and Cures for Neurodegenerative Diseases”

On Thursday, July 29, 2021, at 11 a.m., the Subcommittee on Health of the Committee on Energy and Commerce held a hearing to focus on the challenges of neurodegenerative diseases affecting millions of Americans each year. The hearing focused on educating the public to better understand these diseases, along with increasing support for research and development. Testimony was heard by officials at the Food and Drug Administration and the National Institutes of Health, as well as leading advocates, researchers, and industry representatives for an update on the search for new cures and treatments. Dr. Hodes, Director of the National Institute of Aging at the NIH, highlighted the need for non-human primates to study neurodegenerative diseases such as Alzheimer’s, ALS, and others. He noted that, *“For some types of studies, **nonhuman primates are critical model organisms** because of their anatomical, physiological, and behavioral similarity to humans.”* Adding that *“Nonhuman primates’ vulnerability to neurodegenerative disease is likely closest to that of humans, and the common marmoset has emerged as a promising model system for understanding the primate brain and associated disorders.”*

A livestream of the hearing can be found [here](#).

National Institutes of Health (NIH) Request for Information (RFI) on Clarifying the Reporting Requirements for Departures from the Guide for the Care and Use of Laboratory Animals

The NIH has announced a Request for Information (RFI) seeking input from stakeholders on clarifying guidance to Assured institutions regarding the Institutional Animal Care and Use Committee (IACUC) reporting requirements for departures from the Guide for the Care and Use of Laboratory Animals.

This request was made in consideration of the 21st Century Cures Act, which directed the NIH to conduct a review of applicable regulations and policies for the care and use of laboratory animals and to make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.

To facilitate commenting, NIH has established a web portal that can be accessed [here](#). The deadline for comments is Nov. 11, 2021.

OLAW's New Guides Notice and Website on Conducting Semiannual Animal Facilities Inspections

In response to the 21st Century Cures Act, NIH's Office of Laboratory Animal Welfare (OLAW) and the USDA created a guide notice ([NOT-OD-21-164](#)) to provide flexibilities for conducting semiannual inspections of animal facilities that may reduce administrative burden. The guidance clarifies the nine flexibilities that institutions can implement to reduce administrative burden.

The guidance can be accessed here: <http://go.pardot.com/e/858023/otice-files-not-od-21-164->

[html/9lgbh/251632610?h=dntEXHlxyl0YHW8_HLiXtPBxiPzkf47eJ0zGnFsLr4](http://go.pardot.com/e/858023/otice-files-not-od-21-164-html/9lgbh/251632610?h=dntEXHlxyl0YHW8_HLiXtPBxiPzkf47eJ0zGnFsLr4) For more information on the guidance, visit the Semiannual Facility Inspections website: http://go.pardot.com/e/858023/emiannual-Facility-Inspections/9lgbk/251632610?h=dntEXHlxyl0YHW8_HLiXtPBxiPzkf47eJ0zGnFsLr4.

ANNOUNCEMENTS

EARA Sheds Light on EC's 2018 Animal Numbers

The European Animal Research Association (EARA) recently shared the European Commission's comprehensive statistics on all animals, across the EU, used in scientific, medical, and veterinary research for 2018. The report [states](#)

that the total number of animals used across the EU in 2018 was 8,291,758, which is lower than in 2017 (9,388,162). The total consists of animals used in basic and applied research as well as in regulatory studies aimed at ensuring the safety of medicines and other products.

The total also includes animals used in routine production, education, and training. Mice, fish, and rats made up 88% of the 2018 total, while dogs, cats, and monkeys account for around 0.3% of the total. These percentage figures included Norway for the first time.

Read the full report here: http://go.pardot.com/e/858023/als-pdf-SWD-20part-A-and-B-pdf/9lgbm/251632610?h=dntEXHlxygl0YHW8_HLiXtPBxiPzkf47eJ0zGnFsLr4

Nature: Shortage of NHP Boosts US Government Need for Funding

As NABR Update readers know, the ability to obtain nonhuman primate (NHP) models for biomedical research has become increasingly difficult, especially during the peak of the COVID-19 pandemic. To offset the ongoing primate shortage, [Nature](#) shed significant light on this problem in the context of promoting NHP breeding at national primate facilities for biomedical research.

Over the past two years, the National Institutes of Health (NIH) invested around \$29 million for the refurbishment of housing, development of outdoor enclosures, and the improvement of other infrastructure at the U.S. National Primate Research Centers (NPRCs). NIH also projects to provide another \$7.5 million around October. Furthermore, the Biden administration acknowledged the need to increase primate research by requesting additional \$30 million for NPRCs. The budget [supports](#) “a 27% expansion of non-human primate resource infrastructure.” According to Dr. Deepak Kaushal, director of the Southwest National Primate Research Center, NIH needs to invest \$50 million to fully revamp the structures of NPRCs.

While improving NPRC's is important, access to non-human primates is crucial in order to conduct life- saving research. NABR President Matthew R. Bailey was quoted along with several other individuals, who expressed genuine concern about the lack of available NHPs for research, especially during a time when the demand was already expected to increase even before the current COVID-19 outbreak. The director of NIH Division of Program Coordination, Planning, and Strategic Initiatives James Anderson stated: *"We have been making investments to bring the levels up and to plan for the future. What happens if [a pandemic] happens again, with another virus in three years? We want to be ready for that."* As during peak pandemic, *"non-human primates, largely rhesus, were absolutely critical in the early testing of vaccines and therapeutics"* he said.

Nancy Haigwood, director of the Oregon NPRC (and NABR Board Member), explained: *"A couples of years ago, we were feeling the pinch. We are truly out of animals. We're turning away everyone."* Mr. Bailey indicated, *"It's very encouraging to see the Biden administration make an investment in the future of primate research in the US. It's a smart decision but it isn't like flipping a switch – it's not going to change overnight."*

Read the full Nature article: http://go.pardot.com/e/858023/articles-d41586-021-01894-z/9lgbp/251632610?h=dntEXHlxyl0YHW8_HLiXtPBxiPzkf47eJ0zGnFsLr4

APHIS Announces Animal Health Senior Leadership Changes

The United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) named Dr. Rosemary Sifford as the Veterinary Services' (VS) next deputy administrator and chief veterinary administrator of the United States. USDA also announced Dr. Alecia Naugle as VS' upcoming associate deputy administrator and Dr. Burke Healey as executive director for VS strategy and policy division. All three of these individuals will start their new positions beginning Aug. 1, 2021.

Dr. Sifford previously served as associate deputy administrator of APHIS' Animal Care program and VS' associate deputy administrator. Meanwhile, Dr. Naugle has worked as the VS' executive director for VS strategy and policy, director of VS' Ruminant Health Center, and senior adviser for animal health, production, and products. Dr. Healey has been deputy administrator since 2019 and previously worked as VS associate deputy administrator, area veterinarian in charge for Oklahoma, and various other positions.

Read APHIS administrator's full announcement:

http://go.pardot.com/e/858023/20assume20theSince2020202C20Dr/9lgbt/251632610?h=dntEXHlxygl0YHW8_HLiXtPBxiPzkf47eJ0zGnFsLr4.