

To Congressional Appropriators,

As Congress is set to begin FY2021 appropriations negotiations, it is important to recognize the strain the previous appropriations cycle has placed on the American biomedical research community.

We are grateful for the strong bipartisan support for biomedical research, largely through increased funding for at the National Institutes of Health (NIH) Recently, Congress has mandated for the acceleration of novel cures and treatments through legislation and initiatives such as the 21st Century Cures Act, the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, and the Cancer Moonshot. Each year Congress has provided generous support for the NIH and, in return, has directed the agency to mitigate the harms caused by scores of debilitating diseases that rob Americans of life and health. Yet, we often simply do not know enough about the underlying biology of a disease to start looking for cures. In such cases, the first step must be to conduct basic research to develop the information needed to move towards diagnosis, treatment, and, wherever possible, cures and preventive measures for these ailments.

Unfortunately, at the same time that Congress has provided infusions of new resources for biomedical research spending, it has also added language instructing NIH and other agencies to move away from a critical research method: the use of animal models needed to expand our understanding of normal biology as well as the dysfunctions caused by disease. This work is essential because these treatments alleviate suffering not only in humans but also in our pets and agricultural animals. Therefore, as Congress considers FY 2021 appropriations, we urge you to remedy serious contradictions found in certain FY 2020 funding bills.

Several FY 2020 appropriations bills and reports included language to restrict work with the very animal models that are crucial to accomplishing congressionally-mandated research objectives. The animals in question are non-human primates (NHPs), canines, and felines. Collectively these animals comprise a tiny percentage of all animals needed for research. Nevertheless, these studies are indispensable for the biomedical research community to continue making discoveries about the causes of disease and bringing new drugs and treatments to market.

At a time when emerging threats like coronavirus are a worldwide concern, we urge Congress to ensure that U.S. researchers are free from arbitrary and unscientific restrictions so we can maintain our global preeminence in biomedical research. In any case, this language is unnecessary because federal research oversight requirements already stipulate that studies may not be conducted with NHPs, canines, felines, or any other animal ***when a scientifically valid alternative exists***. In addition to the legislative restrictions mentioned above, research is also subject to pressure tactics in the form of public relations attacks that have led to bans on commercial transportation of laboratory animals and further weaken the state of American research.

We ask you to support American biomedical research by including the following language in FY 2021 appropriations bills and reports:

- I. Support for critical animal models such as non-human primates, canine, and feline research.
 - a. **Suggested language:** *“Research with Non-Human Primates, Canines and Felines. The Committee recognizes the importance of non-human primates, canines, and felines for*

biomedical research. While few in number, research with these models continues to make irreplaceable contributions to advancing our understanding of diseases and disorders that afflict humans and animals. These models are a critical part of the discovery and evaluation of new therapeutics before they go to clinical trials in human and animal patients.

If NIH intends to adopt policies intended to reduce research with non-human primates (NHP), canines, and/or felines, NIH will report the following to this Committee, within 90 days after the passage of this act, the following:

All communication with internal and external parties concerning the scientific justification for reducing the use of these models. NIH should detail what the replacement model is and what impact the change may have on the timeline for accomplishing either basic research objectives or the development of treatments and cures.

Additional language: *If NIH intends to transfer nonhuman primates, canines, or felines no longer needed for research to retirement facilities, sanctuaries, or other third-party facilities, the NIH shall report to this Committee, no later than 90 days after the passage of this act, the following:*

Standards of care in the retirement facilities, sanctuaries, or other third-party facilities including, but not limited to, access to expert veterinary care, housing requirements, and environmental enrichment. The report should also include a comparison of the standards of care provided by retirement facilities, sanctuaries, or other third-party facilities with the regulated research facilities where animals are currently housed.

Anticipated costs to the government to screen animals; prepare them for transfer to retirement facilities and/or sanctuaries; transport them; and maintain them in the facility for the remainder of their lives, particularly in the event that a facility lacks adequate funding to provide for them.”

- II. Support the transportation of critical animal models in a way that is most humane for the animals and most cost-effective for the taxpayer.
 - a. **Suggested language:** *“The committee recognizes the importance of reliable access to animal models in medical research to maintain our country’s competitive advantage in developing cutting edge drug innovation and lifesaving cures for some of the world’s most challenging diseases. The committee, recognizing current challenges in accessing reliable transportation for research animals, directs HHS to work with DOT to find solutions to ensure quick and efficient movement of animals for biomedical research purposes. The Committee further directs the DOT and HHS to produce a report to Congress within 90 days of enactment of this act outlining their efforts to ensure reliable transportation of critical animal models.”*

- III. Support the implementation of regulatory relief because the regulatory relief required by law in the 21st Century Cures Act has not been accomplished as envisioned by the law.
- a. **Suggested language:** *“The National Institutes of Health (NIH) Office of the Director, within 90 days of the passage of this act, will provide a report to this Committee of comprehensive and meaningful revisions to NIH, FDA, and USDA regulations and policies related to the care and use of laboratory animals. In accordance with the 21st Century Cures Act, these revisions are required to reduce regulatory burden on investigators. The report must include quantifiable metrics to demonstrate the efficacy of revisions to eliminate duplicative, inconsistent and overlapping policies related to the care and use of laboratory animals.”*

- IV. Supporting animal welfare in retired research animals and ensuring continued Animal Welfare Act coverage in retirement facilities.
- a. **Suggested language:** *“The Committee supports the retirement of research animals through the use of institution managed adoption programs or to sanctuaries, retirement facilities, or other third-party facilities on the condition that the animals continue to receive protection of their welfare as mandated by the Animal Welfare Act (AWA) and the regulations promulgated by the U.S. Department of Agriculture (USDA) to implement the AWA. Adoption, transfer or transport of retiring animals should only be considered after evaluation by the institution Attending Veterinarian or designee determining health status and fitness to travel. Research institution adoption programs should be under the purview of an oversight body (e.g., an IACUC) and must also comply with federal regulations or policies that protect the welfare and health of research animals. Research institutions will only be permitted to transfer animals to sanctuaries, retirement facilities, or other third-party facilities that maintain AWA licensing in good standing. Such sanctuaries, retirement facilities, and other third-party facilities, shall also be required to submit contingency plans to transfer and support the animals in another licensed facility if they fail to maintain their licensure.*

The Committee believes that the existing language in §2133 of the Animal Welfare Act gives the Secretary of Agriculture the authority to license such sanctuaries. Within 90 days of the passage of this act, the USDA will report to the Committee on efforts to establish a mechanism for issuing licenses to sanctuaries that comply with the requirements specified above and agree, in writing, to comply with all the requirements of this chapter and the regulations promulgated by the Secretary.

Further, within 90 days of the passage of this act, the USDA, FDA, and NIH will report the Committee on the projected costs of mandatory laboratory animal retirement and concrete plans in place to implement these retirements.”

The language suggested above is supported by the undersigned organizations representing biomedical research in all fifty states.

National Association for Biomedical Research

American Brain Coalition
American Physiological Society
Association of American Veterinary Medical Colleges
Envigo
National Primate Research Centers
American Veterinary Medical Association
American College of Neuropsychopharmacology
Pennsylvania Society for Biomedical Research (PSBR)
New Jersey Association for Biomedical Research (NJABR)
Americans for Medical Progress
States United for Biomedical Research (SUBR)
Massachusetts Society for Medical Research (MSMR)
California Biomedical Research Association (CBRA)
American Society for Pharmacology and Experimental Therapeutics (ASPET)
Charles River Laboratories
American Veterinary Medical Association (AVMA)