

May 16, 2018

The Honorable David Rouzer
U.S. House of Representatives
424 Cannon House Office Building
Washington, DC 20515

Dear Congressman Rouzer:

We, the 37 undersigned hospitals, universities, scientific, veterinary, research, and medical organizations write to offer support for your amendment to H.R. 2, which provides a much-needed opportunity to reduce the administrative burden on investigators whose research involves the care and use of laboratory animals. It is imperative to remove as much unnecessary burden as possible from medical researchers so they can go about the work of finding life-saving treatments and cures. Every moment that researchers spend doing compliance work is time not spent in the lab. We owe it to those who are suffering right now to help deliver cures today, not tomorrow.

The 21st Century Cures Act instructs the National Institutes of Health (NIH) Director to work with the Food & Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to reduce the administrative burden on researchers while maintaining the integrity and credibility of research findings and the protection of research animals. A set of recommendations¹ compiled by the Federation of American Societies for Experimental Biology (FASEB), the Association of American Medical Colleges (AAMC), and the Council on Governmental Relations (COGR), with support from the National Association for Biomedical Research (NABR), released in October of 2017 proposes changes to federal regulations, policies, and guidelines governing the care and use of animals in research.

The use of animals in research continues to be vital to understanding human and animal diseases, and researchers take their commitment to the humane care and use of research animals seriously. The proposal to provide regulatory relief via your amendment² in the Farm Bill, similar to the recommendation made in that October report, would modernize the federal Animal Welfare Act (AWA) to give the USDA more resources and authority to inspect based on compliance history, as part of the agency's Risk-Based Inspection System process. This proposed change would also maintain the Secretary's authority to conduct inspection anytime for any reason. Why is this change necessary for regulatory relief?

- A National Science Board report shows researchers spent 42% of their time responding to regulatory and administrative burden.³ Numerous reports over the past decade have demonstrated a counter-productive level of administrative/regulatory burden surrounding animal research.

¹ <http://www.nabr.org/wp-content/uploads/2017/10/Report-on-Regulatory-Burden-2017.pdf>

² [https://amendments-rules.house.gov/amendments/ROUZER_015_xml%20\(002\)51018142107217.pdf](https://amendments-rules.house.gov/amendments/ROUZER_015_xml%20(002)51018142107217.pdf)

³ <http://www.nabr.org/wp-content/uploads/2017/10/Report-on-Regulatory-Burden-2017.pdf>

- The 21st Century Cures Act, enacted last year, mandates that federal agencies overseeing animal research work to find ways to reduce regulatory burden, yet little has been done to follow through on this promise.
- If the reform recommended by COGR, NABR, FASEB, and AAMC was realized, USDA could conservatively save \$13,630,000 over ten years.⁴ The savings to the research community would be even greater. A single inspection, depending on the size of the research facility and duration of the inspection, can cost \$1,321-\$20,000. In a survey of 17 top research facilities, the average inspection cost was \$5,780. This would average out to a savings of \$57,800,000 over ten years.
- In the first two quarters of FY 2018 research facilities have undergone 541 inspections of which 49 resulted in paperwork citations being issued, out of which only 2 were found to have any non-compliance directly related to animal welfare. These numbers represent roughly 1,000 USDA Registered Research Facilities. In FY 2017, 82% of all research facility inspections resulted in no citations.
- Between FY 2006 and FY 2016, the number of citations directly attributable to research facilities dropped 87%.
- This action would begin to harmonize the AWA and bring research into line with how USDA's Animal and Plant Health Inspection Service (APHIS) handles inspections for dealers, exhibitors, intermediate handlers, carriers, or operators of auction sales. Animal research facilities are the only named group under the AWA to have mandatory annual inspections.

The biomedical research community has an outstanding record of compliance with the AWA, employs entire teams of full-time experts in animal welfare, and strongly supports reasonable regulation that ensures responsible animal care and welfare while balancing valuable researcher time. Efforts such as your amendment represent a step in the right direction toward providing much-needed regulatory relief for the expedition of lifesaving discoveries while also saving medical research centers, the USDA, and American taxpayers time and money.

Thank you for your amendment and for the opportunity to submit our support.

Sincerely,

American Academy of Neurology (AAN)
 American Thoracic Society
 Animal Blood Bank, Inc.
 Association for Research in Vision and Ophthalmology (ARVO)
 Biotechnology Innovation Organization (BIO)
 Boston University
 California Biomedical Research Association (CBRA)
 The College on Problems of Drug Dependence, Inc.
 Colorado State University

⁴ <https://www.usatoday.com/story/opinion/2017/12/26/enforce-animal-welfare-act-protect-animals-humans-taxpayers-delcianna-winders-column/953069001/>

Cornell University
Drexel University College of Medicine
Duke University
George Mason University
IACUC 101
Massachusetts General Hospital
National Association for the Advancement of Animal Science (NAAAS)
National Association for Biomedical Research (NABR)
National Association of Veterans' Research and Education Foundations (NAVREF)
Nationwide Children's Hospital
New Jersey Association for Biomedical Research (NJABR)
Northeast Ohio Medical University
Northwest Association for Biomedical Research (NWABR)
Pennsylvania Society for Biomedical Research (PSBR)
PreClinical Research Services, Inc.
RxGen
Sinclair Research Center, LLC
Smithers Avanza
States United for Biomedical Research (SUBR)
Texas Society for Biomedical Research (TSBR)
University of Georgia
University of Houston System
University of Maryland, Baltimore
University of New Mexico
The University of Texas Medical Branch
The University of Texas at San Antonio
University of Wisconsin – Madison
Yale University