National Association for Biomedical Research

UPDATE

September 19, 2017

A Message from the NABR President to Florida Research Institutions

NABR staff extends our deepest sympathies and best wishes to our friends in Florida and the surrounding communities that have been affected by Hurricane Irma. Please do not hesitate to reach out to NABR staff if we can be of service during this difficult time.

Thank you again to all of the “ride-out” teams who have cared for the animals housed in research facilities during this horrendous hurricane season. You are true heroes.

-Matthew Bailey, NABR President

VA Secretary Opposes Defunding of VA Dog Research

Last week, U.S. Secretary of Veterans Affairs (VA) David Shulkin, MD, wrote a powerful column in *USA Today* defending the VA’s canine research program. Secretary Shulkin’s column was published in response to legislation being considered by Congress that targets important dog studies at the VA.

"Science and research are more critical than ever in providing breakthroughs for many unique conditions affecting our veterans. America needs VA’s innovative research programs, and veterans and their families have earned them. We owe it to these patriots to do all we can to develop medical advancements that could help restore some of what they have sacrificed in service to our nation," wrote Secretary Shulkin.

H.R. 3197 (the PUPPERS Act), introduced in July by Representatives Dave Brat (R-VA) and Dina Titus (D-NV) would prohibit the use of dogs in Category D and E studies at the VA. It is awaiting consideration by the House Veterans Affairs Committee. A similar amendment offered by Rep. Brat and subsequently approved in the homeland security "minibus" would defund these studies in FY18. This legislation could negatively affect the future of medicine for veterans and civilians alike.

Secretary Shulkin, the Paralyzed Veterans of America (PVA), The American Legion, Friends of VA (FOVA), the Iraq & Afghanistan Veterans of America (IAVA), Vietnam Veterans Association (VVA), Association of the U.S. Navy (AUSN), National Defense Committee, Square Deal for Veterans, the American Veterinary Medical Association (AVMA), the American Physiological Society (APS), and the American Association for Laboratory Animal Science (AALAS) have publicly opposed this legislation. Now is your opportunity to join them by making your concerns known to policy makers.

We encourage you and your family, friends, colleagues, and neighbors to send this pre-formatted letter to your Representatives and Senators, which outlines concerns about H.R.3197 and Rep. Brat's amendment.

The letter explains the consequences of the legislation as well as the many significant medical discoveries resulting from research with dogs.

CLICK HERE TO TELL CONGRESS TO OPPOSE DEFUNDING OF VA DOG RESEARCH

FDA Calls for Regulatory Burden Comments

The U.S. Food & Drug Administration (FDA) is calling for comments regarding regulatory burden. The agency is specifically seeking information "to help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing us to achieve our public health mission and fulfill statutory obligations."

FDA calls for comments and information from interest groups on the following questions, which have been extracted in full from FDA's notice in the Federal Register:

Is the regulation still current, or is it outdated or unnecessary in some way?

Have there been advancements and innovations in science, technology, or FDA or industry practice, or any other changes that suggest repeal of or modification to the regulation may be warranted or appropriate?

Has the regulation been superseded or made irrelevant or unenforceable by statute, another FDA regulation or guidance, a regulation by another Federal Agency, or controlling legal authority? If yes, identify the statute, regulation, guidance, or legal precedent and explain what FDA regulation is affected and in what way it is affected.

Is this regulation duplicative of requirements in other FDA regulations or other Federal Agency regulations? If yes, identify the overlapping regulation(s) and responsible Federal Agency and describe the way(s) in which the regulations overlap, as well as any suggestions with respect to how best to resolve the duplication.

Have regulated entities had difficulties complying with the regulation? If yes, identify what entity or entities have had such difficulties and the nature of the difficulties.

Does the regulation impose requirements that are also provided for in voluntary or consensus standards or guidance by third party organizations (e.g., International Council for Harmonisation, International Organization for Standardization, Codex Alimentarius)? Do the entities covered by these standards or guidance take steps to meet the standards and to document that they meet the standards? If met, do the standards achieve the same level of public health protection as the FDA regulation? Are there entities who are not covered by these standards or guidances or who choose not to observe them?

Does the regulation contain redundant, outdated, or unnecessary collections of information or retention of records, e.g., reporting, recordkeeping, or labeling requirements? Explain in your response why the information is redundant, outdated, or unnecessary.

Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection? If yes, provide examples of alternatives that may reduce costs to industry while retaining the same level of public health protection.

What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

Comments can be submitted electronically or by mail, and will be accepted through December 7, 2017. Please note all comments must include the Docket No. FDA-2017-N-5093 for "Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration." NABR plans to submit comments and will share them with membership. Public comments can be made and read here after submission. Click here to review FDA's notice in the Federal Register.

"Love Your Dog, Support Animal Research"

In an op-ed published in Monday's print and online editions of *The Wall Street Journal*, NABR and Foundation for Biomedical Research (FBR) President Matthew R. Bailey chronicled the ways in which pets, farm animals, and wildlife benefit from animal research.

We urge you to read the article, share with your networks, and join the conversation by submitting a supportive comment and publishing a post on your social media pages. You can find FBR's posts on Twitter, Facebook, and LinkedIn to share with your friends and followers. It is crucial to build public support for animal research to support the work of scientists seeking cures and treatments for diseases that affect people, as well as companion animals and wildlife. Please join FBR in this effort by passing the op-ed to your friends, colleagues, and families. For a PDF copy of the article, click here.

Monkey Selfie Appeal Settled

Naruto v. Slater, a 2015 copyright lawsuit brought by People for the Ethical Treatment of Animals (PETA) against a wildlife photographer, has been settled. As reported in *NABR Update*, PETA alleges that Naruto, a male crested black macaque, is the proper copyright owner of a viral "selfie" taken with photographer David Slater's camera. The terms of the settlement require Slater to donate 25 percent of future revenue from the photograph to organizations that protect the Indonesian habitat of crested macaques.

PETA and Slater provided a joint statement upon reaching the agreement: "PETA and David Slater agree that this case raises important, cutting-edge issues about expanding legal rights for nonhuman animals, a goal that they both support, and they will continue their respective work to achieve this goal."

Last year, U.S. District Judge William Orrick ruled in favor of Slater, on the grounds that animals do not have standing to sue under the Copyright Act. In July, PETA appealed the decision to the U.S. Court of Appeals for the 9th Circuit and oral arguments were heard in San Francisco by a panel of three judges. PETA considers this a "groundbreaking lawsuit" and progress toward its mission of extending "fundamental rights to animals for their own sake — not in relation to the ways in which they can be exploited by humans."

To read more about the case, click here.

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