

PhysiciansCommittee

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Comments for 21st Century Cures Act Listening Session with
NIH, USDA, and FDA – Held Jan. 9, 2018 in Washington, D.C.

Submitted by:

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The Physicians Committee for Responsible Medicine is a nonprofit organization with more than 12,000 physician members and 150,000 members total.

We acknowledge the mandate put to NIH, USDA, and FDA under the 21st Century Cures Act. But we caution your agencies against enacting reforms that compromise the limited protections for animals in labs.

While opponents of government regulations in this area claim that many rules simply create paperwork and roadblocks for animal experimenters and the institutions that employ them, those rules are rooted in public and Congressional concern for animals and expectations of transparency as a means of ensuring protections.

We should also pair that concern with the federal government's long history of inadequate enforcement of animal welfare in laboratories. In 2014, the USDA's own Office of Inspector General found that:

- the agency closed investigations involving grave Animal Welfare Act violations, including animal deaths and serious repeat violations;
- USDA failed to properly apply financial penalties, reducing fines by an average of 86 percent – despite previous Inspector General recommendations to end this practice; and
- USDA wasted resources by conducting more than 500 inspections at more than 100 facilities that had not housed animals covered by the Animal Welfare Act for more than two years.

All of this should be cause for greater protections for animals and improved openness about what happens inside laboratories. Yet the authors of an October 2017 report recommend that the government pare back its requirements. That report, from the Federation of American Societies for Experimental Biology (FASEB) and others, also recommends giving animal experimenters and their employers greater control over the creation of new rules.

Any review of proposed regulatory or policy changes should include the public, including representatives of the animal protection community and experts in nonanimal research and testing methods.

One of the most troubling recommendations of the FASEB report is a change to one of the core enforcement mechanisms of the Animal Welfare Act. It would strip away the requirement to inspect every registered research facility once per year. Yet billions of dollars of public money are spent on animal experiments each year by the NIH alone, with many facilities receiving millions or hundreds of millions of dollars. The change put forth by FASEB and others would significantly reduce public accountability at those facilities.

In order to ensure proper enforcement of the Animal Welfare Act, we should not reduce inspections. Instead, USDA should address the inefficiencies found by its own Inspector General, and Congress should allocate more funds to USDA to carry out its work.

At its core, the issue we are discussing today is one of volume. In U.S. labs, the number of animals, especially those not covered under the Animal Welfare Act, continues to rise. This is because the current regulatory framework provides no incentive to replace animals. In fact, NIH spends about \$12-13 billion annually on animal research, which only encourages institutions to expand their animal facilities in order to secure more agency funding.

If you want to reduce what some call “regulatory burden,” you should reduce the number of animals in labs. There are at least four ways in which this could be encouraged:

- **First, amend section 2143 of the Animal Welfare Act in order to *require* the use of suitable alternative methods and strategies whenever available. It is clear that the current approach of merely *considering* alternatives is not enough to prompt this simple step.**
- **Second, amend the definition of “animal” in section 2132 of the Animal Welfare Act to include all vertebrates. This change would align USDA and NIH regulations, thereby reducing the regulatory burden of inconsistent enforcement requirements, and bring the U.S. in line with other countries’ standards.**
- **Third, NIH should embed in its application and study section processes the *requirement* to use alternative methods if available. This could be partially achieved by requiring that every grant application be reviewed by at least one expert in nonanimal methods within the study section’s given field.**
- **Fourth, many FDA regulations currently require that drug sponsors submit data derived from animals, hampering companies’ ability to use nonanimal methods. Yet those nonanimal methods, including organs-on-a-chip, are becoming increasingly available and robust. FDA should remove its requirements for animal data to reduce burden and ensure the longevity of the regulations in the face of rapidly advancing human-based science.**

Thank you for taking these comments into consideration. In the near future, I hope NIH, USDA, and FDA will convene more public forums dedicated solely to this important topic.