

Report on Research Compliance Volume 15, Number 2. February 28, 2018 As Agencies Review Regs, Animal Groups Urge Alternatives, Inclusion

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In compliance with the 21st Century Cures Act, federal agencies plan to issue in March a formal request for information to solicit feedback on how they might reduce the regulatory burdens or administrative tasks that accompany animal research.

But they have already begun to gather suggestions, as in January representatives from NIH's Office of Laboratory Animal Welfare (OLAW), the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) held a "listening session" in Washington, D.C., at the conclusion of the recent two-day meeting of the Federal Demonstration Partnership.

Specifically, the Cures Act, signed into law in December 2016, requires a review related to "animal care and use in research." The law states:

Not later than 2 years after the date of enactment of this Act, the Director of National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, shall complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. In carrying out this effort, the Director of the National Institutes of Health shall seek the input of experts, as appropriate. The Director of the National Institutes of Health shall—

1. identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, including with respect to inspection and review requirements by Federal agencies and accrediting associations;
2. take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and
3. take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

USDA regulations are part of the Animal Welfare Act (AWA). OLAW has oversight of NIH-funded animal research.

Listening session participants attended the one-hour meeting in person, but it was also available via teleconference. Nine speakers who addressed the agencies during the session included officials from academia, animal rights organizations and research groups, and hailed from PETA, the Humane Society of the United States (HSUS), as well as the University of Michigan and a pharmaceutical firm.

The animal rights organizations generally urged the agencies to maintain, if not strengthen, protections for animals used in research and the functioning of institutional animal care and use committees (IACUCs), with the overall goal of using fewer animals and employing alternative methods of testing and research.

Meanwhile, those hailing from research organizations and universities nearly uniformly suggested that a good starting point for the government would be the report issued last year that was completed in response to the Cures Act's dictate (RRC 10/26/17).

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