NIH-USDA-FDA 21st Century Cures Act Meeting on Animal Research
March 12, 2018 | AWI, HSLF, PCRM, and HSUS

1. Introduction of Attendees
    - Tracie Letterman, Vice President of Federal Affairs, Humane Society Legislative Fund (HSLF)
    - Nina Wertan, Program Manager for Animal Research Issues, Humane Society of the United States (HSUS)
    - Kathleen Conlee, Vice President of Animal Research Issues, HSUS
    - Nancy Blaney, Director of Government Affairs, Animal Welfare Institute (AWI)
    - Ryan Merkley, Director of Research Advocacy, Physicians Committee for Responsible Medicine (PCRM)
    - Deborah Press, Associate General Counsel, PCRM

2. Introduction of 21st Century Cures Act, Section 2034(d) Working Group Representatives
    Speakers:
    - Patricia Brown, Director, Office of Laboratory Animal Welfare (OLAW), NIH
    - Kay Carter Corker, Director, National Policy Staff, USDA-APHIS, Animal Care
    - Betty Goldentyer, Associate Deputy Administrator, USDA-APHIS, Animal Care
    - Estella Jones, Senior Regulatory Veterinarian, Office of the Commissioner, Office of Counterterrorism and Emerging Threats, FDA

    Other Members:
    - Lori Hampton, Division of Policy and Education, OLAW, NIH
    - Eileen Morgan, Division of Assurances, OLAW, NIH
    - Brent Morse, Division of Compliance Oversight, OLAW, NIH
    - Susan Silk, Division of Policy and Education, OLAW, NIH
    - Axel Wolff, Deputy Director, OLAW, NIH

3. Review of Questions
    a. **Are there any particular areas that have been identified in terms of prioritization for streamlining as per the Cures Act?**
    [OLAW] The 21st Century Cures Act, Public Law 114-255, is comprehensive legislation directed at improving opportunities for next generation researchers in funding, mentorship, workforce diversity, recruitment, and retention. The legislation requires conduct of activities to promote the development of researchers including evaluation and oversight of existing programs. Under section 2034 of the Act, Reducing Administrative Burden for Researchers. NIH, USDA, and FDA are directed, in section (d) Animal Care and Use in Research, to: *…review 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 finding and protection of research animals.* 2034(d) goes on to identify the specific activities expected by Congress: *identify inconsistent, overlapping, unnecessarily duplicative regulations and policies with a focus on inspection and review requirements; take steps to reduce same; take actions, as appropriate, to improve coordination of regulations and policies with respect to research with laboratory animals.* The NIH, USDA, FDA 21st Century Cures Act Section 2034(d) Working Group (Working Group) has prioritized it's work in terms of these 3 specific directions (identifying overlapping regulations and policies, taking steps to reduce such guidance, and taking actions to improve coordination of our guidance) as directed by the US Congress.

b. **Is there anything that you can share with us regarding the status of the review of regulatory burden?**
[OLAW] Yes. The Working Group is in the process of conducting number (1) *identifying inconsistent, overlapping, or unnecessarily duplicative regulations and policies*. This process consists of the following steps: (a) reviewing published studies that address inconsistent, overlapping, or duplicative regulations (including the areas of inspection and review requirements) that contribute to researchers' administrative burden (b) conducting listening sessions. (The working group would like to acknowledge the participation of many present at the FDP listening session conducted on Jan 9. 2018 and (c) issuing an RFI that will be released shortly (during March 2018). Later this year, the working group will begin to develop recommendations for accomplishing task (2) (steps to reduce burden), and task (3) (actions to improve coordination), based on our findings from the working group's earlier effort.

c. **We are concerned about the report, "Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden," released by the research community which contains 20 recommendations to change current welfare standards. Is AC/OLAW/FDA considering any of these? And if so, which ones and why?**
[OLAW] The 21st Century Cures 2034(d) Working Group is currently reviewing this document as one of several under study. We have provided you with a list of those documents under review. Our review of the documents has not been completed at this time so, of course, no information is available yet. When the Working Group has fulfilled its charge, a report describing results and recommendations will be released. A preliminary document is expected to be released by December 2018.

d. **Has there been any discussion with OMB about the Research Policy Board (RPB) via the Cures Act?**
[OLAW] Not by the 2034(d) Working Group as our charge is section (d) the RPB charge is section (f).

If so, what is the timeline for associated activities, including solicitation of public comment?
[OLAW] According to 2014 Reducing Regulatory Burden (f) Research Policy Board (1) Establishment: OPM shall establish the Research Policy Board within not later than December 2018.

Is there a contact at OMB to whom it would be best to direct further questions?
[OLAW] The 2034(d) Working Group is not involved in actions being taken by other offices or agencies concerning other sections of the Act so cannot make any recommendations about who to contact.

e. **Will the public/relevant stakeholders have the opportunity to provide input on the development of the Research Policy Board?**
[OLAW] The 2034(d) Working Group is not privy to the actions being taken related to the 2034 (f) requirements.

Will Animal Care/OLAW/FDA be advocating for inclusion of animal welfare representatives or ethicists? Will experts in non-animal methods be included as well?
[OLAW] The Research Policy Board's purpose and responsibilities as described in Section 2034(d) extend beyond issues of animal care and use. The law directs OMB to establish an appointment process for non-federal members and it is outside of the scope of the 2034(d) Working Group to be engaged in recommendations for non-federal representatives.

f. **Since 2016, appropriations language has defunded the licensing of Random Source Class B Dealers. Would you be supportive of amending 7 U.S.C § 2137 and § 2138 of the AWA to prohibit the use of random source dogs and cats in research?**
[USDA] USDA adheres to the appropriations language and will respond to inquiries/questions. Noted

that the Working Group does not inform or provide recommendations to the Secretary of Agriculture.

g. **Is there any update on the third-party investigation being conducted to review animal research at FDA and what the oversight responsibilities will be for the newly created Animal Welfare Council?** [FDA] No further information is available on investigation activities. The Council has been created and will consist of veterinarians and scientists from each of the FDA Centers.

4. Review of Recommendations

[OLAW] Noted, the below recommendations should be submitted to NIH, USDA, FDA 21st Century Cures Animal Care and Use Working Group through the RFI that will be released shortly. Expected release date is March 2018. Note also that NIH funding decisions are outside the scope of OLAW and the NIH, USDA, FDA 21st Century Cures Section 2034(d) Working Group.

a. NIH
    i. **Fund systematic reviews of all animal research areas.** Such reviews would help NIH determine where animal models are clearly failing to translate to human health outcomes and implement roadmaps for reducing and replacing animals with more effective and less burdensome methods. This approach was exemplified by the Institute of Medicine's 2011 report on the use of chimpanzees in biomedical and behavioral research.
    ii. **Insert a rigorous examination of nonanimal methods into the study section review process for each project involving vertebrates. The proposal would be reviewed by experts in nonanimal approaches within that given field.** Because USDA interprets the AWA as only requiring the consideration of alternatives, mere IACUC approval of a research project is not evidence that replacements are unavailable. NIH also has a role in promoting best ethical and scientific principles when approving studies.

b. USDA
    i. USDA should make the following changes to current regulations:
        1. **Amend 9 C.F.R. § 1.1 to define "Alternatives";**
        2. **Amend 9 C.F.R. § 1.1 to clarify definition of "Painful procedure";**
        3. **Amend 9 C.F.R. § 2.31(d)(1)(ii) to include specific requirements for the consideration of alternatives to procedures likely to produce pain or distress to animals; and**
        4. **Amend 9 C.F.R. § 2.31(a) by adding, as a final sentence, "APHIS is authorized to issue orders to correct deficiencies or deviations from the standards set forth in this section."**

    Reducing research facilities' use of animals for purposes for which nonanimal methods are widely available would ease USDA inspections of those facilities. Amending APHIS's regulations to eliminate ambiguity, providing advance notice to research facilities of Congress's expectations in enacting the statute, and empowering APHIS to provide additional guidance during inspections would, in the long term, streamline inspections and encourage research facilities to proactively reduce their regulated activities.

c. Multiple Agencies
    i. **Harmonize all NIH and USDA requirements on animal welfare to the highest possible standard.** Harmonization of regulations, guidance and policies will help alleviate confusion and make it easier for research facilities to adhere to animal welfare requirements. It is important that any efforts to standardize agency requirements ensure following the best practices as it pertains to animal welfare.
    ii. **Increase diversity on institutional animal care and use committees (IACUCs) to include more members who do not use animals or who can provide guidance regarding alternatives for research applications.** While IACUC membership requirements are specified under the Public Health Service Policy on Humane Care and Use of Laboratory

Animals and the Animal Welfare Act, there is no requirement on the percentage of members who use animals – or exclusively nonanimal methods – in their work. Requiring that IACUCs maintain a minimum membership percentage of individuals who do not use animals or have specialized knowledge of alternatives, as defined under the Animal Welfare Act, would reduce possible conflicts of interest and increase knowledge of nonanimal methods.

5. Discussion and additional Q&A
    a. How long will the RFI comment period be? 90 days.
    b. Has Congress asked for a report? The Act requires that NIH submit a report to Congress by December 2018.
    c. What studies are being reviewed? See Handout.
    d. Will the Working Group accept recommendations for additional studies for review? Yes, all suggestions are to be submitted through the RFI.
    e. Suggest expanding Working Group members to include representatives from other parts of NIH and other FDA Centers.
    f. Can suggestions pertaining to policies on review and funding be submitted? The Working Group focuses only on the Cures Act requirements and investigator burden.
    g. Urge deference to the highest standards of welfare and more diversity on the IACUC.

6. Handout: 21st Century Cures Act: Sec. 2034 and documents under review by Working Group.