

21st Century Cures Act Listening Session with NIH, USDA, and FDA  
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Comments offered by the Ornithological Council

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Thank you for holding this listening session and thank you for affording us the time to speak today.

The ornithological council is a consortium of 11 scientific societies of ornithologists. Those societies span the western hemisphere. Six of them are based in the United States.

It is our mission in part to represent those ornithologists to the agencies that develop and implement the policies that regulate their research, including agencies that issue permits and agencies that implement animal welfare laws.

These comments focus on the burden to the researcher rather than the burden on the institution.

We recognize that the focus of the mandate of the 21<sup>st</sup> Century Cures Act is on the administrative burden and that entails elimination of regulations that are inconsistent, overlapping, or duplicative

Some of the inconsistencies are statutory and probably can't be addressed through this process, except to the extent that it results in recommendations to the Congress for statutory changes.

For instance, the agencies can't change the fact that the AWA covers warm-blooded animal whereas the Health Research Extension Act (HREA; implemented via the PHS Policy) has no definition. And based on current understanding of nociception and behaviors that follow injuries, probably all of us would include some invertebrates at this point.

These are problems that the agencies can't solve themselves.

Meanwhile, the fact that we have two agencies, one regulatory and the other exercising authority through grant conditions, has resulted in divergent requirements.

As the recent FASEB report suggested, perhaps it is time to consolidate oversight of research under one agency with a new statutory authority.

What can be done in the meantime?

Based on our rather unfortunate experience with the Federal Demonstration Project, I would suggest that limited or periodic interactions are not sufficient. We should not get to a point where the regulated community is banging at the doors, virtually begging to have a voice. It shouldn't take an act of Congress to get us to this point.

We appreciate that OLAW generally seeks public comment even though it is not required to do so. And of course, APHIS is bound by the Administrative Procedures Act, though the notice-and-comment process is tail-end and not sufficient. At the very least, we encourage APHIS to use the advance notice of proposed rulemaking process to give the regulated community a voice early in the process, as it did with the rats, mice, and birds rule.

However, these devices are not truly sufficient. The regulated community is not only regulated; it is also a source of expertise and experience.

We suggest that a process of ongoing participation of the community would be more than valuable. There should be a regular feedback process. The regulated community would submit problems and questions to an ombudsperson, the agency would open the discussion to the community and a joint solution would be devised. Community knowledge and practice is particularly valuable where little published research is available.

We also suggest the integration of researchers into the decision-making process, perhaps through the Federal Advisory Committee Act process in the case of APHIS and perhaps through the establishment of a joint "stakeholder-agency" advisory board in the case of OLAW.

Avoid the use of internal guidance documents to add non-regulatory requirements as happened when Animal Care imposed the AVMA Guidelines on Euthanasia via text in its Inspection Manual, which went beyond and contradicted the AWA regulations.

However, these are not the real reasons that regulations are burdensome. The real issue is the value-added for improved animal welfare.

If a standard or process does not achieve that end, it is by definition unjustified burden.

In addition, we urge simplification. This is an enormous challenge but it is essential. It took months – with the assistance of OLAW to write a simple document explaining how to determine which agency's rules apply to a particular research project.

Every time I see the OLAW chart on reporting requirements, I envision Talmudic scholars writing endless reams of biblical interpretations. In part this results from using The Guide as the basis of determination. *However, if the research is being conducted or has been conducted, it means that the IACUC approved the protocol and because the IACUC approved the protocol, then the relevant standard is the protocol, not the Guide.*

Finally, the major issue of concern to ornithologists and other wildlife biologists is the very poor fit between the existing statutes, regulations, and guidance documents, including and especially the ILAR Guide, and wildlife research. We have published and spoken on this repeatedly. The

Federal Demonstration Partnership, which is co-chaired by OLAW, remains largely closed to wildlife biologists. In recent years, OLAW has become more welcoming of input from wildlife biologists but there is room for improvement. Animal Care has had no meaningful dialogue with wildlife biologists. We point to the example set by an APHIS sister agency – the National Import Export Services program, which routinely reaches out to wildlife organizations to ask how a potential change might affect our members and, if it would impose an additional burden, welcomes dialogue about ways to ameliorate the burden while still achieving the agency objectives.

Animal welfare policy and the actual application of that policy must rest on biological science if it is to be effective in protecting the animals we study. Regulators must also take into account the logistical realities of field research. Time and again, we have seen the development of policies that are unsuited to wildlife and the conditions of wildlife research. These policies can be detrimental to the well-being of the animals and hamper the research that is intended to benefit those animals. We urge OLAW and Animal Care to establish a regular practice of including wildlife biologists in the early stages of the formation of new policy, revision of existing policy, and the development of guidance materials and to seek review of policies and guidance materials from wildlife biologists.