21st Century Cures Act: NIH-USDA-FDA Listening Session on Animal Research

January 9, 2018

by Cathy Liss, President

I believe that most of you are familiar with the Animal Welfare Institute, and if not, and you are interested in our Policy on Research and Testing with Animals, it can be found on our website or at the back of our most recent edition of Comfortable Quarters for Laboratory Animals (tenth edition, 2015).

Thank you for the opportunity to provide comment on Section 2034 (d) of the 21st Century Cures Act. It is not possible to provide sufficient feedback in the time we have been allotted today. Therefore, I will respond broadly now and with greater specificity in our written submission.

I'm going to begin with a bit of history too--my work at the Animal Welfare Institute began in the early 1980s when a groundswell had formed and the general public and Congress were determined to see improvements made to address serious problems occurring in laboratories across the country. In 1985 when the Improved Standards for Laboratory Animals Amendment and the Health Research Extension Act were passed, every effort was made to establish a process that kept costs to a minimum, while providing the oversight that the public demanded to protect animals in research.

Now more than three decades later, we are concerned about a move underway to reduce some of the hard won processes that have been in place and working for a very long time. It is appalling to think of this happening despite the fact that our current protections are so limited, weak and out of date. How can we have a law that denies protections to rats, mice and birds, the animals most commonly used in research? Let alone other animals such as fish who can suffer and deserve protection under the law. How can we not have a federal mandate that ensures that all animals in research are maintained in species appropriate housing, not subject to needless distress and pain, handled using positive

reinforcement rather than force, and that strong and swift action will be taken against violators—who are not viewed as "customers"? We should be discussing ways to move forward, rather than this current move to shed whatever responsibilities you can.

Recently, the Department of Health and Human Services has described itself as stewards of Federal investments in biomedical research, with NIH *striving to earn and maintain the public's trust* and as you know, NIH has embraced a mantra that "good animal care and good science go hand in hand." Meantime, the Department of Agriculture Animal Care program's current strategic plan set a goal to "promote animal welfare," optimizing the health and well-being of animals, including the use of all available tools."

This all sounds good. But the reality is that a workshop was held by FASEB, AAMC and COGR with "assistance" from NABR (a group with an agenda that has opposed essentially every proposed protection for animals) to "*reform* animal research regulations." This now is the next step in the process, and we have to wonder why we are being invited to the process so late in the game? Had the effort been to help smooth out the wrinkles in regulation and the supposedly weighty requirements stifling research all while still ensuring the welfare of animals and the good science that goes hand in hand with it, why couldn't an animal welfare representative or two be a part of the early process? Where is the data to demonstrate the burden that has been weighing on researchers? Is it really too much to expect a researcher to conduct a legitimate literature search for alternatives to painful procedures (which as you know isn't even a requirement anymore)? How can just one USDA inspection a year for compliance with MINIMUM standards be a burden to a research institution? Why shouldn't an Institutional Official be aware of "alternative strategies" being employed at the facility he or she is responsible for overseeing?

While we are being presented with various changes under the guise of "streamlining," we have to question the efforts on this issue to date. If this is the track, and our comments are viewed as being merely perfunctory, please know that we will vehemently oppose any efforts to reduce protections for

animals who are experimented on. The use of animals is a privilege not a right. There are responsibilities incumbent on the research industry to ensure pain and distress are minimized, animals are provided with needed care, the number used is kept to a minimum, and unintended duplication is avoided. IACUC and IO oversight is important, but so is the enforcement provided by USDA and the potential for loss of grant funds by NIH.

If this is to be a legitimate process then let's walk through it together—we want to be a part of it. Provide transparency about what needs to be fixed and why, allow us to provide important input, and give us the assurance we must have that animals in research will not be subject to renewed suffering in the laboratory.

As you well know, NIH provides about 20,000 extramural grants totaling approximately $10 billion.

We consider “departures” or “deviations” from “should” in the Guide to warrant reporting in the semiannual report to the Institutional Official.

Long-standing effort to whittle away at Policy #12. Already there is language permitting alternatives to conducting the literature search. It is already underminded!

HHS: ***Enhancing Stewardship***
As stewards of Federal investments in biomedical research, NIH strives to earn and maintain the public’s trust. The role of the United States as a leader in biomedical research depends not only on innovation in the laboratory and the clinic, but also innovation in how science is funded, performed, and managed.

A mantra at NIH has been that good animal care and good science go hand in hand.