

Comments by Jennifer Ball on behalf of The Humane Society of the United States

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

January 9, 2018

I appreciate the opportunity to present input on the review of policies and regulations related to animal care and use in laboratories as required by the 21st Century Cures Act.

First and foremost, The Humane Society of the United States urges that any proposed changes through this process should not result in fewer protections for fewer animals in laboratories. There is no doubt that animal welfare will be negatively impacted by pushing all facilities to the lowest common denominator. Instead, any streamlining and harmonization should be done towards the highest possible standards of care for the most animals.

Further, in order to ensure any suggested changes to regulations or guidance maintain protection for laboratory animals, at least one representative from the animal welfare community should be included in the Research Policy Board that will be established through the legislation. It would also be advisable to seek input from alternative test developers because the best way to protect animals used in research is to replace their use with non-animal methods. Further, public input should be sought on any board or committee membership to help improve transparency as well as ensure public trust and accountability in the process.

We are particularly concerned about a set of 20 recommendations that were released in October by several organizations within the research community. Those recommendations include suggestions like weakening regulations and policies that govern Institutional Animal Care and Use Committees (IACUCs), decreasing the number of APHIS inspections, and removing USDA policy that suggests the completion of literature searches for alternative test methods. If adopted, these recommendations would limit statutory and regulatory oversight of the care and use of laboratory animals and result in adverse effects on animal welfare as well as decrease transparency and public trust in research institutions. We have submitted comments in response to each of these recommendations for your consideration.

In addition, The HSUS would like to suggest four proposals for harmonizing and simplifying oversight requirements of United States Department of Agriculture (USDA) and National Institutes of Health (NIH).

The first is to amend the definition of “animal” in Animal Welfare Act (AWA) to include all vertebrates. This change would not only align USDA and NIH regulations but would also harmonize U.S. policy with other countries and industry standards.

The second recommendation is to amend the AWA to prohibit the use of random source dogs and cats in research. Due to a history of violations related to standards of care for the animals and obtaining animals illegally, USDA Animal and Plant Health Inspection Service (APHIS) has been inspecting random source Class B dog and cat dealers quarterly as opposed to other dealers which are supposed to be

inspected annually. The agency must also perform tracebacks to determine whether animals were obtained from legal sources. Despite the additional oversight, continued concerns about random source dealers led to an NIH decision to end the use of cats and dogs from random sources in federally funded research in 2012 and 2014 respectively. We believe there is no reason to continue to waste resources regulating random source Class B dealers.

The third recommendation is to amend the AWA to require the use of alternative test methods and strategies whenever available. 21st century science is moving away from animal tests. Many effective alternatives to animal testing exist, including 3-D printing, construction of artificial human tissue, and the generation of sophisticated computer programs that can make accurate predictions about chemical safety. Research facilities should be required to use any available methods that replace, reduce, or refine animal use.

And finally, I want to reiterate our recommendation that all NIH and USDA requirements on animal welfare be harmonized 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 best practices are followed as it pertains to animal welfare.

Thank you for the opportunity to present input on this topic and The HSUS looks forward to participating throughout this process.