

Testimony [J.R. Haywood]

I would like to thank NIH, USDA and the FDA for the opportunity to provide oral and written comments at the January 9, 2018 Listening Session in response to the mandate in the 21st Century Cures legislation. My principal goal is to offer into the record the report “Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden”. This document is the result of a one-day workshop that brought together over 30 experts on the regulations, policies, and guidelines designed to ensure the humane care and use of animals used in research and education. The topic of discussion was to provide NIH, USDA and FDA comments and direction in responding to the 21st Century Cures legislation that required the agencies to “...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.” The workshop was organized by four organizations – the Federation of American Societies for Experimental Biology, the Association of American Medical Colleges, the Council on Governmental Relations, and the National Association for Biomedical Research. The attendees represented a cross-section of individuals and organizations in the research community. The goal of the workshop was to provide specific suggestions that would reduce research-related regulatory burdens on investigators directly or indirectly.

“Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden” is the result of that workshop. The 19 recommendations are directed to the specific agencies, but in some cases require action by the Office of the President and/or Congress. The guiding principle in the formulation of these recommendations was that in the search for more efficient regulatory oversight, animal welfare must not be compromised. If anything, it was hoped by reducing paperwork burdens more time can be devoted to oversight of animal care and use. The recommendations range from specific details related to the effectiveness and efficiency of ensuring optimal animal care by the research institutions to big picture ideas related to the agencies charged with oversight of the federal research enterprise.

The document represents over 20 years of discussion, observation, analysis, and recommendations by the lab animal, scientific, and research administration communities. The present oversight system was established more than 30 years ago with the issuance the Health Research Extension Act and the Public Health Service Policy and, subsequently, the Animal Welfare Act Regulations. The system has been expanded through additional legislation and modified and increased through policies, guidances, FAQs, webinars, published comments, and a variety of other means. During this time, the discipline of laboratory animal medicine has evolved and flourished. The scientific community has driven innovation and scientific understanding of the welfare of animals. Development of new technology has provided advances in animal welfare that have been driven by the lab animal and scientific communities. Studies investigating the impact of enrichment, improvements in housing, new ways to study animals repetitively over time, and a greater understanding of animal care and pain management have all contributed to increased animal well-being and better science. However, while all of these advances in animal care have been evolving, we have not stepped back and re-evaluated the effectiveness, utility, and/or necessity of the regulations, policies and guidelines written 30 years ago. The underlying purpose of the 21st Century Cures Act is to enhance discovery and delivery of treatment and cures to patients through research and reduced research-related regulatory burdens. It is time to modernize our regulatory oversight of animals to match our advancements in animal care and scientific discovery with a focus on animal welfare.