SOCIETY for NEUROSCIENCE

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On behalf of the Society for Neuroscience (SfN), thank you for the opportunity to provide feedback on the FDA-NIH Workshop on Reducing Animal Testing and the broader goals outlined in the agencies' strategic plans to support the advancement of New Approach Methodologies (NAMs). As the world's largest organization with nearly 30,000 members dedicated to advancing the understanding of the brain and central nervous system, SfN is committed to advancing biomedical research that drives innovation, improves public health, and maintains the United States' global leadership in scientific discovery. To achieve this, the ethical and responsible use of animal models is essential in areas of research where NAMs are not yet suitable for replacement.

Research with animal models is currently well-regulated and irreplaceable in neuroscience research. Animal models are vital and irreplaceable for scientific progress and in combating the devastation of human brain disorders, such as Parkinson's disease, Alzheimer's disease, addiction, vision and hearing loss, depression, and autism, which affect more than one billion people worldwide. Using animal models provides the basis for the understanding of nervous system function and the general physiology and biology of both humans and animals. It has been essential to nearly every major scientific breakthrough in neuroscience and medical advances improving human health and well-being.

As highlighted in the workshop, both FDA and NIH have made an ongoing commitment to scientific innovation and the integration of NAMs into research and regulatory processes through interagency collaboration, official reports, and internal working groups. SfN appreciates these efforts and embraces the goal of the reduction, refinement, and eventual replacement of animal models in biomedical research, but much more research and time is needed before such a goal is attainable. Premature replacement of animal models may delay or prevent the discovery of treatments and cures, not only for neurological diseases, but also for communicable diseases and countless other conditions. It may also increase the risk to patients due to premature approval without adequate testing in appropriate animal models to understand the potential risks. There are currently no viable alternatives available for studying biomedical systems that advance our understanding of the brain and nervous system; or when seeking treatments for diseases and disorders like depression, addiction, neurodegenerative disorders, and post-traumatic stress disorders.

NIH's recent announcement during the workshop — that all new funding opportunities will include language encouraging the consideration of NAMs and will no longer solicit proposals exclusively focused on animal models—has generated significant concern and confusion within the research community due to the ambiguous wording and potential policy implications. While SfN supports the thoughtful incorporation of validated and appropriate NAMs in biomedical research, these tools must complement, not replace, proven animal models. A hybrid approach, combining NAMs with essential animal models,

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enables researchers to refine their studies, reduce the number of animals used, and enhance the efficiency of biomedical research. SfN is committed to this integrated strategy and urges FDA and NIH to consider this approach moving forward while encouraging NIH to issue formal guidance clarifying the scope, intent, and execution of the announced changes.

Implementing this approach must include diverse perspectives in decision-making processes as mentioned in the workshop. This means not only engaging NAMs experts and technology developers, but also including laboratory animal scientists, veterinarians, animal care staff, and others who are uniquely equipped to provide insight into study refinement, animal care, ethical review processes, and post-study adoption efforts. Experts in drug development would also be critical, as they have a deep understanding of what is necessary to safely bring new drugs to patients. Their voices are vital to shaping policies that are innovative, responsible, and sustainable.

In addition to the inclusion of diverse perspectives, SfN believes biomedical research should operate within the laws and guidelines set by multiple oversight bodies and continue to use the appropriate model where necessary. As highlighted throughout the workshop, the best research emerges when investigators can draw freely on the full spectrum of tools available, from cutting-edge NAMs to essential animal models, without additional barriers. With further hurdles for researchers engaging in critical research involving animal models, there would be limitations in understanding the brain and stalled progress in developing treatments for human brain disorders. The ethical use of animal models for critical research is essential to advancing our knowledge of basic neuroscience processes and working toward curing disease.

SfN is committed to working with federal research agencies to promote transformative science that improves human health and maintains the United States' global leadership in scientific discovery. We thank you for the opportunity to submit comments and look forward to continued dialogue and collaboration. Thank you in advance for your consideration, and please contact SfN's Director of Advocacy and Training, Adam M. Katz, at akatz@sfn.org, with any questions.

Sincerely,
David Beversdorf, MD
Chair
Committee on Animals in Research, Society for Neuroscience