FASEB
Federation of American Societies for Experimental Biology

Representing Over 110,000 Researchers

6120 Executive Blvd., Suite 230, Rockville, MD 20852 | faseb.org

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FASEB Response to the Joint FDA-NIH Workshop on Reducing Animal Testing

On behalf of the Federation of American Societies for Experimental Biology (FASEB), we would like to provide comment on NIH policy changes announced at the joint FDA-NIH Workshop on Reducing Animal Testing. As a coalition of 22 member societies representing over 110,000 biological and biomedical researchers, we at FASEB strongly support policies that promote the use of tailored methodologies to push innovation and progress in the biomedical sciences.

Given the significant impact restricting animal research would have on the research community, FASEB **recommends NIH engage stakeholders on the rollout of policy changes affecting the use of animal models in NIH-funded research**. Implementation of the announced policy has the potential to hamper American biomedical and life sciences research. Therefore, FASEB encourages NIH to integrate the considerations and recommendations detailed below.

Sound science requires tailored approaches

One of the defining strengths of the American approach to biomedical research is a peer-reviewed funding process that elevates the opinions of subject matter experts to ensure scientific and ethical rigor. This process allows research to proceed based on the merit of proposals and the needs of individual research fields. FASEB is concerned that a singular mandate promoting NAMs at the expense of animal research would undermine this rigor and compromise scientific discovery. Animal research continues to be the leading methodology in many fields due to its demonstrated translational potential and relevance to critical scientific inquiry. FASEB urges NIH to consider complete replacement of animal research only for systems in which validated NAMs can perform as well or better than the accepted animal models and promote the use of multimodal systems that include both animal models and NAMs where this is not possible.

NAM validation must precede mandated use

FASEB fully supports the 3Rs framework (Replace, Reduce, Refine) for the ethical use of animals in research. Towards these goals, we applaud NIH's support for the development of NAM technologies that provide an avenue for safe replacement and reduction in the use of animals. Validation of NAMs is the critical first step to ensuring safe and effective research is done in the absence of animal research. Timelines for mandating NAMs over animal models need to reflect this priority.

Validation must go beyond proof of concept to include consistent demonstration of reproducibility, biological relevance, and translational utility across a range of experimental and

disease contexts. Importantly, the successful validation of a NAM in a specific context should not be automatically interpreted as justification for its universal application. Requiring the use of individual NAMs in research should be based on a clear understanding of the method's limitations in addition to its performance. Comparable standards must be applied when evaluating NAMs alongside established animal models. FASEB emphasizes the need for a case-by-case assessment to ensure that any mandated replacement of animal models maintains the scientific rigor, safety, and reliability required to advance human health.

Requesting opportunities for additional stakeholder feedback

FASEB appreciates NIH's longstanding commitment to engaging the scientific community in shaping research policies. Given the potential scope and implications of the policy changes discussed in this workshop – particularly their influence on research infrastructure, funding mechanisms, and workforce training – stakeholder engagement should be central to the planning and implementation process. Critical elements such as transition timelines, criteria for determining where NAMs are appropriate, and strategies to support the continued use of animal models where necessary should be developed transparently and in close collaboration with a broad range of stakeholders. We encourage NIH to proactively include the voices of investigators, especially those working at the intersection of NAM development and animal model refinement, to guide the roll out of future policy changes.

As scientists committed to advancing biomedical research through both humane animal studies and rigorously validated non-animal models, FASEB would appreciate the opportunity to provide feedback on a detailed plan for enacting the announced initiatives. Stakeholder feedback is central to sound policymaking. We look forward to future engagement opportunities on this topic.