FASEB
Federation of American Societies for Experimental Biology

Representing Over 130,000 Researchers

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May 4, 2021

The Honorable Michael Regan
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator Regan,

As the largest coalition of biomedical researchers in the United States, representing 29 member societies and over 130,000 individual scientists, the Federation of American Societies for Experimental Biology (FASEB) seeks to advance public health and welfare by promoting progress and education in biological and biomedical sciences. To fulfill this mission, FASEB strongly supports federal support for pre-clinical research with animals. For decades, toxicological animal research has been central to discovering and developing safe products regulated by the Environmental Protection Agency (EPA), including cleaning products, pesticides, and chemicals used in the manufacturing of pharmaceuticals and other consumer products that have enhanced the quality of life for humans and animals alike.

FASEB applauds the new administration's efforts to restore the role of science and scientists in policy development and thanks the agency for pointedly stating this pledge. As the EPA finalizes its transition and reviews former policies to identify barriers that impede scientific integrity, we urge the agency to discontinue implementation of the 2019 directive that seeks to reduce ongoing animal research and ultimately eliminate mammalian studies by 2035. This directive, introduced by the previous Administrator, will stifle toxicological research progress and is inconsistent with the EPA's commitment to ensure that the best available science informs agency policies.

While non-animal alternative methods are rapidly evolving—particularly within toxicological contexts—the consensus among scientists remains that alternative techniques provide limited information and cannot be used alone to replace animal studies. *In-vitro* methods such as computer simulations, cell culture, and organs on a chip supplement but cannot supplant information gleaned from animal studies. The primary challenge to the use of alternative models is their ineffectiveness in predicting complex biological processes. For example, evaluating the effects of chemicals on different life stages, as in embryonic development, remains a challenge

because experimental techniques that mimic all phases of human development do not exist. Similarly, current non-animal methods are unable to replicate the mechanisms underlying human immunity. Such research is critical considering that environmental toxin exposure can produce significant changes to the immune system and lead to a wide range of diseases that afflict millions of Americans, including cancer, chronic respiratory diseases, and Alzheimer's. Therefore, ensuring access to animal models capable of complete physiological responses is essential for determining the short- and long-term safety of toxicants and, more importantly, their effect on human and animal health.

Toxicologists demonstrate their commitment to the reduction, replacement, and refinement of the use of animals in research by employing a combination of methods, including non-animal alternatives, in pursuit of research questions. For instance, testing for skin sensitization—an inflammatory, allergic skin reaction to a chemical—has made significant progress in recent years. In April 2018, the EPA accepted the use of three non-animal methods that must be used in combination to test active ingredients for skin sensitization. However, ongoing animal studies remain necessary to validate these methods for formulations and mixtures, reinforcing the need for continued use of animals.

Finally, imposing an arbitrary deadline by which mammalian studies must be discontinued conflicts with the EPA's mission to protect human and environmental health and, more broadly, the Biden Administration's commitment to implement evidence-based policies. While FASEB recognizes concerns regarding the time and monetary costs associated with animal research, we are more concerned about the unintended consequences on scientific rigor and public safety that may occur when mandating the use of unvalidated non-animal models.

FASEB urges the EPA to sustain support for animal research and encourages engagement with research stakeholders to inform the design and implementation of future policies impacting the scientific enterprise. Please do not hesitate to contact us should you have any questions regarding this important topic.

Sincerely,

Louis B. Justement, PhD
FASEB President