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March 16, 2022

The Honorable Anna Eshoo
Chairwoman
Subcommittee on Health
Committee on Energy and Commerce
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
Washington, D.C. 20515

Testimony of

People for the Ethical Treatment of Animals

In Support of H.R. 2565 / S. 2952, "FDA Modernization Act of 2021"

Before the Subcommittee on Health, Committee on Energy and Commerce

Thursday, March 17, 2022

The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight

People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million supporters strongly support the FDA Modernization Act.

Many of the tests required by the U.S. Food and Drug Administration (FDA) were developed 70 years ago—long before we had organs-on-a-chip, three-dimensional tissue models, supercomputers, and artificial intelligence. The replacement of animal tests with new tools that reliably promote human health and safety is a cornerstone of 21st century FDA policy.[1,2,3] FDA initiatives like the Innovative Science and Technology Approaches for New Drugs Pilot

[1] FDA. "FDA's Predictive Toxicology Roadmap." Available at: https://www.fda.gov/science-research/about-science-research-fda/fdas-predictive-toxicology-roadmap
[2] National Toxicology Program. "A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States." Available at: https://ntp.niehs.nih.gov/whatwestudy/niceatm/natl-strategy/index.html
[3] FDA. "Advancing New Alternative Methodologies at FDA." Available at: https://www.fda.gov/science-research/about-science-research-fda/advancing-alternative- methods-fda

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- PETA Asia
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- PETA Foundation (U.K.)

Program[4] and the Medical Device Development Tools program[5] are helpful steps in non-animal method implementation, and we strongly support the agency's introduction of these avenues that provide test method developers with a systematic approach that they can follow to bring modern animal-free test methods to the agency's attention. These programs, though, do not have the capacity to respond quickly to every testing area where technology is available that may improve the FDA's ability to identify safe and effective new medical treatments.

HR 2565/S 2952 takes a critical step to reinforce the FDA's commitment to adopting modern science. Despite the agency's development of policies and guidance that emphasize the value of developing non-animal tests, the restrictive language in the FFDCA—written decades before nonanimal tests were in development—continues to suggest that the FDA expects companies to rely on animal tests and does not acknowledge the extensive development of human relevant, animal-free test methods that are currently available.[6] Looking to the future, this foundational conflict between the agency's current policies and the legislation that authorizes that FDA's authority will continue to be a barrier to scientific innovation.

This bill provides statutory authority that is essential for both the FDA and the industry regulated by the FDA to adopt modern science by clearly noting that non-animal test methods—including cell-based assays, organs-on-chips and microphysiological systems, sophisticated computer modeling, and other human biology–based test methods—can be used to show that new treatments are safe and effective. The FDA's ability to adopt modern scientific knowledge is crucial, given that about 95% of new drugs that pass the currently required preclinical animal tests fail in humans, and 10 to 15 years are generally needed to bring a new therapy to market under the existing approach that relies on extensive animal testing.[7] By moving away from a reliance on animal tests while shifting toward modern, human-relevant techniques, the FDA will bring safer and more effective drugs to the public in a timely manner.

Sincerely,

Jeffrey Brown
Science Advisor

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[4] FDA Center for Drug Evaluation and Research. Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program. Available at: https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/innovative-science-and-technology-approaches-new-drugs-istand-pilot-program

[5] FDA Center for Devices and Radiological Health. Medical Device Development Tools (MDDT). Available at: https://www.fda.gov/medical-device/science-and-research-medical-devices/medical-device-development-tools-mddt

[6] National Toxicology Program. "Alternative Methods Accepted by US Agencies." Available at: https://ntp.niehs.nih.gov/whatwestudy/niceatm/accept-methods/index.html

[7] National Institutes of Health. National Center for Advancing Translational Sciences. "About the National Center for Advancing Translational Sciences." Available at: https://ncats.nih.gov/about