Paul, Booker, Braun, Lujan and Kennedy Introduce FDA Modernization Act to Eliminate Animal Testing Requirements

Legislation Aims to Get Safer, Cheaper Drugs to Patients More Quickly, Kick-Starting Innovation, Reducing Animal Testing, and Putting Best Test Methods to Work

Wayne Pacelle at a U.S. Senate Press Conference on 10/7/21 | Photo: Animal Wellness Action

WASHINGTON, DC, UNITED STATES, October 7, 2021 /EINPresswire.com/ -- Today, Animal Wellness Action, the Center for a Humane Economy, the Michelson Center for Public Policy, People for the Ethical Treatment of Animals (PETA), and other affiliated organizations applauded U.S. Senators Rand Paul, R-Ky. Cory Booker, D-N.J., Mike Braun, R-Ind., Ben Ray Lujan, D-N.M., and John Kennedy, R-La for introducing the FDA Modernization Act to eliminate a Depression-era requirement for animal testing for all new drug development protocols and to enable FDA to accept the most effective test methods, regardless of whether animals are used.

> A Depression-era requirement for animal testing for every new drug is retarding safety and efficacy testing."
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> *Wayne Pacelle, president at Animal Wellness Action*

This bill is the companion to a bipartisan House bill, H.R. 2565, led by U.S. Reps. Vern Buchan, R-Fla., Elaine Luria, D-Virginia, Nancy Mace, R-S.C., Mikie Sherrill, D-N.J., and Brendan Boyle, D-Pa., that seeks to spur innovation and open the door to the use of New Approach Methodologies (NAMs) with the goal of improving the science that is the basis for public health protection. The bill recognizes that scientific methods have advanced since its passage more than 80 years ago. The two leaders of the House subcommittee who orchestrate funding for most medical research in the United States – Rosa

DeLauro, D-Conn., and Tom Cole, R-Oklahoma are cosponsors of the legislation.

U.S. Sen. Rand Paul, R-Ky. at a press conference on 10/7/21

Marty Irby, Sen. Kennedy, Sen. Paul, Sen. Braun, Wayne Pacelle, and Aysha Akhtar at a U.S. Senate press conference on 10/7/21

The European Parliament voted in September to phase out animal experiments and invest in NAMs based on human biology. It's time for the United States to take a leadership role to advance science based on human biology to develop cures that we so desperately need. The use of animals in new drug development represents a major category of animal testing in the United States, including the widespread use of dogs and primates.

"A Depression-era requirement for animal testing for every new drug is retarding safety and efficacy testing," said Wayne Pacelle, president of Animal Wellness Action, and the Center for a Humane Economy. "This legislation allows FDA and drug developers to use 21st-century testing methods and do the best screening of drugs that science allows, whether that involves animals or not."

"The FDA Modernization Act would accelerate innovation and get safer, more effective drugs to market more quickly by cutting red tape that is not supported by current science," said Senator Rand Paul, R-Ky. "It would also prevent the needless suffering and death of animal test subjects—which is something I think both Republican and Democrats can agree needs to end."

"Thanks to modern scientific innovation, the use of animal toxicity testing for experimental drugs has become increasingly obsolete," said Senator Cory Booker, D-N.J. "This legislation will eliminate unnecessary suffering for countless animals when scientifically reliable alternative testing methods are available."

"Over the years, research has demonstrated that animal testing can often be inefficient in

predicting drug effects and efficacy in humans. I'm proud to join Sen. Paul in introducing legislation that will cut FDA red tape, allowing drug manufacturers and sponsors to innovate clinical trial designs and utilize modern alternatives to demonstrate safety and efficacy," said Senator Mike Braun, R-Indiana.

"Testing new drugs on animals is often risky for both animals and people. The FDA Modernization Act would allow drug producers to improve safety by using more modern, humane and effective testing. I want Louisianians to get the best medicines as quickly and safely as possible, and I'm thankful to work with Sen. Paul to protect our furry friends at the same time," said Senator John Kennedy, R-La.

"This reform would allow use of the nonclinical test method most likely to predict how a drug will react in humans, including state of the art nonclinical models based on human biology," noted Gerry R. Boss, M.D., board member of the Center for a Humane Economy and a long-time researcher in drug development. "It will ultimately streamline drug development, spur innovation, and move drug development forward, benefiting both patients and industry."

The existing drug development paradigm, established by statute in 1938 under the Federal Food, Drug, and Cosmetics Act (FFDCA) relies on animal tests to determine if they are safe and effective for humans has a 95 percent failure rate in human clinical trials. To move drug development forward, the pharmaceutical industry must be allowed to use emerging technologies in nonclinical testing for new drugs, instead of relying solely on animal tests. This bill is consistent with FDA's initiative to advance regulatory science.

"The most predictive technologies in existence should be available to drug sponsors to provide the safest and most effective medicines for patients," said Gary K. Michelson, M.D., Founder and Co-chair, Michelson Center for Public Policy. "Animal data shouldn't be the automatic reflex if there are superior non-animal test methods that predict what will happen in human clinical trials."

While FDA has expressed concern about the poor performance of current test methods and stated informally that it will accept data from human-based test methods, the FFDCA requires animal data specifically, with no mention of modern human-relevant test methods. Data show that it typically takes 10 years and an investment of an average of $1 billion and up to $6 billion for a new drug, slowing delivery of palliatives and cures for patient groups, driving up drug costs, and sacrificing countless animals. This amendment would broaden options for drug developers for nonclinical testing to include modern, innovative, human-relevant test methods, thereby reducing attrition, shortening time to market, saving millions of dollars, and providing safer and more effective drugs to patients. In the process, countless animals will be saved.

"To best protect humans, the FDA should make decisions based on reliable non-animal tests that reflect human biology," said Dr. Amy Clippinger, president of PETA Science Consortium International, and a molecular and cellular biologist. "The FDA Modernization Act can clear a

path for the use of scientific methods that will swiftly lead to safe and effective vaccines and treatments."

Continuing down the same drug development path for decades hasn't worked. Modernizing the FFDCA to include 21st century science, would mean the opportunity to use human relevant methods to improve the success rate in clinical trials and break the decades-old logjam in bringing life-saving treatments to Americans.

The modifications to the FFDCA will provide drug sponsors more options for testing the safety and efficacy of drugs in order to improve clinical trial attrition rates, cut time to market in half, and substantially reduce R & D costs which could cut drug prices fivefold.

The global race for a COVID-19 vaccine reminded the world about the need for urgent action to address urgent health crisis in our nation and abroad.

Other endorsements from prominent researchers, scientists and biotech:

"There has been exciting progress in using human-relevant cell-based assays, organs-on-chips, microphysiological systems, and sophisticated computer modeling to more accurately predict human response to drugs. Unfortunately, the FFDCA does not officially acknowledge these modern nonclinical tools. This amendment will go a long way to not only to reduce use of animals but also to promote application of the newer technologies that will lead to safer and more effective drugs in the future," says Dr. Paul Watkins, Director of the Institute for Drug Safety Sciences at the University of North Carolina, Chapel Hill.

"The science of toxicity testing has been transformed over the past several decades, but in the absence of regulatory acceptance of non-animal, science-based testing methods, practical change has occurred at a glacial pace. In my role at the FDA, I worked on all issues related to alternatives to animal testing and was responsible for developing FDA's policies related to alternatives. It's time to move forward and rely on 21st century science to find safe and effective cures. I believe that this practical and important amendment to the FFDCA will go a long way to encourage the use of human-relevant non animal test methods", said Neil L. Wilcox, D.V.M., M.P.H., former Senior Science Policy Officer, Office of Science, Office of the Commissioner, Food and Drug Administration.

"During my ten years working at the Food and Drug Administration (FDA) I have seen promising new therapies for a variety of illnesses come through the pipeline repeatedly, only for them to ultimately fail in human trials. In fact, most diseases have little or no treatment available. The high clinical failure rate in drug development across all disease categories is based, in large part, on the inability to adequately model human diseases in animals and the poor predictability of animal tests. We need a better way. Fortunately, cutting-edge research methods that are based on human biology offer great promise. But to foster their use and further development, the FDA must open their doors and think beyond animal testing" said Aysha Akhtar, MD, MPH, President

and CEO, Center for Contemporary Sciences.

As a biotools and organ-on-chip developer in the metabolic space, Obatala Sciences fully supports The FDA Modernization Act. The ultimate impact of human-based tissue models is the advancement of safer, more efficacious solutions to some of the greatest human afflictions globally. The only way that we will accomplish this goal is by working together, both regulators and innovators alike. We are continuing to work with current and former FDA officials to advance the field forward by elucidating mechanisms of addressing standardization, nomenclature, and concepts that are aligned with the agency's 2018 Predictive Roadmap to Toxicology. This is only a step in that direction, and it is encouraging," said Trivia Frazier, PhD, MBA, Co-Founder, President and CEO of Obatala Sciences, Inc and Adjunct Faculty in Department of Structural and Cellular Biology in the Tulane University School of Medicine.

"Organ-on-a-chip and microphysiological systems technology has moved from academic research to industry adoption very quickly in the last 5 years. The pharmaceutical industry is actively embracing and applying human-relevant platforms for internal decision making. The ability to obtain clinically translational data saves time, resources, and improves the chance for success, and stakeholders would like for the FDA to consider this data in their decision making. AxoSim focuses exclusively on neuroscience focused solutions, which represents one of the most difficult spaces in drug development, and with the dramatic increase in neurodegenerative diseases, we need the clinically-actionable data we are already generating to be used in regulatory decision making. We have the ability to accelerate life-saving treatments, and we want to drive the adoption and impact of human-relevant testing," said Lowry Curley, PhD, CEO of AxoSim, Inc, developer of the 3D neuroscience discovery platforms BrainSim and NerveSim.

Click here to watch the full replay of the press conference with Sens. Paul, Braun, and Kennedy this morning.

Animal Wellness Action (AWA) is a Washington, D.C.-based 501(c)(4) organization with a mission of helping animals by promoting legal standards forbidding cruelty. We champion causes that alleviate the suffering of companion animals, farm animals, and wildlife. We advocate for policies to stop dogfighting and cockfighting and other forms of malicious cruelty and to confront factory farming and other systemic forms of animal exploitation. To prevent cruelty, we promote enacting good public policies, and we work to enforce those policies. To enact good laws, we must elect good lawmakers, and that's why we remind voters which candidates care about our issues and which ones don't. We believe helping animals helps us all.

The Animal Wellness Foundation (AWF) is a Los Angeles-based private charitable organization with a mission of helping animals by making veterinary care available to everyone with a pet, regardless of economic ability. We organize rescue efforts and medical services for dogs and cats in need and help homeless pets find a loving caregiver. We are advocates for getting veterinarians to the front lines of the animal welfare movement; promoting responsible pet ownership; and vaccinating animals against infectious diseases such as distemper. We also

support policies that prevent animal cruelty and that alleviate suffering. We believe helping animals helps us all.

The Center for a Humane Economy (CHE) is a non-profit organization that focuses on influencing the conduct of corporations to forge a humane economic order. The first organization of its kind in the animal protection movement, the Center encourages businesses to honor their social responsibilities in a culture where consumers, investors, and other key stakeholders abhor cruelty and the degradation of the environment and embrace innovation as a means of eliminating both.

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