Buchanan, Luria, Mace, Sherrill, and Boyle Introduce FDA Modernization Act to End Mandatory Animal Testing

Legislation Aims to Get Safer Drugs to Patients More Quickly, Embracing Innovation and Shedding Costly, Cruel, Non-Predictive Animal Tests in FDA Protocols

WASHINGTON, D.C., UNITED STATES, April 20, 2021 /EINPresswire.com/ -- Today, Animal Wellness Action, the Center for a Humane Economy, the Michelson Center for Public Policy, and other affiliated organizations applauded U.S. Representatives Vern Buchanan, R-Fla., Elaine Luria, D-Virg. Nancy Mace, R-S.C., Mikie Sherrill, D-N.J., and Brendan Boyle, D-Pa for introducing the FDA Modernization Act, H.R. 2565 to lift requirements for animal testing for any new drug development and to enable FDA to require the most effective testing methods, regardless of whether animals are used.

“This reform would allow the use of the nonclinical test methods most likely to predict how a drug will react in humans, including state of the art nonclinical models based on human biology,” said 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 global race for a COVID-19 vaccine reminded the world about the need for urgent action. Data show that it typically takes 10 years and an investment of an average of $2 billion and up to $4 billion for a new drug, slowing delivery of palliatives and cures for patient groups, driving up drug costs, and sacrificing countless animals, including mice, rats, dogs, and non-human primates.

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.

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 have a 95 percent failure rate in human clinical trials. To move drug development forward, the pharmaceutical industry must be allowed to use emerging, superior 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.

“I would like to see research move away from the animal model, not only for the animals but for the American people who are in need of faster delivery of cures for devastating diseases with drugs at a lower price point,” says Rep. Vern Buchanan, R-Fla. “That means that research must focus on human biology, not animal biology. Our bill does just that.”

“The FDA Modernization Act promotes animal welfare without compromising scientific research,” said Rep. Elaine Luria, D-Va. “There’s no reason we can’t leverage technology to adopt more compassionate standards for testing consumer drugs and other products. This bipartisan solution is a win-win for animal welfare advocates and 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. 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.

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.

“Scientists have known for decades animal testing is far from the best way to test the effectiveness of a new drug. Regardless, the FDA requires anyone developing a new drug to rely on outdated and inhumane animal testing techniques to get their approval,” said Rep. Nancy Mace, R-S.C. “Our bill finally opens the door to new and modern testing techniques to be used at the FDA.”

“It’s paramount that we ensure the FDA keeps up with the cutting-edge innovation that comes out of our incredible research institutions like those in my district,” said Rep. Mikie Sherrill, D-N.J. “That’s one of the many reasons why I’m proud to co-lead the FDA Modernization Act. Whether we’re talking about updating animal testing protocols or ensuring the expeditious approval of treatments for the next global pandemic, the FDA should always be evolving with our industry leaders. This bill will help ensure the FDA is prepared for the challenges and opportunities ahead.”

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.

Other endorsements from prominent researchers and scientists:

"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," said 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.

Animal Wellness Action (Action) 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 (Foundation) 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 ("the Center") 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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