Congress Approves Landmark Measure to Reduce Animal Testing

FDA Modernization Act promises to spare animals, bring safer and better treatments to patients, and drive down drug prices

Today's Congressional vote means the FDA will no longer mandate animal-testing for new pharmaceuticals.

WASHINGTON, D.C., UNITED STATES, December 23, 2022 / EINPresswire.com/ -- The U.S. House gave final approval today to the FDA Modernization Act 2.0, revamping the drug approval process and promising a dramatic reduction in the use of dogs, primates, and other animals in laboratory tests. The provision, attached to an end-of-year spending package and to be signed into law by President Biden later today, eliminates a federal mandate for animal testing for new drugs approved by FDA that had been in place since 1938. The FDA Modernization Act also includes a provision – the Reducing Animal Testing Act – to eliminate a similar mandate for biosimilars regulated by the U.S. Public Health Service.

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"This is the biggest policy development in Congressional history in the quest to replace animal testing with morally and scientifically superior non-animal methods," said Wayne Pacelle, president of Animal Wellness Action and the Center for a Humane Economy. "Lawmakers were persuaded by our campaign to scrap mandatory animal testing in favor of 21st-century testing methods grounded on human biology."

More than 200 organizations, medical associations, biotech, and patient advocacy groups backed the legislation. Pacelle also paid tribute to Laurie McGrath of the McGrath Family Foundation of San Diego and the late Robert "Skip" Trimble of Dallas for helping drive the effort at crucial stages to modernize drug testing in the United States.

The omnibus spending bill also includes $5 million in new money to support an FDA-wide New Alternative Methods Program to reduce animal testing. That funding came as a derivative of lobbying campaign to pass the FDA Modernization Act 2.0.

The Senate and the House had independently approved the FDA Modernization Act in the preceding months. In September, Senators Rand Paul, R-Ky., and Cory Booker, D-N.J., won the unanimous support of their colleagues in passing S. 5002 as a stand-alone measure. S. 5002 also included Senator Ben Ray Lujan's Reducing Animal Testing Act.

The U.S. House passed its FDA legislative package in June by a vote of 392-28. That measure, H.R. 7667, included the original version of the FDA Modernization Act, introduced in April 2021 as H.R. 2565 by Reps Vern Buchanan, R-Fla., and Elaine Luria, D-Virg. Other original cosponsors of H.R. 2565 were Reps. Mikie Sherrill, D-N.J., Nancy Mace, R-S.C., and Brendan Boyle, D-Pa.

"The FDA Modernization Act 2.0 will accelerate innovation and get safer, more effective drugs to market more quickly by cutting red tape that is not supported by current science, and I'm proud to have led the charge with our fellow cosponsors. The passage of this bipartisan bill is a step toward ending the needless suffering and death of animal test subjects – which I'm glad both Republicans and Democrats can agree needs to end," said Senator Paul, M.D.

"Thanks to modern scientific innovation, the use of animal toxicity testing for experimental drugs has become increasingly obsolete," said Senator Cory Booker. "This legislation will eliminate unnecessary suffering for countless animals when scientifically reliable alternative testing methods are available." Senator Booker led a successful Congressional effort in 2016 to require the use of alternative methods where available for assessing risks posed by chemicals, under the Toxic Substances Control Act.

Data show that it typically takes 10 to 15 years and an average investment of $1 billion and up to $6 billion to develop a new drug. Moreover, animal tests are not reliable predictors of the human response to drugs. In addition to sacrificing millions of animals, this antiquated process of drug screening, dictated by the Federal Food, Drug and Cosmetics Act of 1938, slows delivery of palliatives and cures for patients, drives up drug costs, makes it prohibitively expensive for drug developers to explore medical solutions for rare diseases, and sacrifices countless animals.

"New alternative methods, such as Organ-on-a-Chip technology, are not only more predictive than animal model testing, but have the potential to improve global research and development productivity," said Jim Corbett, CEO of Emulate, a biotech company specializing in human-based chip technology. "By increasing the accuracy at which we can predict the safety and efficacy of drugs, pharmaceutical companies are able to make critical decisions related to advancing a compound in the drug development process sooner, ultimately bringing the benefits of modern medicine to patients worldwide."

“We applaud so many lawmakers for taking action to move drug development into the 21st Century and to allow for innovation that will bring much needed cures to Americans,” said Gary Michelson, M.D., founder of the Michelson Center for Public Policy and a co-partner with the Center for a Humane Economy on this legislative initiative.

Animal Wellness Action also singled out Senators Mike Braun, R-Ind., and John Kennedy, R-La., as the other original cosponsors of the FDA Modernization Act. Senators Patty Murray, D-Wash., and Richard Burr, R-N.C., and Representatives Frank Pallone, D-N.J. and Ranking Member Cathy McMorris Rodgers, R-Wash. – who lead Congress’s health policy committees – played crucial roles in getting the legislation in motion and over the finish line, as did Health Subcommittee Chairwoman Anna Eshoo, D-Calif., and Ranking Member Brett Guthrie, R-Ky. The group also praises House Energy and Commerce Committee members Buddy Carter, R-Ga., Kurt Schrader, D-Ore., and Tony Cardenas, D-Calif., for helping lead the effort in committee.

“We are already on the verge of the next phase of modern drug development, and FDA modernization will be the catalyst for this transition to modern science,” said Tamara Drake, director of research and regulatory policy at the Center for a Humane Economy.

The progress of the FDA Modernization Act in the United States has stirred scientists in Spain, the Netherlands, Switzerland, the United Kingdom, India, and other countries to revamp their drug development standards and ground them on human biology. In practical terms, pharmaceutical companies conduct research and marketing across many countries and achieving regulatory harmonization allows them to conduct their business more seamlessly.

“It’s a win-win for people, animals and industry, and it has the potential reduce drug costs and ease the pain for Americans during an era where inflation has driven up the average American family’s living costs,” said Marty Irby, executive director at Animal Wellness Action, who was named one of The Hill's Top Lobbyists for 2019-2021.

Other Expressions of Support for the FDA Modernization Act and Its Enactment

“As a pharmacist, I know we can do better on drug pricing and delivery times to patients by improving both safety and effectiveness as well,” said Rep. Buddy Carter, R. Ga., who led the fight for the provision in Energy and Commerce Committee. “I also know we can do better when it comes to preclinical testing methods and apply 21st century strategies that rely on human biology, not so much on beagles.”

“I was a veterinarian, and any testing that can be done without the use of our four-footed animal friends, I think is to our advantage and certainly to their advantage,” said Rep. Kurt Schrader, D-Ore. “Precision medicine by using tissue cultures and some of the advanced techniques that I think we’re looking at here in the 21st Century is pretty exciting.”

“The FDA Modernization Act opens the door to better science and faster drug development—and

it has the potential to spare millions of animals from misery and death," said Kathy Guillermo, senior vice president, Laboratory Investigations Department, People for the Ethical Treatment of Animals. "PETA is grateful to our tens of thousands of supporters who took action and to the legislators who recognized that testing new medications on animals is less accurate than a coin toss."

"It's time our nation gets on with the task of making the transition away from animal testing for drug development. The FDA Modernization Act 2.0 is a monumental advance, and it puts us on a track to accelerate this long overdue transition," said Lori Kalef, director of Programs at SPCA International.

"The FDA Modernization Act is an important step in improving public health. Scientific methods based in human biology – especially those that are not based on animal models – can open the door to cures and treatments for cancer, neurological and autoimmune conditions. The Act recognizes that these advanced new techniques have an essential role to play in confronting and overcoming diseases that we have not yet conquered," said Dr. Paul Locke, associate professor, Johns Hopkins Bloomberg School of Public Health's Department of Environmental Health and Engineering.

"The passing of the FDA Modernization Act marks a profound change in the way we treat and use animals in laboratory settings and drug development. This law will allow drug companies to pursue alternative technologies that will revolutionize the field and have a monumentally positive impact for animals and people. As a wildlife veterinarian who has worked closely with chimpanzees and other primates, the prospect that the use of these sentient beings in medical research will be dramatically reduced or eliminated is an astounding achievement and a long overdue development," said Dr. Jimmy Desmond, co-founder, Liberia Chimpanzee Rescue and Protection.

"The FDA Modernization Act is a logical step towards a more ethical society where we treat all species with respect and dignity and open the door to humane science," said Shannon Keith, Esq., president and founder, Beagle Freedom Project.

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