Republicans and Dems Introduce FDA Modernization Act 3.0, Requiring FDA to Implement Overdue Animal Testing Reforms

Led by Reps. Carter, Barragán, Harshbarger, and DeLauro, new legislation takes aim at FDA inaction causing harm to millions of animals

Each year, thousands of beagles like this one are needlessly hurt or killed in the name of antiquated, ineffective science.

WASHINGTON, D.C., UNITED STATES, February 8, 2024 /EINPresswire.com/ -- Today, Animal Wellness Action, the Center for a Humane Economy, and Animal Wellness Foundation applauded a set of lawmakers in the House—many of whom were instrumental in passing the FDA Modernization Act 2.0 in the 117th Congress—for introducing legislation to kickstart the U.S. Food and Drug Administration's implementation of the landmark law. That law, passed at the end of 2022, eliminated an animal-testing mandate that had been in place since the Depression era, giving drug sponsors the option to use innovative 21st-century, human-biology-based methods instead.

The new legislation requires the FDA to publish a final rule to implement the FDA Modernization Act 2.0 (FDAMA 2.0) and establish clear guidelines for non-animal test methods that can better predict drug safety and efficacy, and speed the time to market for new treatments and cures.

U.S. Representatives Buddy Carter, R-Ga., Nanette Barragán, D-Cal., Diana Harshbarger, R-Tenn., and Rosa DeLauro, D-Conn.—the first three members of the Health Subcommittee of the House Energy & Commerce Committee—and Rep. DeLauro, the ranking Democrat on the Appropriations Committee, are the lead authors of the new bill, the FDA Modernization Act 3.0. They are joined by Vern Buchanan, R-Fla., the House lead author of the original FDA Modernization Act; Michael Waltz, R-Fla.; Troy Carter, D-La.; Brian Fitzpatrick, R-Pa.; Troy Nehls, R-Texas; Lance Gooden, R-Texas; and Dan Crenshaw, R-Texas.

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archaic regulations relating to animal testing mandates for new drug screening," said Wayne Pacelle, president of Animal Wellness Action and the Center for a Humane Economy. "The use of human-relevant models must be put to use in our drug development programs to benefit patients and drug sponsors and to spare beagles, primates, and other animals needless torment." An astonishing 90-95% of drugs that pass animal tests go on to fail in human clinical trials, wasting precious time for patients.

"The FDA Modernization Act 3.0 will allow for development of safe, effective treatments and therapies without unnecessary animal suffering. We have a law allowing for animal-free testing methods on the books, and it's time we put it to use by expanding testing options," said Representative Buddy Carter, R-Ga.

"Every animal should be treated humanely and not be subjected to cruel laboratory testing methods for human drug development. A stronger implementation of the FDA Modernization Act 2.0 will not only support alternatives for more humane drug testing, but also support more safe and effective delivery of drugs to patients," said Representative Nanette Barragán, D-Cal. "As an animal lover, I am proud to lead this bipartisan effort with Rep. Carter to reduce practices of animal testing for drug development."

"The FDA's outdated animal testing rules are harming animals, hurting patients, and stalling medical innovation," said Congresswoman Diana Harshbarger, R-Tenn. "The FDA Modernization Act 3.0 will cut burdensome red tape to allow drug manufacturers to use modern and more humane alternatives to improve safety for animals and patients alike. As a compound pharmacist for more than 30 years, I understand that ensuring East Tennesseans have affordable access to safe medicines is of the utmost priority, and this bill is a step toward delivering safe medicines in a more humane way."

"The FDA Modernization Act of 2021 was a monumental win that will streamline drug development and spur innovation without having to sacrifice at the expense of animal welfare," said Representative Vern Buchanan, R-Fla. "I look forward to building upon that success with Congressman Carter and ensuring the FDA follows through on delivering speedier cures for diseases without subjecting animals to inhumane and counterproductive experiments."

The FDA's failure to act in more than 13 months is baffling, given the widespread support for FDAMA 2.0 both in the scientific community and among biotech companies and drug developers. More than 450 global publications, including news articles, commentaries, scientific reviews, and primary papers, have been published since enactment and noted the potential for a paradigmatic shift in drug development.

“The FDA’s obsessive reliance on artificial animal models that do not replicate human biology and disease pathology is indefensible when so many diseases, rare and common, remain without cures despite decades of animal testing, which proved to be misleading, distracting, and utterly unwise investments. We have innovative, human-relevant models that can and must be embraced to break this logjam,” said Dr. Zaher Nahle, senior scientific advisor for the Center for a Humane Economy and Animal Wellness Action. “

“Aligning the statute with regulations will eliminate confusion for drug sponsors, lead to more cures, cut drug development time, lower drug prices, and confirm the FDA’s stated commitment to reducing and replacing animals in drug development,” said Tamara Drake, director of research and regulatory policy for the Center for a Humane Economy. “That must be complemented by a clear, accountable, and transparent regulatory process, including the full and speedy implementation of the existing law.”

“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 realize the gains made with FDAMA 2.0”, 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.

A coalition of hundreds of animal welfare groups, biotech and pharmaceutical companies, and patient advocacy groups backed the FDA Modernization Act in the 117th Congress. Senators Rand Paul, R-Ky., and Cory Booker, D-N.J., and Mike Braun, R-Ind., led the Senate bill. In addition to Animal Wellness Action and the Center, key players included the Laurie C. McGrath Foundation, the Michelson Center for Public Policy, SPCA International, Teva Pharmaceuticals, PETA, the Rare and Undiagnosed Network, the International Cancer Advocacy Network, and the late Robert “Skip” Trimble.

Click here to read the full bill text.

ABOUT
Animal Wellness Action is a Washington, D.C.-based 501(c)(4) whose mission is to help animals by promoting laws and regulations at federal, state and local levels that forbid cruelty to all animals. The group also works to enforce existing anti-cruelty and wildlife protection laws. Animal Wellness Action believes helping animals helps us all. X: @AWAction_News

The Center for a Humane Economy is a Washington, D.C.-based 501(c)(3) whose mission is to help animals by helping forge a more 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. The Center believes helping animals helps us all. X: @TheHumaneCenter

Animal Wellness Foundation is a Los Angeles-based private charitable organization whose mission is to help animals by making veterinary care available to everyone with a pet, regardless of economic ability. The Foundation 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. The Animal Wellness Foundation believes helping animals helps us all.

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