

Rep. Brett Guthrie Teams Up with Sen. Rand Paul to Include FDA Modernization Act in Broader FDA Funding Package

The rider will lift animal-testing mandate under federal law and drive use of alternatives

BOWLING GREEN, KENTUCKY, USA, May 5, 2022 /EINPresswire.com/ -- Today, the Center for a Humane Economy, Animal Wellness Action, the Michelson Center for Public Policy, PETA, and dozens of other organizations in a “Modernize Testing” coalition applauded the U.S. House Committee on Energy and Commerce,

including Health Subcommittee Ranking Member Brett Guthrie, R-Ky., for including the [FDA Modernization Act](#) as a rider to a broader legislative package to [reauthorize the Food and Drug Administration \(FDA\)](#) user fee agreements. The FDA Modernization Act, H.R. 2565/S.2952

eliminates a federal mandate for animal testing in new drug development protocols and enables the use of nonanimal test methods in new drug development.

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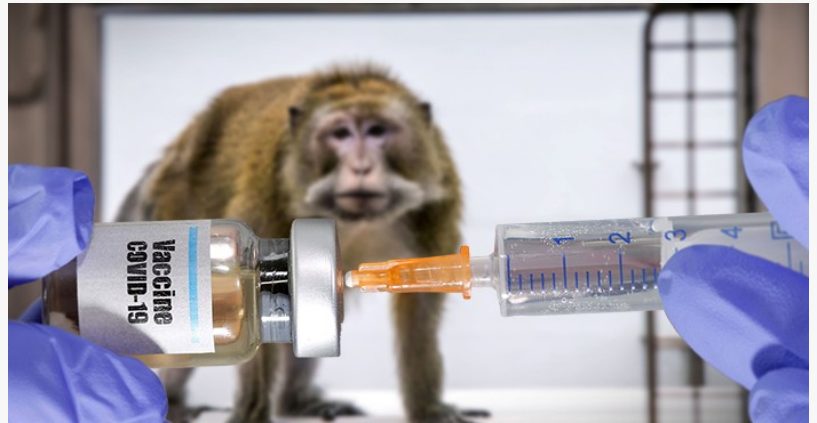
FDA operates under an archaic statute when it comes to drug development, requiring animal-testing strategies even when there are superior non-animal test methods grounded on human biology.”

Wayne Pacelle, president at Animal Wellness Action

The legislation was introduced in the House by Reps. Vern Buchanan, R-Fla., Elaine Luria, D-Va., Nancy Mace, R-S.C., Mikie Sherrill, D-N.J., and Brendan Boyle, D-Pa. As of May 4th, H.R. 2565 has been cosponsored by 42 House Democrats and 37 House Republicans. A Senate companion bill, S. 2952, is led by Senator Rand Paul, R-Ky., with Cory Booker, D-N.J., Ben Ray Lujan, D-N.M., Mike Braun, R-Ind., and John Kennedy, R-La.

“FDA operates under an archaic statute when it comes to

drug development, requiring animal-testing strategies even when there are superior non-animal test methods grounded on human biology,” said Wayne Pacelle, president of Animal Wellness



FDA TESTING | Photo Credit: Craig Swanson

Action. "This important domain of science and drug development should not be bound any longer by Depression-era standards and strategies. We applaud the leadership of Kentucky's Brett Guthrie and Rand Paul for leading this reform effort."

Full committee Chairman Frank Pallone, Jr. (D-N.J.) and Ranking Member Cathy McMorris Rodgers (R-Wash.), along with Health Subcommittee Chairwoman Anna G. Eshoo (D-Calif.), worked with Guthrie to include the provision in the broader legislative package. Committee members Kurt Schrader, D-Oregon, and Buddy Carter, R-Ga., were instrumental in driving the outcome.

The logo for "Animal Wellness Action" is displayed within a light gray rectangular border. The word "animal" is in a large, black, serif font. Below it, the word "wellness" is in a slightly smaller, black, serif font. At the bottom, the word "action" is in a bold, orange, sans-serif font.

animal wellness action

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. Data show that it typically takes 10 to 15 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, including mice, rats, dogs, and non-human primates.

"We applaud the Energy and Commerce Committee for taking action to move drug development into the 21st Century and include this important statute change to allow for innovation which will speed drug development, and bring much needed cures to Americans, said Gary K. Michelson, M.D., Founder and Co-chair, Michelson Center for Public Policy. "The most predictive technologies in existence should be available to drug sponsors to provide the safest and most effective medicines for patients."

"We can apply human biology-based test methods to better predict how humans will respond to drugs in clinical trials," said Tami Drake, director of research and regulatory policy at the Center for a Humane Economy. "We are already on the verge of the next phase of modern drug development and the FDA Modernization will be the catalyst for this transition to modern science."

"Drug testing requirements have not kept pace with scientific innovation and both the public and animals have suffered for it," said PETA Senior Vice President of Laboratory Investigations Kathy Guillermo. "The forward-thinking Energy and Commerce Committee recognizes that modern human-relevant test methods are the way of the future and must be embraced."

The passage of this legislation will provide drug sponsors more options for testing the safety and efficacy of drugs 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 legislation has been endorsed by more than 125 organizations and companies, including the National Medical Association, the National Hispanic Medical Association, Teva Pharmaceuticals, Emulate, Nortis Bio, Beyond Celiac, the San Francisco AIDS Foundation, the United Leukodystrophy Foundation, Myositis Association, SPCA International, the Progressive Animal Welfare Society, and Pasado's Safe Haven.

Chairwoman Eshoo and Ranking Member Guthrie introduce the "Food and Drug Amendments of 2022" this week, and the Health Subcommittee intends to formally mark it up next week.

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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