

## House Health Subcommittee Unanimously Passes Food and Drug Act of 2022, Including FDA Modernization Act rider

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

WASHINGTON, D.C., UNITED STATES, May 12, 2022 /EINPresswire.com/ -- (WASHINGTON, D.C.) – Today, the Center for a Humane Economy, Animal Wellness Action, the Michelson Center for Public Policy, National Medical Association, Emulate Inc., PETA, and dozens of other organizations and corporations in a "Modernize Testing" coalition applauded the House Health Subcommittee for including the FDA Modernization Act as a rider to a



This beagle bears the tell-tale tattoo of having been used for testing.

broader legislative package, H.R. 7667, to reauthorize the Food and Drug Administration (FDA) user fee agreements.

The FDA Modernization Act eliminates a federal mandate for animal testing in new drug



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Wayne Pacelle, president, Animal Wellness Action development protocols and enables the use of non-animal test methods in new drug development. The bill is expected to be marked up by the full Energy & Commerce Committee on May 18. The subcommittee reported out H.R. 7667 by a vote of 30 – 0.

H.R. 7667 was introduced last Friday by subcommittee Chairwoman Anna Eshoo, D-Calif., and Ranking Member Brett Guthrie, R-Ky., along with full-committee Chairman Frank Pallone, D-N.J., and Ranking Member Cathy McMorris Rodgers, R-Wash. Those committee leaders

included a slightly modified but intact version of H.R. 2565, the FDA Modernization Act,

introduced last year 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.

H.R. 2565 has been cosponsored by 42 House Democrats and 37 House Republicans. A Senate companion bill, S. 2952, was introduced by Senators Rand Paul, R-Ky., Cory Booker, D-N.J., Ben Ray Lujan, D-N.M., Mike Braun, R-Ind., and John Kennedy, R-La. The bill has attracted a broad set of Democrat and Republican cosponsors.

"We are grateful to the leaders of the Energy & Commerce Committee and so many other lawmakers from both parties who recognize that the United States must lift an archaic animal-testing mandate for preclinical trials and unleash 21st-century strategies grounded on human biology for new drug development," said Wayne Pacelle, President of Animal Wellness Action.

"This important domain of science and drug development should not be bound any longer by Depression-era standards and strategies," he said.

Animal Wellness Action singled out Committee members Buddy Carter, R-Ga., Kurt Schrader, D-Ore., and Ranking Members McMorris and Rodgers who made this provision a priority.

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. It has a 95 percent failure rate in human clinical trials. In addition, owing to the animal-testing mandate, 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. This slows delivery of palliatives and cures for patient groups, drives up drug costs, and requires the sacrifice of 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 FDA Modernization will be the catalyst for this transition to modern science."

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.

"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 legislation has been endorsed by more than 135 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.

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Animal Wellness 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 Center for a Humane Economy 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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