

Chairwoman Eshoo and Ranking Member Guthrie,

As the lead Democrat sponsor for H.R. 2565, the FDA Modernization Act, I ask for your favorable consideration of this measure. It is appropriate that the Subcommittee consider this reform measure as you examine "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight." This is a commonsense bill that deserves your active and determined support.

The terms set forth in the Federal Food, Drug, and Cosmetics Act require animal testing for pre-clinical testing for drug safety and efficacy. That is an outdated practice in any innovative industry but is especially anachronistic in the domain of scientific testing and drug development. Withholding authorization of non-animal methods of testing forces the FDA to default to using testing strategies that are less effective. The essence of the FDA Modernization Act is that it expands the toolbox of drug testing strategies.

The FDA Modernization Act does not eliminate animal testing in any manner; it eliminates the animal-testing mandate, allowing best science to be applied in the realm of drug development. Currently, I am not aware of any key drug development stakeholder that opposes this bill. Dozens of patient advocacy and animal welfare groups have expressed support.

I have heard from concerned citizens about their opposition to using dogs, primates, and other animals in testing protocols. We should be enthusiastically endorsing the idea of avoiding harm to animals when we can do so. Congress did so when it reauthorized the Toxic Substances Control Act in 2016 for chemical safety testing overseen by the U.S. Environmental Protection Agency.

Using 80-year-old testing strategies has not made us safer. We still do not have cures for so many major disease scourges. Adverse reactions to drugs are the fourth leading cause of death in the U.S. Drugs that pass muster for safety and efficacy in animal tests fail 90 to 95 percent of the time in human clinical trials. These are jarring and alarming facts and we should heed them. The only conclusion one can draw from these peer-reviewed conclusions is that the current animal-testing construct has its own obvious flaws.

I am proud to lead this bill with Reps. Vern Buchanan, Mikie Sherrill, Nancy Mace, and Brendan Boyle. It is one of the few bills in Congress with more than just a handful of cosponsors that has an even number of Democrats and Republicans cosponsoring it. I thank many Members of this committee for cosponsoring it as well.

I hope you will report it favorably and include it as a rider to the User Fee Amendments.