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March 16, 2022

The Honorable Anna Eshoo
Chairwoman
Subcommittee on Health
Committee on Energy and Commerce
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
Washington, D.C. 20515

RE: H.R. 2565, The FDA Modernization Act of 2021

Dear Chairwoman Eshoo and Ranking Member Guthrie,

As a proud cosponsor and co-author of H.R. 2565, the FDA Modernization Act, I write to express unequivocal support for legislation that would improve public-health policy while avoiding animal testing when a scientifically suitable alternative is available and approved by the Food and Drug Administration (FDA).

The intent of the FDA Modernization Act is to eliminate the animal testing mandate for new drug development that is found in statute and then to spur innovation that will quicken the pace of delivery and pricing of new drugs in the marketplace. The bill recognizes that scientific methods are continually advancing and our national science policy should allow for their use when they are superior. The changes to the Federal Food, Drug and Cosmetics Act called for in the FDA Modernization Act will not limit FDA authority. On the contrary, FDA will now have the authority to work with drug developers to use the best science in the vital realm of drug development.

American consumers face several dilemmas when it comes to the drugs they need: extraordinarily high costs for drugs, inordinately long wait periods in bringing the drugs to market, and, even after the drugs are approved for common use, serious health side effects for consumers often result from taking the drugs. The FDA Modernization Act will improve outcomes by allowing better cheaper methods of testing to be used.

The reality is pharmaceutical industry is burdened by outdated FDA statutes and regulations and this bill is a step toward remedying that problem.

Some testing strategies are not put into practical use because of FDA requirements to use animal testing strategies even when it's clear they produce inferior results, apart from their higher cost and longer time frame for completion. Animal tests, in large part, are not predictive of the human response to drugs, with 90 to 95 percent of drugs and vaccines found safe in animal tests failing during human clinical trials.

Where a scientifically recognized modern test method exists or a particular purpose, sponsors would have the option to use the test method in consultation with FDA.

While the FDA has claimed that statutory change is unnecessary and it has "discretion" to accept non-animal models in new drug submissions, a recent federal case (*Vanda Pharmaceuticals v. FDA*) addressed this issue in the context of clinical (human) trials. The Court's decision is unambiguous in directing drug developers who seek relief from the animal-testing mandate to turn to Congress and secure a statutory change. That's the prescription provided by the FDA Modernization Act.

The FFDCA has promoted the *status quo*, requiring traditional testing during preclinical studies, and creating an unreceptive environment that fails to encourage or support the development of modern and emerging test methods. Despite that intransigence, we are on the verge of the next phase of modern drug development with human-based models that can predict human drug response. Testing drugs on animals doesn't reflect 21st Century scientific advancement. H.R. 2565 and S. 2952 will be catalysts for this transition to modern science.

Congress and the FDA must unleash the power of science in overseeing U.S. drug development.

Sincerely,

Nancy Mace
Member of Congress