March 16, 2022

The Honorable Anna Eshoo
Chairwoman
Subcommittee on Health
U.S. House of Representatives

The Honorable Brett Guthrie
Ranking Member
Subcommittee on Health
U.S. House of Representatives

Dear Chairwoman Eshoo and Ranking Member Guthrie:

I write to thank you for including H.R. 2565, the FDA Modernization Act, in your hearing, "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight." Along with my co-leads, Reps. Elaine Luria, Nancy Mace, Mikie Sherill, and Brendan Boyle, I ask for your favorable consideration of this legislation. As you know, the bill would amend the Federal Food, Drug and Cosmetics Act of 1938 to eliminate the animal testing mandate. In 2022, this Depression-era requirement is out-of-touch with the pace of technology. I am grateful for the bipartisan support H.R. 2565 has received from Members of the full committee.

Our drug development paradigm needs a reboot, and this bill moves us in that direction in one simple but meaningful way. It will help drive non-animal test methods in safety and efficacy testing for new drugs. Animal tests, in large part, are not predictive of the human response to drugs, with very high failure rates when the drugs go to clinical trials. Adverse drug reactions are the fourth highest cause of death in the U.S.

As I've pointed out in earlier remarks about this bill, Congress writes legislation not just for today, but for 10 or 20 years down the road. Innovation in the years ahead will almost certainly produce superior methods to animal testing in nearly all cases. The intent of the FDA Modernization Act is to allow these new technologies and strategies to be used for the benefit of people.

Let me remind you that the FDA and the pharmaceutical companies all embrace the "Three Rs" approach to animal testing – Reduction, Refinement, and Replacement. The FDA Modernization Act allows the government and pharmaceutical companies to act on their pledges. Without lifting the animal-testing requirement, the Three Rs approach is just rhetoric, not reality. Primates, beagles, and millions of animals will continue to suffer for a broken drug development paradigm that is a throwback to the first half of the 20th century.

There are currently non-animal methods for testing skin irritation, eye irritation, phototoxicity, skin sensitization, reproductive and developmental toxicity, mutagenicity, and other endpoints. Congress can remove confusion about whether these methods can be exclusively used in the pre-clinical testing phase of drug development. There are many other methods that are also remarkably promising, including Organs on Chips and Computer Modeling. For instance, in one

recent study, researchers assessed the performance of 780 human Liver-Chips across a set of 27 known hepatotoxic and non-toxic drugs. The study demonstrated that the Emulate Liver-Chip was able to correctly identify 87 percent of the tested drugs that caused drug-induced liver injury in patients despite passing through animal testing.

This bill has been endorsed by a number of stakeholder groups, including the Center for a Humane Economy, the Center for Responsible Science, Beyond Celiac, United Leukodystrophy Foundation, Myositis Association, Reflex Sympathetic Dystrophy Syndrome Association, National Hemophilia Association, National Medical Foundation, and National Hispanic Medical Association, among others.

H.R. 2565 has 30 Republican and 30 Democrat cosponsors and counting, including bipartisan Members of this Committee. I hope you will ultimately report it favorably and include it as a part of the final User Fee Amendments.

Sincerely,

Vern Buchanan
Member of Congress