September 7, 2022

The Honorable Frank Pallone
Chairman, House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member, House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Patty Murray
Chair, Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member, Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Pallone, Ranking Member McMorris Rodgers, Chair Murray, and Ranking Member Burr:

We are writing to urge you to support the FDA Modernization Act (S. 2952 in the Senate and H.R. 2565 in the House), a bill that will enable researchers to use the best available tools to determine whether candidate drugs are safe for humans. The bill was included as a rider in H.R. 7667, the Food and Drug Amendments Act of 2022, and in S. 4348, Food and Drug Administration Safety and Landmark Advancements Act of 2022 (FDASLA). The FDA Modernization Act is at risk of being removed as a rider in the final legislative package, despite strong bipartisan support.

In 1938, Congress passed the Federal Food, Drug, and Cosmetics Act (FFDCA) in response to the horrors of a mass poisoning the year prior. Among other stipulations, the FFDCA mandates that all new drugs be tested in animals prior to clinical trials to protect patients from toxicity. Though animal models have been essential in the evolution of modern drug development, 21st century science now allows the FFDCA to move beyond its reliance on animal models and minimize situations of human and animal suffering.

Recently, an Envigo animal research center in Virginia was forced to close and 4,000 beagles were placed for adoption due to their abhorrent treatment. Studies have also revealed how unreliable animals are in predicting human response:

- Liver toxicity causing patient death is the primary reason for post-approval drug withdrawal, despite each drug having been declared safe in preclinical animal studies
- One study found that, of 43 post-approval drugs with serious toxicity effects, only 19% showed direct correlates of toxicity in animal studies

Fortunately, scientific advances have produced human-relevant preclinical models known as Microphysiological Systems; Organ-Chips, Spheroids, and Organoids. Evidence thus far suggests these models are highly accurate and better able to predict how the human body will respond to both therapeutics and toxins. However, such models are underutilized in drug development owing to the FFDCA's narrow focus on evidence generated by animal models when reviewing new drug candidates.

In a world where industry and government agencies have embraced technology to advance innovation and public safety, the FDA remains dated in their perspective. With human-relevant science now available, why must we continue to rely on animal models and other methods that fail to predict human response? Shouldn't we be using the best technology available to relieve human and animal suffering? We believe passing the FDA Modernization Act will allow us to achieve this.

Please continue to support the FDA Modernization Act as part of the final FDA user fee legislative package.

Sincerely,

Donald Ingber, MD, PhD
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Wyss Institute for Biologically Inspired Engineering
Harvard University

Thomas Hartung, MD, PhD
Center for Alternatives to Animal Testing
Bloomberg School of Public Health
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