AxoSim
Human Data, Faster.

March 17, 2022

To:

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

Subject: Testimony - March 17th Health Subcommittee HEARING ON "THE FUTURE OF MEDICINE: LEGISLATION TO ENCOURAGE INNOVATION AND IMPROVE OVERSIGHT

March 17, 2022

Testimony of
Lowry Curley, PhD, PhD, CEO AxoSim Inc
Before the Subcommittee on Health of the Committee on Energy and Commerce
Thursday, March 17, 2022
The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight

On behalf of AxoSim Inc, a New Orleans biotech company that empowers advancements in human neuroscience and partners with biopharma to facilitate breakthroughs in the most devastating neurodegenerative diseases, I offer this testimony in support of the FDA Modernization Act of 2021 (H.R. 2565 and S. 2952).

This legislation broadens the scope of acceptable nonclinical models for drug development, enabling researchers to test a drug's safety and efficacy using more advanced and humane methods in place of animal testing where possible. Such an amendment, if enacted, could pave the way for faster, more effective, and more humane therapeutic development.

When the FFDCA was enacted in 1938, animal models seemed like the best way for drug developers to study how therapeutics might act within a biological setting. In theory, then, animal testing should ensure that only the safest, most effective drugs make it to clinical trials. Over the years, innovation has changed the equation, and better models are now available in many cases. Innovation in the years ahead will almost certainly produce superior methods than animal testing in nearly all cases.

Under the current regulatory scheme:

- 90 to 95 percent of drugs found safe in traditional nonclinical tests fail during human clinical trials due to toxicities not predicted by traditional animal tests or because of lack of efficacy, in large part, because animal data are not predictive of the human response.
- It takes from 10 to 15 years to develop a new drug, costing between $1 to $6 billion.
- Estimates suggest that, relative to *in vitro* models, animal testing is 1.5- to 30-times more expensive.

We can apply human biology-based test methods to better predict how humans will respond to drugs in clinical trials. We are already on the verge of the next phase of modern drug development and allowing for the use of only animal models doesn't reflect 21st Century scientific advancement. H.R. 2565 and S. 2952 will be catalysts for this transition to modern science.

Sincerely,

J. Lowry Curley

J. Lowry Curley, PhD
Co-Founder and CEO