LABORATORY ACCESS & BENEFITS COALITION

May 22, 2022

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

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

Dear Chairwoman Murray and Ranking Member Burr:

We write to request that you not include the VALID Act of 2022 as part of the FDA Safety and Landmark Advancements (FDASLA) Act. Instead, we ask that you consider modernization of laboratory oversight through a pilot program to give both the industry and FDA the time and experience to get this right.

The Laboratory Access and Benefits (LAB) Coalition is a diverse group of professionals across the laboratory industry working together to improve laboratory and testing policies. The LAB Coalition is committed to driving policies to create a more robust, sustainable, predictable, and accessible market for testing with a focus on improving care and outcomes for patients. We recognize the importance of safe and reliable tests, and our members support common sense modernization of testing oversight.

As drafted, we believe the VALID Act of 2022 could cause many laboratories to cease operations, causing increases in costs, limited access to tests, and a decline in medical innovation overall. We believe that any direct oversight of laboratory operations and testing development and protocols by FDA should itself be tested before being made the law of the land. A voluntary pilot program at FDA modeled after current regulation by the New York State Department of Health would give labs and the FDA an opportunity to learn each other's processes and perfect a regulatory model over time. A five-year pilot could be used to inform permanent legislation during the next user fee negotiations, should Congress wish to pursue it.

Specifically, we believe that any approach to directly regulate in vitro clinical tests should be focused on certification of the laboratory itself, similar to a centers of excellence model and current oversight in place through CLIA and New York State Department of Health. Such a certification program would encourage well-established facilities to participate and serve as a model for others in the industry. Following a review of the facility and its practices, FDA would certify the facility under the pilot. Tests developed under the certification would be cleared by FDA and subject to review, temporary holds, and complete removal from the market. This pilot could serve as the foundation for oversight going forward, and as such, the pilot should be formed through a transparent process involving direct input by industry stakeholders through public comment sessions and meetings. We have included draft legislative language for your consideration.

We thank you for the opportunity to comment on the FDASLA drafts and thank you for your leadership and dedication to improve our health care system. We hope you will carefully consider our suggestion to pursue a pilot program for laboratory testing oversight rather than the VALID Act at this time.

Sincerely,

Brett Meeks
Executive Director
Laboratory Access and Benefits Coalition