



May 20, 2022

The Honorable Patty Murray
Chair, Senate Committee on
Health, Education, Labor and Pensions
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member, Senate Committee on
Health, Education, Labor, and Pensions
217 Russell Senate Office Building
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr,

Thank you for the opportunity to comment on the discussion draft of the FDA Safety and Landmark Advancements (FDASLA) Act. APHL works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories, state, local and territorial governmental public health laboratories, protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats. Our member laboratories have provided critical data during public health emergencies such as Zika, the opioid crisis, EVALI and SARS-CoV-2.

APHL has [longstanding concerns](#) that the workforce and financial commitment needed for the registration, listing, technology certification and user fees in the VALID Act, are designed around the resources of corporate, for profit, diagnostic manufacturers. The VALID Act language will restrict the ability of our not for profit members to provide the range, quality, responsiveness and equitable availability of testing that are the hallmarks of the public health laboratory system.

While the HHS TA did not fully address this fundamental concern, it did clarify many opaque and contradictory areas in the prior draft and provided some consideration for the needs of public health. We are particularly disappointed that the immediate response exemption was not included in this new draft. This exemption provided some flexibility for our members to continue to develop tests in response to immediate outbreak needs. The discussion draft also dismissed the TA's cleaner definition of public health surveillance, a decision that could cause problematic, inconsistent interpretation of public health surveillance across HHS.

We appreciate the thought that staff have put into the many revision of this bill. However, we continue to articulate that our recommended approach would be a straightforward provision of authority to FDA to develop a new risk based system through regulation, with consideration of the important roles of CDC and CMS. While attempting to fix some real concerns for commercial testing, this detailed legislative "solution" is setting the stage for a new set of challenges for public health.

Please contact Peter Kyriacopoulos, Chief Policy Officer (Peter.Kyriacopoulos@aphl.org, (240) 485 2766), with any questions,

Handwritten signature of Scott J. Becker in black ink.

Scott Becker
Chief Executive Officer

Handwritten signature of Denise M. Toney in black ink.

Denise Toney
President