



May 22, 2022

The Honorable Patty Murray
Chairwoman
Senate Health, Education, Labor & Pensions
Committee
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Senate Health, Education, Labor & Pensions
Committee
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr:

Thank you for the opportunity to submit comments on the “Verifying Accurate Leading-edge IVCT Development Act of 2022” or the “VALID Act of 2022.” The American Society for Clinical Laboratory Science (ASCLS) has reviewed the draft and believes this legislation will benefit the health of patients. ASCLS intends to encourage our 70,000 laboratory professional stakeholders to actively advocate for its passage.

For more than a decade, ASCLS has taken the position that reasonable regulation of high-risk laboratory developed tests, defined in VALID as “In Vitro Clinical Tests” is in the best interest of patients. As the capabilities of America’s clinical laboratories and professionals have grown exponentially, so has the need for a framework to ensure the awesome potential of these diagnostics is patient focused.

While we would have preferred adoption of more of the language suggested in the FDA’s technical assistance, in particular those provisions the agency identified as closing loopholes, we now believe that the current draft of VALID released by the Committee is the best chance for our nation to adopt a workable model. We appreciate the collegial work of the sponsors in the Senate and the House of Representatives to engage stakeholders to learn how best to protect patients while sustaining innovation. The current draft bill reflects significant progress over years of work.

Please contact Patrick Cooney at (202) 413-2629 or via email at patrick@federalgrp.com if you have questions regarding this correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "James Flanigan", is written over a printed name and title. The signature is fluid and cursive.

James Flanigan, CAE
Executive Vice President/CEO

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