

December 12, 2022

The Honorable Frank Pallone, Jr.
Chairman
U.S. House of Representatives
Energy and Commerce Committee
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
Washington, DC 20515

The Honorable Patty Murray
Chair
U.S. Senate
Health, Education, Labor and Pensions Committee
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
U.S. Senate
Health, Education, Labor and Pensions Committee
Washington, DC 20510

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

We are writing to you today as representatives of the health care, patient, clinician, consumer, industry, and other advocacy groups. More importantly, we are writing on behalf of millions of patients across the country who rely on accurate and reliable in vitro diagnostic tests over the course of their medical treatments. To that end, we are concerned about longstanding regulatory issues that will jeopardize the advancement of the next generation of diagnostics and, thus, patient outcomes. **To address these concerns, which have been recognized by administrations of both political parties, we urge you to support the VALID Act discussion draft currently under review by the committee and include it on an end of year appropriations package.**

This legislation, which has received bipartisan support in Congress and enjoys broad support from the stakeholder community, would modernize the regulation of all Laboratory Developed Tests (LDTs) and in vitro diagnostic tests under a single framework under the Food and Drug Administration. It would create a flexible, risk-based regulatory system that would incentivize and improve the development of advanced, reliable tests.

The VALID Act would be an important step forward for patients and their clinicians who expect the highest quality innovative tests available to diagnose and treat illnesses. Absent these reforms, the current, outdated oversight of the development and quality of these tests will lead to inaccurate and unreliable tests and undermine clinical decision making and patient health outcomes.

As you know, this diagnostics reform language reflects years of engagement and collaboration between Congress and the stakeholder community. We appreciate your continued support for meaningful diagnostics reform, and we are committed to working with you and our bipartisan Congressional champions to advance the VALID Act before the 117th Congress comes to a close.

Signed,

AdvaMed
American Cancer Society Cancer Action Network
Association for Clinical Oncology (ASCO)
Association of Black Cardiologists
College of American Pathologists
Friends of Cancer Research
Heart Valve Voice US
LUNgevity Foundation
The Pew Charitable Trusts