

December 9, 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

The Honorable Frank Pallone
Chair, House Energy and Commerce
Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member, House Energy and
Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chair Murray, Ranking Member Burr, Chair Pallone, and Ranking Member McMorris Rodgers,

We write to you today to express our significant concerns with the Verifying Accurate Leading-edge IVCT Development (VALID) Act which we understand is being considered for inclusion in an end of year legislative package. We appreciate your efforts to improve the legislation, however, the most recent draft text of the VALID Act still does not resolve the concerns that were outlined in a previous letter signed by 130 organizations

(<https://www.amp.org/AMP/assets/File/advocacy/Sign%20on%20Letter%20re%20VALID%20Act%20May%202022%202022%20Final.pdf>) and in some respects exacerbates them. We believe that this legislation stifles innovation and constricts patient access to care, duplicates existing federal requirements overseeing laboratory quality, lacks clarity in several key features including the risk categorizations, and creates an unpredictable regulatory process due to substantial discretion given to the Secretary. Moreover, we are alarmed that the legislation continues to leave out language to address the major problems associated with the FDA emergency use authorizations during the COVID-19 pandemic.

The legislation also includes a new exemption intended for certain clinical laboratories at academic medical centers; unfortunately, the language fails to meaningfully give these institutions the ability to provide necessary care to patients. Further, this new language raises a number of additional questions on how it will be implemented as it does not accurately reflect how these clinical laboratories function within the healthcare system.

At this time, we do not support the advancement of the VALID Act. It is imperative that the significant issues with this new draft are resolved and that such a large and controversial bill be considered through regular order in the House of Representatives prior to being added to fast moving legislative vehicles.

We welcome the opportunity to work with you on this issue.

Sincerely,

American College of Medical Genetics and Genomics
American Society for Histocompatibility and Immunogenetics
American Association for Clinical Chemistry
Association for Molecular Pathology
Association of Pathology Chairs

CC:

The Honorable Chuck Schumer
Senate Majority Leader

The Honorable Mitch McConnell
Senate Minority Leader

The Honorable Nancy Pelosi
Speaker of the US House of Representatives

The Honorable Kevin McCarthy
US House of Representatives Minority Leader

The Honorable Amy Klobuchar
Chair, Senate Committee on Rules and Administration

The Honorable Roy Blunt
Ranking Member, Senate Committee on Rules and Administration

The Honorable Jim McGovern
Chair, House of Representatives Committee on Rules

The Honorable Tom Cole
Ranking Member, House of Representatives Committee on Rules