June 30, 2021

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

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

Dear Chairman Pallone and Ranking Member Rodgers,

We represent a broad group of public interest organizations that believe reforming the regulatory framework for clinical laboratory diagnostics is essential to protect patients and ensure access to innovative and high-quality testing. The ongoing COVID-19 pandemic has only underscored the importance of reliable testing and reinforced the need for a uniform regulatory framework that consistently holds all clinical tests to the same risk-based standards. We write to urge your committee to prioritize diagnostics reform this Congress, taking into consideration the significant work that has been done thus far in the development of the current version of the Verifying Accurate Leading-edge IVCT Development (VALID) Act—which reflects years of negotiation and compromise among industry and stakeholder groups and represents the most comprehensive reform effort to date. We deeply appreciate Representative DeGette's and Representative Bucshon's ongoing leadership on this legislation and look forward to continuing to work with your offices so that the bill better addresses concerns from the patient and public health communities.

The current system of diagnostics oversight is inadequate, having failed to both keep pace with changes in the testing industry and match regulatory requirements with the risk that certain tests pose to public health. While commercially manufactured *in vitro* diagnostics are regulated by the Food and Drug Administration (FDA), laboratory-developed tests (LDTs) are instead primarily regulated through the Clinical Laboratory Improvement Amendments (CLIA), which does not ensure the clinical validity of tests or require developers to report adverse events that may arise from inaccurate test results. This fragmented regulatory system does not serve public health and has put patients at risk.

Additionally, the change in administration policy last year in response to a memorandum issued by the U.S. Department of Health and Human Services General Counsel[1] has only exacerbated existing regulatory uncertainty and raised doubts about FDA's ability to safeguard patients from flawed LDTs, whether for COVID-19, cancer, or other conditions. With your leadership, we believe the goal of an appropriate new statutory framework can be achieved and we stand ready to support your efforts to finalize a consensus diagnostics reform package this year. The VALID Act represents an important step forward in that conversation, and we implore the Committee to address this urgent public health need through the timely consideration of this bill. Should you have any questions, or if we can provide any assistance, please do not hesitate to contact Elise Ackley at The Pew Charitable Trusts at 202-527-3860 or eackley@pewtrusts.org.

Sincerely,

[1] www.politico.com/f/?id=00000174-e9b2-d951-a77f-f9fe04fa0000

American Cancer Society Cancer Action Network
American Society of Clinical Oncology
Cancer Support Community
Emerson Collective
FORCE: Facing Our Risk of Cancer Empowered
Friends of Cancer Research
Global Liver Institute
LUNGevity Foundation
Lymphoma Research Foundation
Muscular Dystrophy Association
National Center for Health Research
National Consumers League
National Organization for Rare Disorders
Pew Charitable Trusts
Prevent Cancer Foundation
Theresa's Research Foundation
Triage Cancer
U.S. Public Interest Research Group

CC: Reps. Diana DeGette, Larry Bucshon, M.D.