April 5, 2022

The Honorable Xavier Becerra
Secretary
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra:

We represent a broad group of public interest organizations that believe reforming the regulatory framework for clinical laboratory diagnostics—both laboratory-developed tests (LDTs) and in vitro diagnostics (IVDs)—is essential to protect patients and ensure access to innovative and high-quality diagnostic tests. 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 risk-based standards. We appreciate your continued focus on the issue and your willingness to engage with Congress in discussion around the Verifying Accurate Leading-edge IVCT Development (VALID) Act (H.R. 4128, S. 2209, offered by Representatives Diana DeGette (D-CO) and Larry Bucshon (R-IN) in the House and Senators Richard Burr (R-NC) and Michael Bennet (D-CO) in the Senate).

Recent Pew research found that 3.3 billion *in vitro* tests are performed every year in the United States,[1] and a sizable portion of these tests are run as laboratory developed tests (LDTs) overseen by the Center for Medicare and Medicaid Services (CMS') Clinical Laboratory Improvement Amendments (CLIA) program, which requires no clinical validation or public adverse event reporting. This means that patients are routinely exposed to risk and regulators have no way of knowing when or the extent to which patients may have been harmed by faulty or unreliable tests.

Over the last two decades, advances in diagnostic technologies—which have enabled more labs to develop complex and high-risk tests—along with changing business models in the clinical testing industry have elevated the need for a modernized regulatory framework. The current system for oversight fails to adequately address risk where it exists and can actually impede the rapid development of new testing to meet clinical needs unserved by the current market. The COVID-19 pandemic has only underscored the inadequacies of the current approach.

Though imperfect in its current form, the framework described in the VALID legislation provides a solid foundation to build on, as it seeks to match the level of regulatory oversight to the risk of a given test and provide more flexibility for responsible developers to bring new tests to market. And though the specific changes envisioned in the bill have been debated for many years, there is general agreement among many test manufacturers, clinical laboratories, and patient-focused groups that change is urgently needed and that the basic approach outlined in the bill should be the foundation for that reform.

[1] The Role of Lab-Developed Tests in the In Vitro Diagnostics Market | The Pew Charitable Trusts (pewtrusts.org)

With the engagement of a wide spectrum of stakeholder groups, and the benefit of lessons learned during COVID-19, VALID presents a unique opportunity for meaningful reform that could strengthen public health protections for generations to come. We sincerely appreciate the administration's efforts to provide substantive technical assistance to the bill's cosponsors, which includes many recommendations that would significantly improve the bill, and we encourage lawmakers to adopt your recommended changes to key elements of the legislation, including improvements to risk definitions, provisions to shore up FDA's postmarket authorities, and the inclusion of an Immediate Use Exemption.

One of the clearest lessons of the COVID-19 pandemic is that diagnostic testing reform cannot wait. As HHS describes in its technical assistance to the sponsors, certain key changes will ensure that we strike the right balance between patient protection and support for diagnostics innovation. As we continue working with Congress to address the areas you identified and urge the timely consideration of this legislation, we urge you to continue your engagement and dialogue with all parties interested in reform that will safeguard patients and enhance public health. Should you have any questions, or if we can provide any assistance, please do not hesitate to contact Kyle Kinner at kkinner@pewtrusts.org or (202) 540-6597.

Sincerely,

American Society of Clinical Oncology
Cancer Support Community
Center for Science in the Public Interest
FORCE: Facing Our Risk of Cancer Empowered
Lymphoma Research Foundation
Muscular Dystrophy Association
National Center for Health Research
National Consumers League
Pew Charitable Trusts
Public Interest Research Group
Triage Cancer

cc: Robert M. Califf, M.D., Commissioner, U.S. Food and Drug Administration
Jeffrey E. Shuren, M.D., J.D., Director of the Center for Devices and Radiological Health, U.S. Food and Drug Administration