AdvaMedDx
Vital Insights | Transforming Care

June 24, 2021

The Honorable Richard Burr
217 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Michael Bennet
261 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Larry Bucshon, MD
2313 Rayburn House Office Building
Washington, D.C. 20515

Dear Ranking Member Burr, Senator Bennet, and Representatives DeGette and Bucshon:

On behalf of AdvaMedDx, a division of the Advanced Medical Technology Association representing global manufacturers of in vitro diagnostic tests (IVDs) and technologies, I am writing to thank you for reintroducing the "Verifying Accurate Leading-edge IVCT Development Act" (or "VALID" Act), comprehensive diagnostics regulatory reform legislation.

AdvaMedDx member companies produce innovative, high quality tests that facilitate evidence-based medicine, improve quality of patient care, promote wellness, enable early detection of disease, and often reduce overall health care costs. The current fragmented regulatory framework governing these increasingly important technologies needs reform.

Reintroduction of the VALID Act is a critical step towards achieving a unified regulatory system and the result of tireless dedication and hard work by you and your staff, based on intensive dialogue with stakeholders, including providers, laboratories, patient organizations, and the diagnostics industry. We are grateful for your efforts.

This legislation seeks to modernize the regulation of all in vitro clinical tests (IVCTs), to allow patients and providers to benefit more broadly, rapidly, and confidently from the latest diagnostic technologies. In the wake of the COVID-19 pandemic and lessons learned in our nation's response, it is clear now more than ever that regulatory clarity and certainty for all IVCTs regardless of where they are developed is paramount.

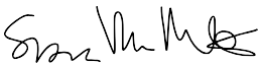
The VALID Act would do this by aiming to establish a single, predictable regulatory framework for all IVDs and laboratory developed tests (LDTs), under which the Food and Drug Administration (FDA) would have clear responsibility for regulation of all IVCTs under a risk-based framework. This modernized approach would provide patients and their clinicians confidence in the accuracy and reliability of diagnostic tests that inform 70 percent of all health care decision-making.

AdvaMedDx greatly appreciated the engagement with your offices throughout the revision and reintroduction process. We are committed to continuing to work with you and the Senate Health, Education, Labor, and Pensions Committee, the House Energy & Commerce Committee, as well as with our partners in the patient, provider, and laboratory communities, to make modernization of the regulatory framework for IVCTs a reality.

701 Pennsylvania Ave, N.W. | Suite 800 | Washington, D.C. 20004-2654
T - 202-783-8700 F - 202-783-8750 AdvaMedDx.org

Thank you again for taking this major step forward for patients, innovation, and public health in this country.

Sincerely,



Susan Van Meter
Executive Director
AdvaMedDx

Cc:

The Honorable Patty Murray
Chairwoman, Senate Committee on
Health, Education, Labor and Pensions

The Honorable Cathy McMorris Rodgers
Ranking Member, House Committee on
Energy and Commerce

The Honorable Frank Pallone
Chairman, House Committee on
Energy and Commerce