

May 9, 2018

The Honorable Lamar Alexander  
Chairman, Senate Committee on  
Health, Education, Labor and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510

The Honorable Patty Murray  
Ranking Member, Senate Committee on  
Health, Education, Labor and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510

The Honorable Greg Walden  
Chairman, House Committee on  
Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

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

Dear Senators Alexander and Murray and Representatives Walden and Pallone:

On behalf of the broad group of undersigned organizations that represent patient advocates, providers, laboratories, and diagnostics manufacturers, we are writing to urge Congress to enact legislation in 2018 to modernize the statutory oversight of clinical laboratory diagnostics, including laboratory developed tests (LDTs) and *in vitro* diagnostics (IVDs).

Both the House Committee on Energy & Commerce (E&C) and the Senate Committee on Health, Education, Labor and Pensions (HELP) have demonstrated dedicated leadership on the critical issue of clinical laboratory diagnostics through extensive stakeholder engagement. We believe your leadership has created a unique opportunity to enact comprehensive legislative reform and ensure our nation's patients and their health care professionals continue to have robust access to innovative and high quality clinical laboratory diagnostics.

Last year, Representatives Larry Bucshon (R-IN) and Diana DeGette (D-CO) released the Diagnostic Accuracy and Innovation Act (DAIA) discussion draft, and led listening sessions with a wide range of stakeholders to discuss key issues. It is our understanding that the Food and Drug Administration (FDA) is currently reviewing an amended discussion draft to provide technical assistance to the sponsors, in addition to the narrative comments the FDA has already provided.

FDA Commissioner Scott Gottlieb has made repeated public comments that comprehensive legislative reform of clinical laboratory diagnostics is timely and appropriate. Additionally, as demonstrated by the breadth and diversity of the signatories on this letter, the recognition of the need for diagnostics reform has only grown among stakeholders. Therefore, we the undersigned, believe the time has arrived to enact a new statutory oversight framework to unleash diagnostic innovation and improve the quality of care available to patients. Diagnostics

reform is a bipartisan, bicameral issue that has the support of the FDA, making it a suitable issue to be completed in 2018.

Stakeholders have never been more aligned on the need for diagnostics reform than we are now. With leadership provided by you, your fellow committee members, and the administration, we believe the goal of a new statutory framework is within reach. As stakeholders we stand ready to continue the work necessary to finalize a consensus diagnostics reform package this year.

If you have any questions, kindly contact Caroline Powers, American Cancer Society Cancer Action Network, at [caroline.powers@cancer.org](mailto:caroline.powers@cancer.org); Tom Sparkman, ACLA, at [tsparkman@acla.com](mailto:tsparkman@acla.com); or Duane Wright, AdvaMed, at [dwright@advamed.org](mailto:dwright@advamed.org).

Sincerely,

AdvaMedDx  
American Cancer Society Cancer Action Network  
American Clinical Laboratory Association  
Friends of Cancer Research  
Abbott  
American Brain Tumor Association  
American Society for Clinical Laboratory Science  
American Society of Clinical Oncology  
ARUP Laboratories  
BD  
Beckman Coulter, Inc.  
Biotechnology Innovation Organization (BIO)  
Biodesix  
bioMérieux Inc  
Bio-Rad Laboratories  
Bladder Cancer Advocacy Network  
Bonnie J. Addario Lung Cancer Foundation  
CancerCare  
Cancer Support Community  
Cardinal Health  
Cepheid  
Colorectal Cancer Alliance  
Corgenix Diagnostics  
Cure CMD  
Exact Sciences  
Fight Colorectal Cancer  
FORCE: Facing Our Risk of Cancer Empowered  
Foundation Medicine  
Free ME from Lung Cancer

Genomic Health  
Guardant Health  
Hologic, Inc.  
Illumina  
Immune Deficiency Foundation  
Instrumentation Laboratory  
International Cancer Advocacy Network  
IFAA - International Foundation for Autoimmune and Autoinflammatory Arthritis  
Johnson & Johnson  
Joint Venture Hospital Laboratories  
Kidney Cancer Action Network  
Laboratory Corporation of America Holdings  
Li-Fraumeni Syndrome Association  
Living Beyond Breast Cancer  
Lung Cancer Alliance  
Lung Cancer Circle of Hope  
Lung Cancer Initiative  
LUNGeivity Foundation  
Lupus and Allied Diseases Association  
Lupus Foundation of America  
Mayo Medical Laboratories  
MLD Foundation  
MPN Research Foundation  
Myriad Genetic Laboratories  
National Alliance of State Prostate Cancer Coalitions  
National Infusion Center Association  
National Lymphedema Network  
National Ovarian Cancer Coalition  
NeoGenomics Laboratories  
NothingPink  
Oncology Nursing Society  
Orgentec Diagnostics  
Ortho Clinical Diagnostics  
Ovarian Cancer Research Fund Alliance  
Prevent Cancer Foundation  
Prostate Health Education Network  
QIAGEN  
Quest Diagnostics  
Quidel Corporation  
Roche Diagnostics  
Seikisui Diagnostics  
Siemens Healthcare Diagnostics  
Society for Women's Health Research  
Sonic Healthcare USA

Stago  
Sysmex America, Inc.  
The Coalition for 21<sup>st</sup> Century Medicine  
Thermo Fisher Scientific  
Tigerlily Foundation  
Veracyte  
WaterStreet Healthcare Partners  
ZERO – The End of Prostate Cancer