

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; Tom Sparkman, ACLA, at tsparkman@acla.com; or Duane Wright, AdvaMed, at 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 21st Century Medicine
Thermo Fisher Scientific
Tigerlily Foundation
Veracyte
WaterStreet Healthcare Partners
ZERO – The End of Prostate Cancer