

May 3, 2019

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 Frank Pallone
Chairman, House Committee on
Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

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

Dear Senators Alexander and Murray and Representatives Pallone and Walden:

On behalf of the broad group of undersigned organizations that represent patient advocates, providers, laboratories, and diagnostics manufacturers, we are writing to thank you for your continued leadership in urging Congress to modernize the statutory oversight of clinical laboratory diagnostics – including laboratory developed tests and *in vitro* diagnostics. We believe your continued leadership in 2019 will allow for enactment within this Congress of comprehensive reform ensuring our nation's patients and their health care professionals continue to have robust access to increasingly innovative and high-quality clinical laboratory diagnostics.

Last year, as Energy and Commerce Committee leaders, Representatives Pallone and Walden joined with Senators Michael Bennet and Orrin Hatch, and Reps. Diana DeGette and Larry Bucshon to develop and release the Verifying Accurate, Leading-Edge In Vitro Clinical Test Development (VALID) Act discussion draft. Many of our organizations appreciated the opportunity earlier this year to provide formal comments on the draft. Recently, the Food and Drug Administration (FDA) provided technical assistance (TA) to Congress on the draft.

As you consider all feedback on the VALID Act discussion draft, we encourage you to convene public forums with stakeholders and the FDA this spring to discuss ways to revise the draft, to improve the quality of care to patients while fostering greater innovation in the diagnostic testing community.

As stakeholders, we remain steadfast in our alignment on the need for diagnostics regulatory reform. With leadership provided by you, your fellow committee members, and the Administration, we believe the goal of an appropriate new statutory framework can be achieved. 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 Phylicia Woods, American Cancer Society Cancer Action Network, at Phylicia.woods@cancer.org; Laura Lasiter, Friends of Cancer Research, llasiter@focr.org. Tom Sparkman, American Clinical Laboratory Association, at tsparkman@acla.com; or Duane Wright, AdvaMedDx, at dwright@advamed.org.

Sincerely,

23andMe

Abbott

ACLA

Adaptive Biotechnologies Corporation

AdvaMedDx

American Cancer Society Cancer Action Network

American Society of Clinical Oncology

ARUP Laboratories

BD (Becton, Dickinson and Company)

Beckman Coulter, Inc.

BIO

Biodesix

bioMerieux Inc.

Bio-Rad

Bladder Cancer Advocacy Network (BCAN)

Cancer Support Community

Cardinal Health

Caris Life Sciences

Cepheid

Colorectal Cancer Alliance

Corgenix Diagnostics

Day Zero Diagnostics

Exact Sciences Corp

Exosome Diagnostics

Fight Colorectal Cancer

Foundation Medicine

Friends of Cancer Research

Fujirebio Diagnostics, Inc.

Genomic Health, Inc.

Global Liver Institute

Go2Foundation for Lung Cancer, formerly Lung Cancer Alliance

Guardant Health

Hemex Health

HemoCue

Hologic, Inc.

ICAN, International Cancer Advocacy Network

Inflammatix

Instrumentation Laboratory Company

Johnson and Johnson
JVHL
Kidney Cancer Coalition
Laboratory Corporation of America Holdings
Leica Biosystems
Leukemia & Lymphoma Society
Linden Capital Partners
Living Beyond Breast Cancer
Lucid Diagnostics
Lung Cancer Circle of Hope
LUNGeivity Foundation
Lupus and Allied Diseases Association
Lupus Foundation of America
Mayo Clinic Laboratories
MPN Research Foundation
Myriad Genetics, Inc.
National Alliance on Mental Illness
National Council for Behavioral Health
NeoGenomics Laboratories
Novartis
Oncology Nursing Society
Orgentec Diagnostics
Ortho Clinical Diagnostics
Ovarian Cancer Research Alliance
Personal Genome Diagnostics Inc
Personalized Medicine Coalition
Prostate Health Education Network, Inc.
QIAGEN
Quest Diagnostics
Quidel Corporation
Radiometer
Roche Diagnostics
Sekisui Diagnostics
Siemens Healthineers
Society for Women's Health Research
Sonic Healthcare
STAGO
Streck, Inc.
Sysmex America
The Coalition for 21st Century Medicine
Thermo Fisher Scientific
Veracyte
Water Street Healthcare Partners
Ximedita
ZERO - The End of Prostate Cancer