

August 8, 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:

We represent a broad group of organizations including patient advocates, providers, laboratories and diagnostic manufacturers that believe modernizing the regulatory framework for clinical laboratory diagnostics, including laboratory developed tests (LDTs) and *in vitro* diagnostics (IVDs), is critical to ensure patients and their health care professionals continue to have robust access to innovative and high quality laboratory diagnostics. We are appreciative of the Food and Drug Administration's (FDA) detailed technical assistance on the discussion draft by Representatives Larry Bucshon (R-IN) and Diana DeGette (D-CO), the Diagnostic Accuracy and Innovation Act (DAIA), as it represents an important and necessary next step in the pursuit of comprehensive legislative reform.

Earlier this spring, over 80 stakeholders, including the organizations on today's letter, wrote to you urging prioritization of diagnostic reform. Our respective organizations have already begun an in-depth review of the TA to inform our continued discussions with Congress and the Administration. We are committed to continuing to work with the House Committee on Energy & Commerce and the Senate Committee on Health, Education, Labor and Pensions to advance diagnostic reform legislation expeditiously so that comprehensive reform may be enacted in 2018.

Thank you for your leadership. We look forward to continuing to work with you, the Congress, the Administration, and the full range of stakeholders to ensure that comprehensive diagnostics regulatory reform is enacted in 2018.

Sincerely,

AdvaMedDx
American Cancer Society Cancer Action Network
American Clinical Laboratory Association
American Society of Clinical Oncology
Biotechnology Innovation Organization
Clinical Laboratory Management Association

The Coalition for 21st Century Medicine (C21)
Diabetes Patient Advocacy Coalition
Friends of Cancer Research
LUNgevity Foundation
National Alliance on Mental Illness
Society for Women's Health Research