November 12, 2024

The Honorable Bernard Sanders
Chair
Committee on Health, Education, Labor and Pensions
U.S. Senate

The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education, Labor and Pensions
U.S. Senate

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Brett Guthrie
Chair
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Anna Eshoo
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives

Dear Chairs Sanders, McMorris Rodgers, and Guthrie, and Ranking Members Cassidy, Pallone and Eshoo:

On behalf of the undersigned members of the Coalition for Effective Diagnostics (CED), we urge Congress to pass comprehensive diagnostics reform this year in order to establish a regulatory framework at the U.S. Food and Drug Administration (FDA) uniquely tailored to diagnostic tests. The CED is a broad-based group of leading voices in the diagnostic testing ecosystem, representing major stakeholder categories: diagnostics manufacturers, laboratories, academic medical centers, physicians and patient groups. We came together this year with a shared goal of developing consensus legislation to establish a fit-for-purpose regulatory paradigm for diagnostic tests that preserves innovation and ensures continued access to accurate and reliable tests. We write in the spirit of collaboration to work with you on a policy that achieves these goals.

Earlier this year, FDA ended the agency's longstanding enforcement discretion policy for "lab-developed tests" (LDTs), finalizing a rule that brings all diagnostic tests, including those developed in a lab, under FDA's regulatory authorities governing medical devices (FDA Final Rule). The FDA Final Rule establishes an enforcement discretion policy that phases in medical device requirements on LDTs in five stages over four years. The FDA clearly states that the enforcement discretion policy can change through the guidance process. The requirements proposed in the rule require significant investment by many laboratories and the Agency's discretion to change the policy at any time creates significant regulatory uncertainty.

The CED supports passage of comprehensive diagnostics legislation that offers the opportunity to tailor premarket review pathways to the unique characteristics and risk profiles of diagnostic tests, and to facilitate new regulatory paradigms that have gained broad stakeholder approval in the past – such as a technology certification program or abbreviated premarket pathway included in the VALID Act. Through legislation, specific categories of tests should definitively be exempted from certain regulatory

requirements to facilitate innovation of tests for rare and pediatric diseases. Legislation is the only option that will provide regulatory certainty for developers and physicians to ensure continued patient access.

Efforts to comply with the phased approach set forth in the final rule are already underway. Congress must act now to ensure regulatory certainty and avoid disruption to patient access to life saving and life preserving diagnostics. The Coalition stands ready to work with you toward this goal.

Sincerely,

The Coalition for Effective Diagnostics

ALEXION

COLLEGE of AMERICAN PATHOLOGISTS

FRIENDS of CANCER RESEARCH

MAYO CLINIC

Roche

ThermoFisher SCIENTIFIC