AdvaMedDx
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More Than 80 Leading Health Organizations Call on Congress to Modernize Clinical Diagnostic Oversight

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Washington, D.C. – As part of a renewed push to advance comprehensive diagnostic reform, more than 80 leading health care companies and organizations representing patients, providers, laboratories and diagnostic manufacturers reiterated the urgent need for Congressional action on a modernized regulatory framework for clinical laboratory diagnostics.

Patients have yet to benefit from groundbreaking clinical diagnostics that monitor and support treatment for complex and rare diseases. Conflicting guidelines and regulations for bringing new tests to market have failed to evolve with the new generation of medical innovation, leaving patients with limited options for their care.

This letter marks the second collective effort over the past year in support of evolving the current antiquated diagnostic framework to one that can foster the next generation of diagnostic innovation for patients.

Congress can take immediate action – building on the work already underway as part of the latest Verifying Accurate, Leading-Edge In Vitro Clinical Test Development (VALID) Act discussion draft – to advance comprehensive reforms that would have a meaningful impact on patient care. Priority reforms include:

- Continued recognition of diagnostics as distinct services that require their own regulatory framework for review, rather than being forced into existing and conflicting regulatory frameworks designed specifically for medical devices;
- Inclusion of “grandfathering” and clear transition policies to ensure patients who depend on currently available clinical laboratory services retain access to them;
- A flexible modification policy to exempt many common changes to existing and grandfathered tests from premarket submission absent a meaningful clinical impact; and
- The right regulatory balance to ensure that patients can rely on and have access to innovative and lifesaving tests when they need them while also maintaining the regulatory oversight necessary to ensure the accuracy and reliability of the tests.

Advancing meaningful diagnostic reform involves developing a comprehensive approach that fosters innovative care delivery and is vital to efforts to tackle the most challenging and complex health needs of the country.

“Reliable, innovative diagnostics are central to providing the comprehensive care that patients need,” saidJulie Khani, President of the American Clinical Laboratory Association. “Through modernized regulations, Congress can remove the roadblocks preventing patients and providers from taking advantage of life-saving clinical laboratory diagnostics.”

“Few things are more essential to cancer care than an accurate diagnosis,” said Lisa Lacasse, President of the American Cancer Society Cancer Action Network.“Making sure the tests used to determine someone’s treatment are precise and reliable is at the core of ensuring patients can benefit from targeted therapies now and in the future.”

“We are proud to stand with our stakeholder partners as we work collectively to secure a modernized and predictable, risk-based, diagnostics regulatory framework that would speed the pace and reach of innovation in diagnostics, allowing patients to benefit more broadly and rapidly from breakthrough

diagnostic technologies," Susan Van Meter, Executive Director of AdvaMedDx, said. "We urge Congress to help us get these much-needed diagnostic reforms across the finish line."

"A more streamlined and modernized regulatory approach to diagnostics and clinical lab tests will open the door to a new era of medicine and cancer care," Jeff Allen, President and CEO of Friends of Cancer Research, said. "We applaud Congressional leaders who have already made progress in advancing common-sense policy changes and look forward to working with policymakers in both parties to make diagnostic reform a reality."

To view the full letter, click here.

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About the American Clinical Laboratory Association
ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, hospital, ESRD and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion to the nation's economy.

About the American Cancer Society Cancer Action Network
ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN works to encourage elected officials and candidates to make cancer a top national priority. ACS CAN gives ordinary people extraordinary power to fight cancer with the training and tools they need to make their voices heard.

About AdvaMedDx
AdvaMedDx member companies produce innovative, safe and effective in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, promote wellness, enable early detection of disease and can reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMedDx is dedicated to the issues facing in vitro diagnostic companies in the United States and abroad.

About Friends of Cancer Research
Friends of Cancer Research (Friends) drives collaboration among partners from every healthcare sector to power advances in science, policy and regulation that speed lifesaving treatments to patients.