Opening Statement
Health Subcommittee Hearing "Examining the Regulation of Diagnostic Tests and Laboratory Operations"
Rep. Gene Green
November 17, 2015

Good morning and thank you all for being here today.

The role of diagnostic tests in our health care system has changed dramatically since Congress passed the Medical Device Amendments in 1976 and added in-vitro diagnostics to the device definition.

It has been almost four decades, and the evolution of modern medicine and advancement of science has surpassed what anyone could have imagined at that time.

The enthusiasm around precision medicine is high, and the potential of diagnostics to further transform the treatment of disease is limitless.

When FDA first began regulating medical devices, applicable regulatory requirements for lab-developed tests or "LDTs" were not enforced because they were relatively simple tests, generally confined to local labs, and frequently used for rare conditions.

Today, LDTs have increased in complexity and availability. They are often used to diagnose serious medical conditions, and many have a major impact on patient care.

Not only have LDTs become more sophisticated, the role these tests play in the delivery of health care has expanded.

The Centers for Disease Control and Prevention estimated that approximately 6.8 billion laboratory tests are administered each year.

Another analysis found that results from clinical laboratory tests influence around 70 percent of health care decisions.

The Clinical Laboratory Amendments of 1988 created minimum standards of quality for all clinical labs in the country.

The Centers for Medicare and Medicaid Services (CMS) has jurisdiction over the program, and CLIA has successfully improved the quality of clinical labs and accuracy of testing for nearly 25 years.

However, under CLIA, CMS does not confirm the clinical validity of LDTs, meaning they do not look at whether a particular test accurately identifies, measures, or predicts the absence or presence of a clinical condition.

These known gaps in oversight have been a source of concern to this committee, and to the health care community at large.

Yesterday, the Food and Drug Administration (FDA) released a report that included 20 case studies of problematic tests from labs that were following the minimum requirements of CLIA, but posed real risk to patients.

In an of area so such promise and significance to patient care, the accuracy, reliability and clinical meaningfulness of all diagnostic tests - regardless of where they are created - must be

a top priority of health care providers, test developers, regulators, and lawmakers.

Last year, the FDA issued a draft regulatory framework to phase in enforcement of regulatory requirements, including premarket review and adverse event reporting, for LDTs that pose greater risk to patients if their results are not accurate and reliable.

I appreciate the FDA's efforts to ensure that tests are supported by rigorous evidence, and that patients and health care providers can have confidence in their results.

That said I share the opinion of my colleagues that legislation is both appropriate and necessary to modernize clinical laboratory diagnostics oversight.

A legislative solution is the surest way to establish a framework that will be embraced by stakeholders, avoid litigation and extended uncertainty, and foster innovation of new clinical diagnostic tests.

The FDA's approach in its draft guidance led to a number of important questions, but the guidance documents also spurred a larger conversation about the overarching need to modernize oversight of these unique and increasingly important tests.

During the 21st Century Cures Initiative, as part of the broad effort to close the gap between the science of cures and how we regulate medical products, the committee hosted a roundtable on precision medicine and advances in diagnostic testing.

The committee also released a white paper on diagnostic test regulation, and received an outpouring of feedback from stakeholders.

While all parties did not agree on all principles, much less specifics, it was abundantly clear that any regulatory framework for diagnostic tests must prioritize patient benefit, and allow for continued innovation and investment through regulatory certainty and appropriate regulatory controls.

There is an urgent need to establish clear and logical lines separating the practice of medicine, the actual conducting of a diagnostic test and the development and manufacturing of such tests, so that the promise of 21st century medicine can be fully realized.

Today, we will hear from FDA and CMS about each agency's respective role in the oversight and regulation of clinical laboratory testing.

Members of the committee will have questions about the appropriate role of each agency in any updated framework, and how Congress can best promote robust investment and innovation, while protecting patient safety.

I look forward to hearing from our witnesses and I yield back the balance of my time.