Diagnostic Tests are often the least expensive component of the health care pathway, yet they influence more than 70 percent of health care decisions.

There are tens of thousands of different diagnostic tests available today.

Diagnostic tests are performed close to 7B times each year in the United States.

What is the Problem?
Lack of Food and Drug Administration oversight means no independent assurance of safety and effectiveness. Historically, FDA did not exercise its oversight authority over LDTs because they were typically low risk tests with well-established test methods or used in low volumes.

Now, however, LDTs have become more complex and even the most advanced molecular diagnostics — such as genetic tests that guide choices among cancer treatments or tests used in the diagnosis and treatment of common and serious or life threatening disorders — are regularly developed by laboratories.

Leading patient groups have expressed concerns that lab developed tests do not undergo the scrutiny of other diagnostic tests leading to serious concerns about their validity and the patient impact.

What is Laboratory Developed Tests?
Diagnostic tests are developed either by manufacturers for distribution to laboratories or by laboratories themselves for use in their facilities. The tests developed by labs are referred to as laboratory developed tests (LDTs).

What are the Laboratory Developed Tests?
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CMS’ Laboratory Regulation is Not a Substitute for FDA
Unlike FDA oversight of diagnostics, CMS:
- Does not regulate the safety and effectiveness of diagnostic tests;
- Does not require pre-market review of tests;
- Does not require demonstration of clinical validity;
- Does not require systematic adverse event reporting;
- Does not have a process for corrections or recalls.

What is the Solution?
FDA has announced a plan to apply existing diagnostics regulations to LDTs under a risk-based approach.

- High and moderate risk tests will be subject to FDA pre-market review to assure safety and effectiveness.
- All clinical laboratories that perform LDTs will be required to report adverse events to FDA.
- Several categories of LDTs will be exempt from pre-market review, including low risk tests, rare disease testing, traditional LDTs, and unmet needs LDTs.
- FDA will implement a risk based phased in approach to support test continuity.

*Unfortunately, FDA is also aware of faulty or unproven LDTs, including problems with several high risk LDTs such as claims for diagnosing ovarian cancer that are not adequately supported with evidence; lack of appropriate controls yielding erroneous results; and misattribution of data for determining which breast cancer therapy would be most beneficial.*

*FDA Testimony to House Energy & Commerce Health Subcommittee, September 2014

*Centers for Medicare and Medicaid Services

Diagnostic Tests are Critical to Health Care
The Essential Role of FDA

Diagnostic tests are performed on samples taken from the body, and used in a broad range of applications to diagnose health conditions and guide treatment options. These tests are also referred to as “in vitro diagnostics” or “IVDs.”

*Patients and their physicians need to be able to be confident that diagnostic tests are accurate... The current regulatory infrastructure for genetic tests and molecular diagnostics have important gaps...*