

Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Hearing on “21st Century Cures: Examining the Regulation of Laboratory Developed Tests”
September 9, 2014

(As Prepared for Delivery)

Today’s hearing is another in a series of 21st Century Cures hearings and primarily focuses on FDA’s July 31, 2014 notification to Congress that it intends to issue draft guidance on a framework for oversight of laboratory developed tests (LDTs).

This notification was required by Section 1143 of the Food and Drug Administration Safety and Innovation Act of 2012, and provides us with an opportunity to hear from the agency about whether it has adequately answered the myriad of procedural and substantive questions that were the subject of much debate leading up to the passage of FDASIA.

It is indisputable that the draft guidance documents the agency recently released would fundamentally alter the regulatory landscape for the review and oversight of LDTs and the clinical labs that develop them. That fact alone has raised legitimate concerns about whether FDA can or should use guidance to promulgate a new regulatory approach.

It is also indisputable that innovative laboratories and health care providers develop and perform tests and procedures that advance personalized patient care. Because of the critical role they can play in the decisions patients make with their doctors, these tests—regardless of who develops or manufactures them—must be accurate and reliable.

Any framework adopted must not only prioritize patient safety—which should always be paramount—but also encourage robust investment and allow for continued innovation.

In order for that to happen, a company or venture capitalist that invests in the development, testing, and FDA review of a diagnostic product must have the certainty that labs will not copy it and promote their alternatives the next day.

On the other hand, many innovative tests and procedures are developed in labs—including continuous, iterative improvements to FDA-approved products that often become the standard of care. Any regulatory approach must carefully address these complex issues.

Dr. Shuren has been a key voice throughout the 21st Century Cures initiative, and I thank him for his willingness to come to the table yet again.

The Committee invited CMS to testify on its roles and responsibilities administering the Clinical Laboratory Improvement Amendments regulations, which includes lab practices, certification, and personnel, but they were unable to do so.

We have a number of questions about FDA’s proposed path forward, and I look forward to hearing from all our witnesses on the second about its potential impact.

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