Rep. Joseph R. Pitts

Opening Statement

Energy and Commerce Subcommittee on Health

Hearing on "Examining the Regulation of Diagnostic Tests and Laboratory Operations"

November 17, 2015

The Subcommittee will come to order.

The Chairman will recognize himself for an opening statement.

Throughout the 21st Century Cures initiative, "biomarkers," "precision medicine," and "targeted therapies" were a few of the most consistently uttered terms and concepts. In order to advance each of them, we must establish a regulatory environment that fosters the development of and access to innovative, accurate and reliable diagnostic testing.

Such tests are increasingly important, not only diagnosing the onset of a specific disease or condition, but in determining the right course of treatment or procedure. It goes without saying that tests providing information to a doctor or consumer are fundamentally different products than traditional medical devices which actually deliver therapy to or are implanted in a patient. Nonetheless, while FDA has used its

medical device authorities to review and oversee tests developed by outside entities that are then sold to laboratories, the agency has not actively regulated laboratory developed tests, or LDTs.

Last year, a week after we held a roundtable downstairs that highlighted the importance of this very topic, FDA announced that it would no longer exercise such enforcement discretion and detailed how the agency proposes to apply its medical device authorities to LDTs.

Today, I am far less interested in litigating the boundaries of current FDA or CMS legal authority than in hearing from our witnesses about how such authority could be clarified or improved, understanding the unique and evolving nature of what it is being regulated and each agency's areas of expertise.

In response to a white paper the committee circulated at the end of last year asking these very questions, we heard from a number of labs and pathologists that FDA should only have a limited role, if any, in regulating a select set of tests as medical devices. The rest, in their opinion, should be overseen by CMS, through an updated Clinical Laboratory Improvement Amendments program. This is despite the fact that CMS has stated that they do not have the resources, the expertise or

the willingness to take on what is being asked of them. I am eager to hear what Dr. Conway has to say on the matter.

We also received comments from a number of manufacturers, as well as over forty patient groups, that FDA—not CMS—needs to be in the driver's seat and that tests that have the same impact on a patient should be held to the same standards, regardless of who does the development. This is despite the fact that laboratories are uniquely nimble environments where pathologists continually modify and improve tests in ways that manufacturers cannot.

I am well aware that this has been, at times, a heated debate with passionate advocates on both sides. With such a backdrop, I want to particularly commend the manufacturers, laboratories, and other health care institutions that have been willing to roll up their sleeves and find as much common ground as possible through constructive dialogue, a willingness to compromise, and a pragmatic understanding of what a viable, modern framework entails.

I do not believe imposing a new regulatory reality on an increasingly important component of our health care system via guidance is the best way to address these issues. These products warrant a regulatory system

designed with them in mind. They should not be shoehorned into a system that was drafted in the 1970s.

This committee has clearly shown that we are willing and able to move complicated, comprehensive, bipartisan legislation. The discussion draft the committee circulated along with the hearing notice is of course not perfect, but it is a serious document based on significant consensus. I would ask that all of the stakeholders out there, including our two distinguished witnesses, help us improve it as this process continues.

With that I would like to thank Dr. Shuren—a frequent and always welcome visitor—as well as Dr. Conway, for their willingness to testify today. I look forward to working with them on these issues going forward.