

**Opening Statement of the Honorable Fred Upton**  
**Subcommittee on Health**  
**Hearing on “21st Century Cures: Examining the Regulation of Laboratory Developed**  
**Tests”**  
**September 9, 2014**

*(As Prepared for Delivery)*

Today marks the seventh Health Subcommittee hearing Chairman Pitts has convened as part of the bipartisan 21st Century Cures initiative. I would like to thank him again for his tireless work on this effort, including the exceptional roundtable he hosted in Lancaster, Pennsylvania, in late August that I had the pleasure to attend along with Ranking Member Pallone and Dr. Burgess.

Over August and the early part of September, members from both sides of aisle held roundtables across the country to solicit feedback on accelerating cures and treatments for patients. This really has been a collaborative effort, and we need everyone to continue providing us with specific ideas - none too big, none too small - about how we can make a significant reduction in the time and costs associated with the discovery, development, and delivery of safe and innovative new treatments and cures for patients who need them.

Personalized medicine has really been a recurring theme throughout this entire discussion. According to the Personalized Medicine Coalition, “While the potential benefits of personalized [medicine] are straightforward—knowing what works, knowing why it works, knowing whom it works for, and applying that knowledge to address patient needs—the intervening variables that determine the pace of personalized medicine’s development and adoption are far more complex. Among those variables are the laws and regulations that govern personalized medicine products and services used in clinical practice.”

Today’s hearing is an important opportunity to hear from a variety of stakeholders about just that. Particularly since the mapping of the human genome, diagnostics provide researchers and clinicians with valuable tools to match the right patients with the right course of therapy. We must ensure that our laws and regulations keep pace so that innovation in this space continues and patients benefit from accurate and reliable tests.

On July 31, 2014, FDA notified the committee that the agency intends to issue draft guidance to implement a new risk-based framework governing the review and oversight of laboratory developed tests. FDA has indicated for several years that it planned on taking this step. Because it will have such a substantial impact on how these products and services are currently being used in practice, we required the agency notify the committee before moving forward. This provision in the Food and Drug Administration Safety and Innovation Act was not an endorsement of such an approach but recognition of the fact that a number of legal, procedural, and substantive questions about FDA’s role in this complex policy area remained outstanding.

I thank Dr. Shuren and our other witnesses for their testimony about whether the agency has adequately addressed these issues and what role Congress can play in making sure that personalized medicine continues to flourish.

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