Opening Statement of the Honorable Fred Upton
Subcommittee on Health
Hearing on "21st Century Cures: Modernizing Clinical Trails"
July 9, 2014

(As Prepared for Delivery)

At our first 21st Century Cures roundtable, we learned that there are treatments for only 500 of the more than 7,000 known diseases affecting our nation's patients. We have also heard about the increasing time and expense involved in bringing new drugs and devices to market. We've learned that the costs and regulations surrounding clinical trials are a primary contributor to this delay. This means new treatments and cures cost more and are getting to patients more slowly. This system is simply unsustainable.

Here in the U.S., it is incredibly complicated to navigate the processes involved in simply getting a trial up and running, particularly for small companies. Overall, the size, duration, costs, and failure rates are higher than ever. In some instances, trials are being moved overseas as a direct result of these challenges. This leaves patients in the United States waiting longer for cures and treatments and also takes good jobs away from folks here at home. Safety is always the top priority, and I believe we can safely do better; we must work together to remove any needless administrative or operational burdens that do not benefit patients.

In addition, we would like to learn more about recent advances in technology and data collection that can help modernize our system, encourage better participation, and allow for continued learning about the risks and benefits of new drugs and devices in the real world. How can we take what we learn in the development and delivery phases and translate that back to new, more innovative discovery in the cycle of cures? How can we leverage patient registries and innovative new protocols like the Lung-MAP Trial, as well as other collaborative efforts, into more advances in molecular medicine?

Electronic health records, increased data sharing, and patient-reported outcomes will undoubtedly play a critical role in this regard. Ultimately, this will accelerate and modernize the discovery, development, and delivery cycle.

Today's hearing is another important opportunity to discuss what can be done to further our journey on the path to cures.

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