

Opening Statement of the Honorable Fred Upton
Subcommittee on Health
Hearing on “21st Century Cures: Examining Barriers to Ongoing Evidence
Development and Communication”
July 22, 2014

(As Prepared for Delivery)

When we first launched the 21st Century Cures initiative in the late spring, we had a pretty good idea that learning about the benefits and risks of a drug or device doesn't end when FDA initially approves or clears the product for use. In fact, this discovery, development, and delivery cycle has been this initiative's emblem, illustrating that each phase of the process must influence the next. This sentiment has been echoed throughout our many hearings, roundtables, and in feedback from white papers.

Different uses for drugs or devices are constantly being discovered by physicians, researchers, and scientists in academia and industry. Particularly in the context of devices, improvements are continually made to products based on new evidence being developed about how certain patients are responding to certain treatments, technologies, or combinations thereof. We must work to ensure that our regulatory and reimbursement policies encourage this iterative process and do not stifle innovation.

This type of ongoing evidence development, collaboration, and communication must be facilitated, not hindered. And any policies in place must ultimately benefit patients and quality of life. Through 21st Century Cures we are committed to evaluating how Congress can play a role in breaking down any of these legal or regulatory barriers and encouraging communication and collaboration among patients, doctors, and scientists regarding new data, research, and results.

At our recent digital healthcare roundtable, we learned about the many exciting opportunities to capture and analyze data in real-world delivery settings. This real-world data can help lead to additional insight and evidence about the effectiveness and safety of cures and treatments. During last week's joint hearing of the Health and Communications and Technology Subcommittees, we learned more about the role electronic health records and increased data sharing can play in that process, but also heard about the challenges and privacy issues we must address in order for such potential to become reality.

As we stated from the outset in our first white paper, the policies we have in place must allow for health care delivery to serve as a platform for new discovery and development. This hearing will provide a great opportunity to learn how we can encourage and reward ongoing evidence development and not unduly limit how such evidence is discussed or communicated to patients and providers.

###