

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

When we first launched the 21st Century Cures initiative in April, 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 certain patients with a specific disease or set of conditions. Since then, we have heard repeatedly that in many ways it is only just beginning.

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 by any policies in place that do not ultimately benefit patients. As part of the 21st Century Cures initiative, I am committed to evaluating how Congress can play a role in breaking down any of these legal or regulatory barriers and encouraging communication and collaboration between and among patients, doctors, and scientists regarding new data, research, and results.

At our digital healthcare roundtable, we learned about the many exciting opportunities to capture and analyze data in real-world delivery settings to generate meaningful insight and specific evidence about which type of treatments are working better on which type of conditions or diseases in which type of patients—often right down to the molecular level. During our joint hearing of the Health and Telecommunications 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 Cures 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.