

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

(As Prepared for Delivery)

In this, the sixth hearing of our 21st Century Cures Initiative, we are examining continued evidence development and communication of information regarding treatments and cures in the real world setting.

Discovery of the risks and benefits of a drug or treatment does not end with FDA approval or clearance. It is often just the beginning of learning about different uses for drugs and devices, for different indications, conditions, and populations.

Treatment in the real world also brings out additional information on safety and efficacy, and ensuring that this knowledge is shared widely among providers, patients, and researchers is critical.

As a result, the ability of patients, physicians, and developers to communicate effectively is so important for the future of cures in this country.

Unfortunately, many of the witnesses and participants we have had before us since the Cures initiative began have raised concerns regarding barriers to communication and evidence development.

This hearing is a direct result of the feedback we have received from patient groups and other interested parties.

As today’s witnesses will discuss, efforts to limit off-label use among the provider community, limitations on communication found under HIPAA, and the Physician Sunshine Act are just a few of the barriers to 21st Century Cures that have been raised with us over the past few months.

It is my hope that this hearing allows the members an opportunity to consider these potential barriers and the role they play in our health care system.

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