

Rep. Joseph R. Pitts
Opening Statement
Energy and Commerce Joint Hearing
Subcommittees on Communications and Technology and Health
Hearing on “21st Century Cures: Examining Barriers to Ongoing Evidence
Development and Communication”
July 22, 2014

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

In this, the fourth 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.

In such ways, 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 concern regarding barriers to communication and evidence development.

As our 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.

The importance of today’s hearing and the reason for our calling it is really a direct

result of the feedback we have received from patient groups and other interested parties.

With that though in mind, I would like to thank all of our witnesses for being here today, and I yield the balance of my time to Rep. _____.