



# THE COMMITTEE ON ENERGY AND COMMERCE

## MEMORANDUM

July 18, 2014

To: Members, Subcommittee on Health

From: Majority Committee Staff

Re: Hearing Entitled “21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication”

---

On Tuesday, July 22, 2014, at 3:00 p.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled “21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication.” This hearing will focus on issues surrounding continued evidence development and communication of information regarding treatments and cures in the real world setting.

### I. WITNESSES

- Mary Grealy, President, Healthcare Leadership Council;
- Michael A. Mussallem, Chairman and CEO, Edwards Lifesciences;
- Gregory Schimizzi, M.D., Cofounder, Carolina Arthritis Associates, *On Behalf of the Alliance for Specialty Medicine*;
- Josh Rising, MD, MPH, Director, Medical Devices, The Pew Charitable Trusts; and,
- Louis Jacques, Senior Vice President and Chief Clinical Officer, ADVI.

### II. BACKGROUND

Learning about the benefits and risks of a drug or device does not end when the Food and Drug Administration approves, licenses, or clears the product for use in certain patients based on the evidence presented during the premarket review process. In many ways, the process is just beginning.

Different uses for drugs and devices are being discovered constantly, many times for treatment of new conditions and diseases or for populations of patients other than for which they were initially approved. Treatment in the real world setting also provides the opportunity to learn more about both the benefits and risk profile of a drug and device for its indicated use, as well as other uses.

Learning and data sharing regarding safety and efficacy are happening through a multitude of platforms around the globe. Dialogue regarding this enhanced learning--whether

through the Internet, social networks, or other platforms--should be facilitated among doctors, patients, researchers, and scientists because the free flow of data, research, and results related to what a therapy or combination of therapies does or does not do well and in what types of patients could help advance the discovery, development and delivery cycle.

### **III. STAFF CONTACTS**

Should you have any questions regarding the hearing, please contact John Stone, Carly McWilliams, Robert Horne, or Paul Edattel at (202) 225-2927.