



THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

July 7, 2014

To: Members, Subcommittee on Health

From: Majority Committee Staff

Re: Hearing Entitled “21st Century Cures: Modernizing Clinical Trials”

On Wednesday, July 9, 2014, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled “21st Century Cures: Modernizing Clinical Trials.” Designing and conducting clinical trials of new drugs and devices in the United States has become increasingly complex, time consuming, and expensive. This hearing will focus on ways to make trials more efficient and effective by leveraging recent advances in science and technology.

WITNESSES¹

- Roy S. Herbst, MD, PhD, Chief of Medical Oncology, Yale Cancer Center;
- Sundeep Kholsa, MD, Director, Center for Clinical and Translational Science, Mayo Clinic;
- Jay P. Siegel, MD, Chief Biotechnology Office and Head, Global Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson; and,
- William V. Murray, President and CEO, Medical Device Innovation Consortium.

BACKGROUND

Since the launch of the 21st Century Cures initiative, the Committee has received substantial input on how to accelerate the discovery-development-delivery cycle of cures. This input includes the invaluable discussion at the two roundtables,² two Health Subcommittee hearings,³ as well as the comments submitted in response to the white papers.⁴

According to the input received thus far, drug and device clinical trials can and must be modernized in order to expedite access to cures and treatments, reduce unnecessary burdens and

¹ Additional witnesses will be added.

² Roundtable held on May 6, 2014, opening the 21st Century Cures initiative and roundtable held on June 24, 2014, on digital medicine.

³ Hearing held on May 20, 2014 entitled: “21st Century Cures: The President’s Council of Advisors on Science and Technology (PCAST) Report on Drug Innovation” and hearing held on June 11, 2014 entitled “21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients.”

⁴ The white papers and stakeholder comments can be found here: <http://energycommerce.house.gov/cures>.

costs, and help patients. Recent advances in science and technology make it clear that this modernization can be achieved. This hearing will provide an opportunity to learn more about our clinical trial system and what Congress can do to help modernize the system.

STAFF CONTACTS

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