



THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

June 9, 2014

To: Members, Subcommittee on Health

From: Majority Committee Staff

Re: Hearing on “21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients”

On Wednesday, June 11, 2014, the Subcommittee on Health will hold a hearing entitled “21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients.” The Subcommittee will convene at 10:00 a.m. in 2322 Rayburn House Office Building to gain a better understanding of whether current economic and regulatory incentives are sufficient to encourage robust investment in the research and development (R&D) of innovative drugs and medical devices, particularly for those that would provide hope to patients with unmet medical needs and the families that care for them.

I. WITNESSES

- Dr. Kenneth Davis, President and Chief Executive Officer, Mt. Sinai Health System;
- Marc Boutin, Executive Vice President and Chief Operating Officer, National Health Council;
- Alexis Borisy, Partner, Third Rock Ventures;
- Mike Carusi, General Partner, Advanced Technology Ventures;
on behalf of National Venture Capital Association
- Dr. Fred Ledley, Professor, Natural & Applied Sciences and Management Director, Center for Integration of Science and Industry, Bentley University.
- C. Scott Hemphill, Professor of Law, Columbia Law School; and,
- Dr. Steven Miller, Senior Vice President Chief Medical Officer, Express Scripts Holding Company.

II. BACKGROUND

On May 20, 2014, the Health Subcommittee held its first hearing as part of the 21st Century Cures Initiative to discuss the President’s Council of Advisors on Science and

Technology (PCAST) *Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation*.¹ While the report primarily focused on “promoting innovation through increasing the probability of success, decreasing the expense, shortening the time, and enhancing the regulatory certainty of drug development,” the eighth and final recommendation was to “study current and potential economic incentives to promote innovation in drug development.”² This hearing will provide an opportunity for the Committee to begin to assess how Congress can foster additional investment, particularly in areas where patients lack effective treatments or public health demands innovation.

Citing antibiotics and Alzheimer’s disease, the President’s advisors highlighted the fact that “economic incentives for certain areas of drug development important to public health may be insufficient to elicit adequate investment in innovation” and posited that “it may be important to consider tools, such as vouchers for priority review, exclusivity periods, and targeted tax credits.”³ The Committee recently acted on an overwhelmingly bipartisan basis to pass the Generating Antibiotic Incentives Now (GAIN) Act, which extends by five years the exclusivity period for new antibiotics. This law has already been successful in spurring what was a languishing antibiotics pipeline, although most agree that work remains.

As discussed at the first 21st Century Cures roundtable, we only have treatments for 500 of the 7,000 known diseases impacting patients today.⁴ While there are many reasons behind this significant gap, the time, expense, and risk involved in bringing new drugs to market often make it less attractive for venture capital or R&D dollars, particularly if the period for return on investment is less likely to justify the cost of development. As Dr. Francis Collins recently stated, “Developing a drug takes time and money: on the average, around 14 years and \$2 billion or more” and “[m]ore than 95 percent of the drugs fail during development.”⁵

Concerns about whether current incentives are sufficient to ensure robust investment in innovative new treatments are not limited to drugs. Venture investment in the medical technology sector declined by one-third between 2007 and 2012 and declined an additional 17 percent in 2013. In fact, the number of venture capital firms investing in medical technology has declined from 39 in 2007 to just 11 today.⁶ The Subcommittee will hear testimony on what incentives Congress should examine to spur investment in medical devices.

¹ See PRESIDENT’S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, EXECUTIVE OFFICE OF THE PRESIDENT, REPORT TO THE PRESIDENT ON PROPELLING INNOVATION IN DRUG DISCOVERY, DEVELOPMENT, AND EVALUATION (Sept. 2012) available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-fda-final.pdf>.

² *Id.* at 73.

³ *Id.* at ix.

⁴ See statement of Margaret Anderson, Executive Director of FasterCures, at the 21st Century Cures Roundtable held on May 6, 2014, <http://www.youtube.com/watch?v=Fr4Re7sfDzE&t=33m21s>.

⁵ Francis Collins, Dir., Nat’l Institutes of Health, *Crowdsourcing Therapeutic Molecules for Drug Discovery*, June 18, 2013, available at <http://directorsblog.nih.gov/2013/06/18/crowdsourcing-therapeutic-molecules-for-drug-discovery>.

⁶ See Nat’l Venture Capital Ass’n, *Patient Capital 3.0*, April 2013, available at http://www.nvca.org/index.php?option=com_content&view=article&id=268&Itemid=103.

III. STAFF CONTACT

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