THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

March 18, 2013

To: Health Subcommittee Members

From: Majority Staff

Re: Hearing entitled "Health Information Technologies: How Innovation Benefits Patients"

On Wednesday, March 20, 2013, the Subcommittee on Health will hold a hearing entitled "Health Information Technologies: How Innovation Benefits Patients." The Subcommittee will convene at 10:00 a.m. in 2123 Rayburn House Office Building. This hearing will focus on how these innovative technologies will benefit American patients and what steps need to be taken to foster this innovation.[1] The following provides background on the hearing witnesses and health information technologies.

I. Witnesses

Joseph M. Smith, M.D., Ph.D.
Chief Medical and Chief Science Officer
West Health Institute

Jacqueline Mitus, M.D.
Senior Vice President, Clinical Development and Strategy
McKesson Health Solutions

Mr. Jim Bialick
Executive Director
Newborn Coalition

Ms. Christine Bechtel
Vice President
National Partnership for Women and Families

David Classen, M.D.
Chief Medical Information Officer, Pascal Metrics
Associate Professor of Medicine and Consultant in Infectious Diseases
University of Utah School of Medicine

[1] This hearing is one of three this week on health information technologies at the Energy and Commerce Committee. On March 19, the Subcommittee on Communications and Technology will hold a hearing entitled "Health Information Technologies: Harnessing Wireless Innovation." On March 21, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Health Information Technologies: Administration Perspectives on Innovation and Regulation."

II. Health Information Technologies

The advent and use of health information technologies, including mobile medical applications (apps), electronic health records, personal health records, computerized health care provider order entry systems, and clinical decision support, offers tremendous benefits to American patients.

Medical apps in particular have advanced the ability of patients to better understand their own health care, and their potential benefit to patients and our health care system is seemingly unlimited. Despite the nascent nature of the app industry, there already are many uses for these apps, from data products that teach users to understand their physiological health to apps that allow the transport of electronic health records from patient to provider. Now and in the future, these apps hold the potential to help educate patients about their own health care needs, to aid patients in making choices that can improve the quality of their lives, and to provide tools to create true consumerism within health care – something that has been lacking for decades.

In July 2011, the Food and Drug Administration (FDA) issued a draft guidance indicating its intent to regulate apps as medical devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Under this draft guidance, apps that perform any of the following could be subject to FDA regulation:

- Display, store, or transmit data in its original format;
- Control a medical device whether remotely or through direct connection;
- Turn a mobile platform, such as a smartphone, into a medical device; or
- Create alarms or recommendations based on the data received from a medical device.

This draft guidance pertains to apps, but some believe that FDA may use the definition of medical device to drag other technologies, even smart phones and tablets, under the agency's authority. Subjecting these technologies to FDA regulation, and the delays, expense, and other issues associated with such regulation, could inhibit innovation. Further, because the medical device tax of the Patient Protection and Affordable Care Act (PPACA), as amended, is based on section 201(h) of the FFDCA, FDA's decision to treat health information technologies as medical devices may have tax implications as well (e.g., the 2.3 percent medical device tax).

At the hearing, the Subcommittee will explore the unique role that health information technologies have in advancing the health and well-being of patients nationwide. Further, it will begin a public dialogue on the extent to which FDA should be involved in regulating these technologies considering the concerns about its impact on innovation and the harm a 2.3 percent tax could have on future development. As part of this dialogue, the Committee will examine whether legislative action is necessary to address these concerns.

III. Staff Contacts

Should you have any questions regarding the hearing, please contact Robert Horne or Clay Alspach at (202) 225-2927.