THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

November 15, 2013

To: Health Subcommittee Members

From: Majority Committee Staff

Re: Hearing entitled "Examining Federal Regulation of Mobile Medical Apps and Other Health Software"

On Tuesday, November 19, 2013, the Subcommittee on Health will hold a hearing entitled "Examining Federal Regulation of Mobile Medical Apps and Other Health Software." The Subcommittee will convene at 10:00 a.m. in 2322 Rayburn House Office Building. This hearing will focus on the Food and Drug Administration's (FDA) final medical app guidance published in September 2013 and H.R. 3303, Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act of 2013. It will build on the "Health Information Technology" hearing series held by the Subcommittees on Health, Communications and Technology, and Oversight and Investigations in March 2013.

I. Witnesses

Panel I

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Panel II

Mike Marchlik
Vice President, Quality Assurance and Regulatory Affairs
McKesson Technology Solutions

Jim Bialick
Executive Director
Newborn Coalition

The Honorable Zachary J. Lemnios
Vice President, Research Strategy
IBM Research

Robert Jarrin
Senior Director, Government Affairs
Qualcomm Incorporated

J. Leonard Lichtenfeld
Deputy Chief Medical Officer
American Cancer Society, Inc.

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, offer the possibility of life-improving and life-saving benefits to American patients.

Medical apps in particular have advanced the ability of Americans 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.

In September 2013, FDA issued final guidance indicating its intent to regulate apps as medical devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act. While this move would allow the agency to regulate all mobile medical apps, FDA also announced its intention to use enforcement discretion to regulate only a subset of all mobile medical apps, including those that are used as an accessory to a regulated medical device; or transform a mobile platform into a regulated medical device.

Prior to FDA releasing the final guidance announcement in September, some patient advocates and experts in the field of emerging technologies raised concerns with FDA's decision to regulate software technologies as medical devices.

III. H.R. 3303, The Software Act

Representative Marsha Blackburn (R-TN), along with Reps. Gene Green (D-TX), Greg Walden (R-OR), Diana DeGette (D-CO), Phil Gingrey (R-GA), and G.K. Butterfield (D-NC), introduced H.R. 3303, SOFTWARE Act of 2013 on October 22, 2013. The bill would create regulatory certainty by giving FDA a new tool to regulate some forms of these emerging technologies without regulating them as medical devices.

IV. Staff Contacts

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