House Energy and Commerce Subcommittee on Health Hearing
"Health Information Technologies: How Innovation Benefits Patients"
March 20, 2013

Background

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In July 2011, the Food and Drug Administration (FDA) issued a draft guidance indicating its intent to regulate apps as medical devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Under this draft guidance, apps that perform any of the following could be subject to FDA regulation: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This draft guidance pertains to apps, but some believe that FDA may use the definition of medical device to drag other technologies, even smart phones and tablets, under the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.

Chairman Jim Pitts (R-TX) called attention to the progress of EHRs, health IT, and mobile apps over the last couple of years. The Chairman raised concerns over the regulatory impact of health IT on patients and innovation in the industry, as the FDA moves to expand regulatory oversight to include smartphones and tablets. Other Congressmen expressed similar concerns, citing the lack of a reliable and consistent regulatory process for this industry. Some members argued the essential role of the FDA in ensuring the

safety of health IT products, and insisted that the FDA would not regulate smartphones in the same way that it regulates medical devices or impose taxes on health IT products.

Witnesses

Joseph M. Smith, M.D., Ph.D., Chief Medical and Chief Science Officer, West Health Institute, spoke on the importance of having empowered and informed healthcare users. Dr. Smith offered three priorities for achieving the goals of health IT:

- Streamlined regulation that fosters innovation
- Standards based interoperability
- Reimbursement that aligns stakeholder incentives, and places priority on value and outcomes

Jacqueline Mitus, M.D., Senior Vice President, Clinical Development and Strategy, McKesson Health Solutions, presented the committee with two priorities for health IT and regulation:

- Health IT is fundamental to improving quality, safety and affordability of healthcare
- New, risk based regulatory framework that is particular to health IT, and not just medical devices, is needed. The safety of medical devices is dependent upon how the device in manufactured, while the safety of health IT is dependent upon how it is implemented. Medical devices are directly involved in care, while medical software simply offers physicians data and guidance support in giving care.

Dr. Mitus cited the Bipartisan Policy Center's framework model as a viable alternative to other models, offering 3 risk categories and flexibility while leveraging existing quality standards.

Mr. Jim Bialick, Executive Director, Newborn Coalition, illustrated the value of health IT through the example of parents acting as caretakers for newborn babies, and the potential for mobile apps to assist in monitoring the newborns' care. Mr. Bialick argued for risk-based frameworks for health information management applications and medical devices that are flexible and adaptive to new technology.

Ms. Christine Bechtel, Vice President, National Partnership for Women and Families, gave an update on the Meaningful Use EHR Incentive Program, noting the high rates of adoption seen by hospitals and providers over the past few years, citing the program's success. Ms. Bechtel stated the need for a wider array of standards, and the need to create a business case for care coordination, and expand the Meaningful Use program to more types of providers.

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, spoke on unintended consequences and the importance of safe implementation and use of health IT, which is a complex process. Health IT in operation looks much different than health IT on the shelf, and iterative feedback from users is essential.

Questions from the Committee

Chairman Pitts (R-TX) asked witnesses if they believed data should be considered a medical device, to which all responded no. The Chairman also asked if witness were concerned about the possibility for regulatory creep on the health IT industry, and if FDA has the expertise to regulate health IT apps and software. The panelists felt that at present, FDA does not have the in-house expertise to take on this task.

Members asked the witness panel about Meaningful Use adoption rates and the government's role in contributing open data, citing initiatives like Blue Button and healthdata.gov.

Multiple Members focused on the distinction between health IT and medical devices. Panelists expressed the importance of this distinction for regulatory purposes. Witnesses on the panel admitted that drawing the line between health IT software and medical devices can be a challenging gray area and that no single entity should be charged with making these distinctions.

The witness panel cautioned against creating an over-prescriptive framework that draws sharp lines, as regulatory entities like the FDA tend to move slowly. Instead, a risk-based framework approach should be considered for health IT.