Opening Statement of the Honorable Joe Pitts
Subcommittee on Health
Hearing on "Health Information Technologies: How Innovation Benefits Patients"
March 20, 2013

(As Prepared for Delivery)

Today's hearing is part of a series of Energy and Commerce subcommittee hearings this week that focus on health, technology and innovation.

In the last few years, health information technologies, including mobile medical applications, electronic health records, personal health records, computerized health care provider order entry systems, and clinical decision support, have transformed the provision of health care in this country.

Electronic health records hold great promise for the delivery of care given and quality of care received in this country. They have also been identified as key components of future payment reforms such as those envisioned for medical providers under the SGR.

There are now mobile medical apps for wireless thermometers, apps that calculate body mass index, apps that track the number of miles a runner has jogged and those that can wirelessly transmit data to wearable insulin pumps.

These apps can range from the complex, like mobile cardiac outpatient telemetry that uses wireless sensors, to those that allow users to count calories.

To give you a sense of the scope of their importance, it has been estimated that 500 million people will be using medical apps by 2015.

Therefore, it goes without saying that these technologies hold great potential for patients and providers. However, with the proliferation of these technologies have come concerns about how their use may negatively impact patients. Some have argued that federal oversight of these health information technologies is important to safeguard patients from malfunctioning technology.

In response to these concerns, the Office of the National Coordinator in December 2012 put out a proposal for a risk-based regulatory scheme for electronic health records that sought to address the needs of Americans both as consumers and patients.

The Food and Drug Administration has also put forward a proposal, in the form of draft guidance issued in July 2011, indicating its intent to regulate certain apps as medical devices under section 201(h) of the Federal Food, Drug and Cosmetic Act.

While FDA's attention to the needs of patients is commendable, its action requires very close scrutiny. This subcommittee has examined in the past the negative impacts that FDA regulation – with its uncertainty, high costs, and long approval times – has had on the medical device industry. If we allow the same to happen in this space, such negative impacts could cripple a still evolving and promising industry, where the average developer is small and the cost of these apps are relatively inexpensive.

Some have also raised concern that the FDA may further expand the definition of "medical device" in the future to include other technologies, such as smartphones or tablets, and thus the medical device tax passed in the Patient Protection and Affordable Care Act could apply to them.

Therefore, this hearing is an appropriate place to examine the extent to which the FDA – and other federal agencies – should be involved in regulation of health information technologies and what such a regulatory framework might look like.

With these thoughts in mind, I want to thank our witnesses for being here today and look forward to their testimony.

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