Opening Statement of the Honorable Tim Murphy
Subcommittee on Oversight and Investigations
Hearing on "Health Information Technologies: Administration Perspectives on Innovation and Regulation"
March 21, 2013

(As Prepared for Delivery)

Today we convene the Subcommittee on Oversight and Investigations to discuss development and innovation in health care technologies, particularly mobile medical applications or "apps," and how federal regulations may impact this growing industry.

We are joined by two witnesses from the administration. Dr. Farzad Mostashari is the head of the Office of the National Coordinator within HHS. Christy Foreman is the Director of the Office of Device Evaluation within the Center for Devices and Radiological Health at FDA.

Both of these agencies have been leading the government's response to the rapid changes that new technologies are making to our nation's health care system.

On March 4, this committee sent a letter to the FDA on its approach to regulating the rapidly growing market for applications used on smartphones and tablets. With this explosive growth, the use of those apps to monitor health information is growing as well. News reports indicate that there are as many as 40,000 medical applications on the market for smartphones and tablets.

We are here today to discuss the discretion FDA has in regulating these apps as devices under the Food, Drug, and Cosmetic Act. I have seen that in today's testimony the FDA is now definitely saying: No, we will not regulate the general sale of smartphones or tablets — I thank the FDA for providing certainty on this matter.

Over the last few days we have heard a number of examples of medical apps and concerns from apps companies about whether these apps are devices. For example, where does an app that transmits photos of potential skin cancer cross the line to FDA scrutiny? If an app that turns a smartphone into an ultrasound can be regulated, what about apps that let you view images from an ultrasound or X-ray?

In 2011, the FDA issued draft guidance on how the agency planned to regulate mobile medical applications. FDA has not yet issued final guidance. To our witness from the FDA, over the last two days we have heard from a variety of witnesses and members of both sides of the aisle — the message is clear: we need final guidance. The developers of these apps and the health care industry need certainty.

That certainty is also needed because of the tax on medical devices put in place by the new health care law. As we have heard this week, a tax on medical devices can make capital needed to develop these apps and new breakthrough technologies more scarce. The tax can slow innovation.

This isn't about scaring people into thinking this tax will apply to their iPhones, Blackberries or iPads, but this tax could absolutely halt the development of new apps to run on those devices.

Everyone here recognizes the need to balance patient safety and innovation. I hope that today's hearing will provide some certainty in that regard.

We will also hear from Dr. Mostashari on the efforts that have been made by the Department of Health and Human Services to encourage the utilization of health information technology, and particularly the incentive payments that have been made to providers to adapt to new health care technologies. Recently, HHS announced that for this year they hope to have 50 percent of physician offices using electronic health records, with 80 percent of eligible hospitals receiving incentive payments by the end of the year.

While the movement to increased use of electronic health records may seem like an obvious choice as doctors and hospital employees become more comfortable with new technologies, as a supporter of health information technology, I am concerned that the promised benefits of electronic medical records have yet to arrive. I've personally heard from physicians in my district who've struggled to adapt or received unclear guidance from the agency. Of particular concern are complaints that systems in place are unable to share information with other systems. I hope our witness today will be able to address these concerns over interoperability.

I am encouraged by the work this committee has done this week. We've had a great dialogue on these issues and today I hope we'll be able to hear the administration's views on its approach to innovation and regulation of health care technologies.

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