The Committee on Energy and Commerce

Memorandum

March 15, 2013

To: Members and Staff, Subcommittee on Communications and Technology

From: Majority Committee Staff

Re: Hearing on "Health Information Technologies: Harnessing Wireless Innovation"

On March 19, 2013, at 10:30 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Communications and Technology will hold a hearing entitled "Health Information Technologies: Harnessing Wireless Innovation."

I. WITNESSES

Ben Chodor, CEO
Happtique

Dr. George Ford, Chief Economist
Phoenix Center for Advance Legal and Economic Public Policy Studies

Robert Jarrin, Senior Director
Government Affairs, Qualcomm

Jonathan Spalter, Chairman
Mobile Future

Bradley Merrill Thompson
mHealth Regulatory Coalition

Dr. Teo Forcht Dagi, M.D., Partner
HLM Venture Partners

II. OVERVIEW

Low barriers to entry, quick time to market, inexpensive retail prices, and rapid upgrade cycles have made the mobile application economy an American economic success story. Anyone with a good idea and computer coding ability can get into the business and distribute their innovation around the world. And thanks to the proliferation of subsidized smartphones and the popularity of "app stores," mobile apps are projected to be a $25 billion industry this year and are estimated to have already produced 500,000 jobs.

Health-related applications are a growing segment of this market. Five percent of smartphone owners have downloaded an app to track or manage their health, according to a September 2012 Pew study. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration could potentially classify these applications—as well as the smartphones and tablets that run them—as medical devices, subjecting them to a lengthy

clearance or approval process. Further, this classification could subject these products to the 2.3 percent medical device tax from the Patient Protection and Affordable Care Act (PPACA), as amended. Overbroad application of this classification could stall the innovation, investment, and job creation that wireless smartphones and apps are bringing to healthcare, as well as ultimately impact the larger wireless ecosystem.

III. BACKGROUND

Under section 201(h) of the FFDCA, a product is a medical device subject to FDA regulation if it is:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is … [either] intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals … [or] intended to affect the structure or any function of the body of man or other animals.

Given this definition, a host of software tools and mobile devices are potentially within the FDA's regulatory ambit.

The FDA released draft guidance in July 2011 on how it will regulate mobile medical applications and devices under its medical device authority. The FDA indicated that an app that is used "as an accessory to a regulated medical device" or that "transforms the [smartphone] into a regulated medical device" would be subject to FDA regulation. Further, the FDA provided specific guidance and examples on the types of apps that would trigger FDA regulatory oversight (*e.g.*, apps that store or display historical data from a blood glucose monitor, apps that allow the user to view medical imagery, apps that use the device's built-in features such as the camera for a medical purpose) and those that would not (*e.g.*, dietary tracking logs, appointment reminders, dietary suggestions based on a calorie counter, posture suggestions, exercise suggestions, or similar decision tools that generally relate to a healthy lifestyle and wellness that are not intended to treat a specific health condition). The FDA's draft guidance also sets out specific criteria for whether a smartphone or tablet is subjected to regulatory oversight as a medical device.

Certain medical devices were also subject to a 2.3 percent excise tax beginning Jan. 1, 2013, as part of PPACA. Depending on how the law is interpreted, this tax potentially could apply to mobile health applications as well as smartphones and tablets.

IV. DISCUSSION

Treatment of apps, smartphones, and tablets as medical devices could hinder the growing mHealth app sector and the broader mobile wireless ecosystem by disrupting the virtuous cycle of innovation and investment between applications and devices and the timely and cost effective upgrade cycle for both. Mobile health apps and devices that fall within the medical device regime are subject to a variety of regulatory requirements ranging from registration and labeling to a full, pre-market approval process. This can slow time to market or even discourage development of the applications in the first place. The app ecosystem is also made up of many wireless devices and operating systems. Updates to operating systems, application programming

interfaces, and other software changes outside the control of the app developer occur regularly. How will the FDA handle small, iterative updates to apps to accommodate operating system changes? Does the FDA process contemplate the potentially short life span of a particular wireless device or version of an operating system? Does the FDA intend to reevaluate apps each time there's a change anywhere in the ecosystem? Why is an app even considered a medical device under the FFDCA?

The lack of clarity surrounding the definition and guidelines has also exacerbated the problem by creating a cloud of uncertainty around applications and device uses that do not fit clearly into the examples the FDA provides. For example, the triggering mechanisms at the FDA for regulation generally have hinged, until recently, on the intended use of the product. In the case of apps, this can produce a strange dichotomy in which the same app that is used to track caloric intake might not be considered a medical device when used by an individual for personal diet purposes, but may be considered a medical device when recommended by a doctor to treat a specific condition (*e.g.*, obesity). And an app that is used to log blood glucose readings is considered a medical device when it interacts directly with a blood glucose meter, but not when the readings are manually entered into the app. How the FDA will apply its device marketing guidance is also unclear. For example, if a company markets its tablets to a nursing school or hospital, or includes an example of a health-related use in an advertising campaign, has it marketed the tablet for use as a medical device?

Applying the medical device tax to apps and wireless devices also threatens this market by raising consumer costs, reducing already thin margins, discouraging investment, and delaying the time to profitability. For every success story like Angry Birds there are tens of thousands of apps and app developers that never turn a profit. Additional costs in the form of lengthy approval processes at the FDA and the imposition of an excise tax could cause developers and investors to focus their mobile app efforts on areas outside the health and wellness arena. What additional costs does classification as a medical device place on app creators? Will application of the medical device excise tax cause app developers to turn away from the health and wellness category of apps, harming innovation? How long is the average app approval at the FDA as compared to unregulated apps? How would application of the tax to smartphones and tablets impact that market? Might raising costs to consumers slow the pace of device innovation?

Ultimately the wireless marketplace is an ecosystem in which changes to one element necessarily impact other parts of the ecosystem. Use of new and innovative wireless devices drives consumers to purchase apps for the devices, which in turn drives demand for improved networks and devices. If private equity is faced with the prospect of smaller margins on investment in a regulated app economy, could that impact the wireless ecosystem as a whole?