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Subcommittee on Communications and Technology

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Chairman Walden, Ranking Member Eshoo, and members of the Subcommittee, thank you for inviting me to testify before you today on behalf of the mHealth Regulatory Coalition ("MRC"). MRC members represent a diverse array of stakeholders, including medical device manufacturers, smartphone healthcare application developers, cellular handset manufacturers, network operators, and back end software services and data storage providers, as well as representatives of provider organizations, and other industry and trade associations. Our members share the common goals of protecting patient safety and promoting a balanced approach toward regulation in order to foster innovation and get new products to the market for patients.

First and foremost, we would like to thank the Committee and the Congress as a whole for the passage for the Food Drug Administration Safety and Innovation Act, and specifically Section 618, which calls upon the Department of the Health and Human Services (HHS) through the Food and Drug Administration ("FDA"), the Federal Communications Commission ("FCC") and the Office of the National Coordinator for Health Information Technology "(ONC") to develop a strategy and recommendation for Health IT, including mobile health technologies, by the end of

this year. This section further authorizes the formation of a workgroup to afford the agencies an opportunity to seek input from all relevant stakeholders as they seek to define a balanced regulatory framework that promotes innovation while ensuring patient safety.

The goal of this hearing, as I understand it, is to identify changes in federal regulatory policy needed to help ensure that patients have access to important, innovation tools for healthcare in the form of mobile medical apps. In my remarks today, I want to focus on the need for clarity around the scope of federal regulation when it comes to which mobile medical apps are subject to regulation, as well as the need for balanced FDA enforcement of those regulations.

I. FDA NEEDS TO CLARIFY THE RULES FOR MOBILE MEDICAL APPS

Mobile health technologies are quickly changing the way we manage our health, and the way healthcare is delivered. The development and adoption of these technologies has been so swift that thousands of mobile health apps are already on the market, and include everything from calorie counters to more complex apps that perform diagnostic or critical clinical functions. Indeed, many simply replace traditional medical devices, for example allowing doctors to view ultrasound images.

Many mobile apps, however, present essentially no risk to the patient, and therefore should not be regulated. For example, apps allow users to actively monitor and trend their exercise activity on a daily basis, as a way to maintain or improve their overall condition. Apps also enable users to monitor their sleeping cycle, helping users understand their sleeping patterns. These types of

apps allow consumers to be much more actively engaged in managing their health and wellness than even just a few years ago. Regulation should be commensurate to the risk the apps pose to the patients. Overregulating these apps negatively impacts manufacturers and developers who have to comply with requirements that are disproportionate to the very low risk level of these products.

Other mobile apps such as apps that function as an electrocardiogram device, or apps intended to diagnose skin cancer present a risk to the patient, and therefore ought to be regulated.

We appreciate FDA's efforts in preparing the Draft Mobile Medical Apps Guidance in July 2011. The guidance was helpful in explaining the scope of federal regulation.

Like others, we filed comments on that draft guidance and have met with FDA to offer suggestions on ways to make the guidance even more useful. The agency seems very open to improving the document to sharpen the line between the regulated and unregulated worlds.

We have been discussing with FDA the need to address additional issues that go beyond the issues specific and limited to mobile apps, including products used for wellness, rather than the treatment of disease, and the scope of what medical device accessories get regulated. We believe FDA understands our needs for further guidance and is preparing to address them.

Now we need final guidance on mobile medical apps to assure innovative products get to market so that healthcare professionals, patients and consumers all have access to needed tools to

manage their health. A final guidance would provide the regulatory predictability necessary for investors to support, and manufacturers to develop, important new products.

II. FDA NEEDS TO TAKE BALANCED ENFORCEMENT ACTION IN ORDER TO ENSURE PATIENT SAFETY

At least some app developers already follow FDA's regulation, and implement appropriate quality systems, registration, adverse event reporting processes in order to ensure compliance with the regulatory requirements. Very recently, I saw an innovative app that allows you to do urinalysis with your iPhone. The company website presents the app as able to help patients understand and manage diseases like diabetes, urinary tract infections and pre-eclampsia, a high blood pressure pregnancy complication.

You do the test mostly the old-fashioned way of collecting urine in a cup and then inserting a test strip. All the app does is objectively read the results using the camera on the phone. According to a company press release, the plan is to make the app available from the App Store for 0.99 cents and a kit consisting of a color mat to calibrate the app plus 5 sample urine dipsticks for $19.99 through the company's website.

But here is the problem--this app falls within longstanding FDA regulation for urinalysis. It seems to me that the company must be aware of the potential for FDA regulation, because on its home page, at the very bottom, after extolling the clinical uses of its product to monitor disease, the company tries to simply disclaim FDA medical device status.

The problem is the company's website is also full of statements suggesting that people use their kit in lieu on the FDA regulated instruments used for urinalysis. It states the smart phone app "can help you analyse, interpret and trend your urinalysis data to help you understand and manage diseases like diabetes and its, urinary tract infections and pre-eclampsia."

Further, it couldn't be any clearer that instruments used for urinalysis are indeed medical devices, and in particular class I. The device classification regulation, 21 CFR Sec. 862.2900 Automated urinalysis system, clearly establishes that FDA regulates urinalysis systems:

"An automated urinalysis system is a device intended to measure certain of the physical properties and chemical constituents of urine by procedures that duplicate manual urinalysis systems. This device is used in conjunction with certain materials to measure a variety of urinary analytes."

So here's the problem. There are all sorts of companies out there trying to do this kind of stuff right. They follow the rules, and that costs money. In the case of the class I device that means using a quality system to make sure the device actually does what it's supposed to do. It would appear that this company wishes to avoid using the quality system, registering, reporting adverse events and doing all the other things that bona fide medical device companies do.

This app will sell for about 20 bucks. Companies that employ a quality system will probably have to charge more than that to make a decent return. How can a company lawfully compete with those that are willing to try to avoid FDA regulation with a simple disclaimer?

Yes, FDA has not published its final guidance on mobile medical apps. But it certainly doesn't need to publish that guidance to enforce the statute and a 26-year old regulation that requires FDA compliance for a urinalysis test.

On the one hand, it might seem like I am picking on this company. But frankly, it is simply typical of what we are seeing day in and day out show up in the various app stores.

At the end of the day, these rules are there for a reason. People get hurt when medical devices do not possess the quality they need to reliably perform their functions. If this test, for example, under-reports or over-reports an analyte, a person might be lulled into believing they do not have a medical condition when in fact they do. For diseases like diabetes, that can have deadly consequences. Of course, if FDA regulation is no longer necessary for urinalysis, I am sure everyone in that business would appreciate FDA rescinding that regulation.

For a regulated industry, one of the worst things that can happen is a law on the books that is not enforced. That puts every ethical company in a dilemma -- do you sink to the level of your competition that seems to be getting away with flouting the laws, or do you stick to your ethical guns.

Since this app was just announced, obviously FDA has not had time to respond. It will be interesting to see what they do. To enforce these laws, FDA has the burden to develop evidence of a violation, which may be especially complicated and expensive when the developers are

located overseas. FDA is going to need to develop an enforcement process that is fair, efficient and effective. On the one hand, I would hate to have that responsibility myself, because fairness costs money and that is in short supply. But on the other hand, I hate to see these ethical companies struggling mightily while trying to do the right thing. There must be a better way.

III. WE FAVOR WORKING WITH FDA

In our opinion, it would not make sense to try to separate out apps from other medical devices that have the same functionality. Take the urinalysis app for example. FDA has long regulated instruments used for that test. It would make no sense for an app used for urinalysis to be regulated under different standards. Creating artificial distinctions between a traditional device and a mobile platform will result in regulatory duplication and confusion.

Nor does it make sense to create a new agency, or move responsibility to another existing agency. Stakeholders are looking for more certainty and clarity from the existing federal government agencies, and a whole new regulatory scheme would frankly be counterproductive in that regard.

FDA has the longstanding expertise to protect the public health and to balance regulation with permitting innovation. In "mobile health" there is the term "mobile" but there is also "health," and FDA has been successfully protecting public health through regulating devices for more than 40 years.

We certainly agree we are entering a novel phase in health product development. As such, the MRC believes that an office within FDA dedicated to mobile and wireless health technologies could focus on balancing public health interests and safety, and innovation.

This obviously does not mean we favor more regulation, but that we need a clearer and more transparent regulatory framework.

FDA should coordinate work with other agencies such as FCC, ONC, and the Federal Trade Commission ("FTC") to build a clearer and more predictable regulatory environment for these medical devices. Those agencies all have a certain expertise regarding wireless health technology and the healthcare sector will benefit from these agencies sharing their expertise with FDA.

Moreover, FDA already has sufficient statutory powers such as requiring registration and adverse events reporting, just to name a few, that will protect patient safety. It is unclear how a new agency would enhance patient safety with regard to these mobile apps over what FDA does already. Nor is it clear how another agency would do any better at allowing innovation to flourish.

We fear the added complexity and jurisdictional confusion likely following the creation of a new agency will cause the U.S. patients to see novel medical devices well after the rest of the world.

FDA has been actively working collaboratively with the MRC and industry more generally to improve the regulatory landscape. The existing statutory framework gives FDA the flexibility it needs to further adapt the regulatory scheme to this novel form of technology.

An additional challenge the industry is facing is the excise tax on medical devices. The Congress imposed the excise tax on medical devices of all stripes. We believe the tax will negatively impact innovation and development of all medical devices, including mobile devices. One other benefit of the FDA's drive to adopt a clearer, more limited definition of mobile medical apps is to reduce the number of apps subject to the 2.3% excise tax on medical devices. Based on FDA's current thinking reflected in the draft guidance, it would appear that FDA is trying to exclude some apps from the definition of a medical device that might otherwise fall within that statutory framework. FDA can only go so far in reducing the scope of the excise tax, but ultimately, the Congress will need to take action.

CONCLUSION

Mobile technologies are changing the fundamental behaviors of patients and consumers to make them more engaged in their health. Mobile technologies are also changing the way healthcare providers offer care to their patients. This new model of healthcare has its challenges - innovative developers are creating more sophisticated products, and the regulatory framework will need to be flexible in order to leave room for future developments. FDA has the resources and expertise to address these challenges.

The MRC looks forward to continue working with FDA, other regulatory agencies, and Congress to find the appropriate and balanced regulatory framework governing mobile technologies. This will ensure that patients have access to the best available resources to manage their health, and manufacturers and developers are able to bring innovative products to market.

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I. FDA NEEDS TO CLARIFY THE RULES FOR MOBILE MEDICAL APPS

Many mobile apps present essentially no risk to patients including, for example, apps allow users to track their exercise activity on a daily basis, as a way to maintain or improve their overall health. FDA should clearly distinguish between disease-related apps that merit regulation and wellness related apps that do not. FDA needs to be careful not to overregulate harmless apps that offer the opportunity for enhanced patient engagement, as well as accessories that offer simple connectivity to sensors and the like.

II. FDA NEEDS TO TAKE BALANCED ENFORCEMENT ACTION TO ENSURE PATIENT SAFETY

Unless FDA deregulates a category of devices, mobile apps should comply with the existing regulatory requirements, and FDA should implement an enforcement process that is fair, efficient and effective.

III. WE FAVOR WORKING WITH FDA

Creating a new agency, or moving responsibility to another exiting agency, would create confusion that would be counterproductive, stifling innovation, not encouraging it. FDA has the longstanding expertise to protect public health interests and innovation.