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HEALTH INFORMATION TECHNOLOGIES: HARNESSING WIRELESS INNOVATION

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMUNICATIONS AND TECHNOLOGY

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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HEALTH INFORMATION TECHNOLOGIES: HARNESSING WIRELESS INNOVATION

TUESDAY, MARCH 19, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMUNICATIONS AND TECHNOLOGY,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:37 a.m., in room 2123 of the Rayburn House Office Building, Hon. Greg Walden (chairman of the subcommittee) presiding.

Present: Representatives Walden, Latta, Terry, Shimkus, Terry, Blackburn, Scalise, Lance, Guthrie, Gardner, Kinzinger, Long, Ellmers, Matsui, Luján and Waxman (ex officio).

Staff present: Ray Baum, Senior Policy Advisor/Director of Coalitions; Matt Bravo, Professional Staff Member; Andy Duberstein, Deputy Press Secretary; Neil Fried, Chief Counsel, Communications and Technology; Debbee Hancock, Press Secretary; Sydne Harwick, Staff Assistant; Brittany Havens, Staff Assistant; Sean Hayes, Counsel, Oversight and Investigations; Robert Horne, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; David Redl, Counsel, Telecom; Charlotte Savercool, Executive Assistant, Legislative Clerk; Roger Sherman, Democratic Chief Counsel; Shawn Chang, Democratic Senior Counsel; Patrick Donovan, FCC Detailee; Margaret McCarthy; and Kara van Stralen, Democratic Special Assistant.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. We are going to call to order the Subcommittee on Communications and Technology for our hearing on "Health Information Technology: Harnessing Wireless Innovation."

I want to welcome our witnesses and our participants in today's hearing. It is not every day that the Subcommittee on Communications and Technology holds a hearing addressing FDA regulation, but the fact that we are having such a hearing is a testament to the breadth of innovation using wireless smartphones and tablets, and all that that is bringing to nearly every aspect of our lives. There are literally thousands of apps in the various smartphone and tablet app stores in the health and wellness categories, actually tens of thousands, everything from simple calorie counters to complex analytical tools. The more than 300 million wireless devices we depend on every day are revolutionizing health and wellness.

If I stopped here, this hearing could be about the success of bringing the innovation and investment of the wireless ecosystem to bear on the ever more costly health care system. And make no mistake about it, that could still be the outcome. But the specter of costly and time-consuming regulation, to say nothing of a 2.3 percent excise tax, looms large over this industry. We have heard from investors, wireless device manufacturers, and application developers that are concerned about the uncertainty of a FDA regulatory regime, that may or may not apply to them, and the possibility of an additional excise tax that cuts into already thin margins.

The collision of worlds in the mobile health, or mHealth, is a study in contrasts. The app economy is characterized by low barriers to entry, quick time to market, and the ability to adapt to quickly changing user needs. Medical devices, on the other hand, face a long and costly premarket approval process at the FDA. Now, we all want to make sure that patient safety is taken care of first, but why would we treat mobile applications the same as a dialysis machine? These are the kinds of questions we need to get answers to about where that sweet spot is and that fine.

The answer may be that the wireless economy represents a tempting target for the 2.3 percent excise tax that the President's health care law placed on medical devices. While the IRS and the FDA have provided some draft guidance on how they will apply the medical device definition and the medical device tax, their analysis is not a poster child of clarity and it leaves large parts of the economy wondering if they will be on the hook for what is essentially a tax on innovation, and we certainly are hearing that from our witnesses and others.

The FCC and the Obama administration have both joined the wireless industry in trumpeting the virtuous cycle of innovation and investment in mobile technologies: investment in wireless networks and devices creates opportunities for app developers to create new and innovative uses for wireless services, which in turn spurs further investment in networks and devices. MHealth is part of this virtuous cycle that is driving faster speeds, lowering costs, spurring innovation and creating patient benefits. Given the interconnected nature, we should be aware that an impact on one segment of this industry has the potential to slow the entire cycle.

The overbroad application of FDA regulation and the health care law's medical device tax are not, as some have suggested, outside the realm of possibility. In a 2012 report by the Institute of Medicine, one expert author suggested that all health IT products should be treated as class III medical devices, which receive the highest level of regulatory scrutiny and therefore should be subject to the tax. Now, that is just one person's opinion but it is in the prestigious Institute of Medicine report.

Luckily, while these are not hypothetical concerns, they are also by no means foregone conclusions, which is why we are having a hearing today. Wireless has and can continue to be a system that brings the mobile revolution to our Nation's health and wellness sector, but we must ensure that as we bring the innovation of the wireless economy to health and wellness that we not place unneces-

sary hurdles in the way of the developers and investors that are fueling mHealth.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

It's not every day that the Subcommittee on Communications and Technology holds a hearing addressing FDA regulation. The fact that we are having such a hearing is a testament to the breadth of innovative uses wireless smartphones and tablets are bringing to nearly every aspect of our lives. There are literally thousands of apps in the various smartphone and tablet app stores in the health and wellness categories—everything from simple calorie counters to complex analytical tools. The more than 300 million wireless devices we depend on every day are revolutionizing health and wellness.

If I stopped here, this hearing could be about the success of bringing the innovation and investment of the wireless ecosystem to bear on the ever more costly health care system. And make no mistake, that could still be the outcome. But the specter of costly and time-consuming regulation—to say nothing of a 2.3 percent excise tax—looms large over this industry. Investors, wireless device manufacturers and application developers all face the uncertainty of an FDA regulatory regime that may or may not apply to them and the possibility of an additional excise tax that cuts into already thin margins.

The collision of worlds in the mobile health—or mHealth—market is a study in contrasts. The app economy is characterized by low barriers to entry, quick time to market, and the ability to adapt to quickly changing user needs. Medical devices, on the other hand, face a long and costly pre-market approval process at the FDA. We all want to ensure patient safety, but why would we treat mobile applications the same as a dialysis machine?

The answer may be that the wireless economy represents a tempting target for the 2.3 percent excise tax that the president's health care law placed on medical devices. While the IRS and the FDA have provided some draft guidance on how they will apply the medical device definition and the medical device tax, their analysis is not a poster child of clarity and leaves large parts of the economy wondering if they will be on the hook for what is essentially a tax on innovation.

The FCC and the Obama administration have both joined the wireless industry in trumpeting the "virtuous cycle" of innovation and investment in mobile technologies: investment in wireless networks and devices creates opportunities for app developers to create new and innovative uses for wireless services, which in turn spurs further investment in networks and devices. mHealth is part of this virtuous cycle that is driving faster speeds, lowering costs, spurring innovation and creating patient benefits. Given their interconnected nature, we should be aware that an impact on one segment has the potential to slow the entire cycle.

The overbroad application of FDA regulation and the Obamacare medical device tax are not, as some have suggested, outside the realm of possibility. In a 2012 report by the Institute of Medicine, one expert author suggested that all health IT products should be treated as Class III medical devices, which receive the highest level of regulatory scrutiny and could be subject to the tax.

Luckily, while these are not hypothetical concerns, they are also by no means foregone conclusions. Wireless has and can continue to bring the mobile revolution to our nation's health and wellness sector. But we must ensure that as we bring the innovation of the wireless economy to health and wellness that we not place unnecessary hurdles in the way of the developers and investors that are fueling mHealth.

# # #

Mr. WALDEN. So I want to thank our witnesses for being here, and I would now recognize the vice chair of the subcommittee, Mr. Latta.

OPENING STATEMENT OF HON. ROBERT E. LATTA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. LATTA. I thank the chairman for yielding, and I also thank our distinguished panel for testifying today.

The mobile application industry is a modern American economic success story. Just this year alone, mobile apps were projected to be a $25 billion industry. No one, at least no one in Washington, could have predicted the incredible growth and the extraordinary uses for these apps, particularly in the mobile health world. The health and wellness opportunities for mobile apps have great potential for our health care delivery system.

I am concerned that the regulatory uncertainty coming from the FDA will discourage innovation and investment in mobile apps and that Americans will lose out on potentially lifesaving technology. This climate of regulatory uncertainty could also have adverse effects on the overall wireless ecosystem, which continues to drive economic growth in this country. Furthermore, I believe the medical device tax will be extremely detrimental to our economy. The potential application of the medical device tax to mobile apps will only further deter investment and development in the industry.

Mr. Chairman, I look forward to our testimony today and our witnesses, and I yield back.

Mr. WALDEN. I thank the gentleman for his comments. We now recognize the ranking member of the subcommittee today, Ms. Matsui of California.

OPENING STATEMENT OF HON. DORIS O. MATSUI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. MATSUI. Thank you, Mr. Chairman, and I would like to thank the witnesses for being here today.

Technology is changing health care as we know it. A smart spectrum policy that is driving wireless revolution is also transforming our health care sector. We are seeing the benefits of health care providers utilizing WiFi and high-quality, unlicensed spectrum to spur the development of next-generation patient care monitoring applications that could transmit patients' vital health data to their doctor or hospital. Whether it is monitoring diabetes, glucose levels, tracking blood pressure or providing real-time hydration levels, the list goes on and on.

We are seeing cloud technologies transforming health IT through the creation of select community health clouds forming in regions across the country, enabling hospitals to better treat patients while ensuring HIPAA-compliant transfers of secure medical information. It will only become more important as the mobile app economy continues to drive consumer demand for smartphones and tablets.

The fact is, the ever-evolving app economy is helping to transform the health care sector, integrating science, medicine and technology to provide individuals with real-time access to vital health information, much of which was previously unavailable outside of a hospital or a doctor's office. House calls are becoming a thing of the past. Virtual checkups are becoming the new digital-age house call. Doctors are using iPads to issue prescriptions and diagnose patients. Smartphones are creating new paths of virtual interactions between doctors and patients. Texting your doctor has become a more common practice as more Americans, particularly young people, are finding greater comfort and accessibility in communicating electronically with their doctors.

The Affordable Care Act also has allowed the health care industry to become more innovative using technology. I believe we will see a growing ecosystem of health IT innovation now that the Affordable Care Act is here to stay.

My home State of California has been a pioneer in ACA implementation. Our exchange, Covered California, has already begun using mobile devices to launch online features so consumers can estimate their monthly premiums and compare health care options. Physicians and hospitals in my district of Sacramento are using the exchange to improve their health IT capabilities. For example, the Live Health Online Initiative already permits doctors to care for patients through a secure online visit using laptop Web cams and ultimately through video-enabled tablets and smartphones regardless of where the doctor and patient are located.

With more than 50 million additional Americans expected to obtain health insurance this year due to the law, an efficient and effective health IT network is even more imperative. In order to realize the full potential of innovative health technologies, the regulatory environment must keep pace with rapidly changing technology.

In 2011, the FDA released draft guidance to provide rules of the road for medical app developers clarifying which medical apps would require its attention and which would not. I believe the draft guidance attempts to strike the appropriate balance between enabling innovative medical apps and ensuring patient safety, and I urge the agency to move forward expeditiously. Now, moving forward, I believe the FDA must be mindful of the fact that technology continues to evolve at a rapid pace and the need for them to provide clarity to the marketplace.

Another way to foster greater innovation in the health sector is through creating a workable federal definition for telehealth services. I am developing legislation to do just that. I believe having certainty here would spur innovation and research in the private sector and in programs like Medicare. We must continue to chart a technology-friendly course that promotes better patient care for all Americans.

And Mr. Chairman, I would like to ask unanimous consent to enter into the record the following three items: a report from the Center on Budget and Policy Priorities on the medical device excise tax, a letter from SDI Diagnostics, a small medical device manufacturer, regarding FDA regulatory oversight of the medical device market, a study published in the peer-review journal, JAMA Dermatology, identifying risks and depending on smartphone apps for diagnosis.

Mr. WALDEN. Without objection.

[The information appears at the conclusion of the hearing.]

Ms. MATSUI. Thank you. And I look forward to working with my colleagues to continue to promote health IT. I look forward to hearing from our witnesses today. Thank you. I yield back.

Mr. WALDEN. The gentlelady yields back the balance of her time. The Chair now recognizes the gentlewoman from Tennessee, Ms. Blackburn, for 5 minutes.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman, and I want to thank our witnesses for being here today. We are deeply appreciative that you all are here, and we are appreciative of what you are doing in the industry and in this space in which you are working.

You know, I was stunned in doing some work on this and talking with some of the innovators in Nashville. Five hundred thousand jobs are attributed to your sector, and you are one of the few areas where there has actually been some job growth since the misery that was there in 2008 and 2009 and when you look at mHealth, you are talking about a $27 billion industry within the next couple of years, so we thank you for this. Not only is it productive and not only is there opportunity to profit from your innovations, there is the opportunity to encourage R&D and to provide better outcomes and better wellness and maintenance of effort in health to expand the use of telemedicine and mobile health. So hearing from you where you think we need to travel with this is going to be helpful and it is going to be instructive as we look at this entire space for health care informatics and the opportunities that exist there.

I think that we are all concerned about what would help with the medical device tax being applied to this. Of course, it is muddy as muddy water when you are trying to figure out where the FDA is actually looking to go. I know there are about 300,000 apps that are available, or 50,000 apps, I think it is, and 300,000 downloads, that are through the Apple app store. So people like the convenience of this, and we want to do what we can to make certain that it remains accessible and affordable and is not levied with a tax that is going to end up being a hindrance.

So we appreciate your ability to make way for us in your schedules to be here, and Mr. Chairman, I yield back.

Mr. SHIMKUS. Would the gentlelady yield?

Mrs. BLACKBURN. Yes.

Mr. SHIMKUS. Thank you. I would just like to weigh in.

The medical device tax is a very pernicious tax by itself. One of the problems I have is the gross nature, taxing just gross versus obviously net after costs and expenses. I mean, where else but in Washington can you dream up such a bad tax provision? But as was stated earlier by my colleagues, what is critical for you all in your testimony today is to help us sort through your concerns, your risks, your level of being able to capitalize or not, and then where is this line? I mean, it is very vague, and so when there is uncertainty, there is higher risk. When there is higher risk, there is more cost of capital and it could be damaging to any business model that you would address.

So we really appreciate you being here. We are probably going to ask some pretty specific questions, especially for those of you who are in that space innovating and creating jobs. We thank you for coming.

And with that, I yield back to my colleague.

Mrs. BLACKBURN. I thank the gentleman for yielding back. Did Mr. Lance, one of my other colleagues, want any of the remaining time? OK. Mr. Chairman, I yield back.

Mr. WALDEN. The gentlelady yields back. The Chair now recognizes the former chairman of the committee, the gentleman from California, Mr. Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman.

This is a hearing to look at mobile medical applications, and this is the first of three hearings on this subject this week. The high-speed wireless broadband access is creating new opportunities in consumer services in nearly every segment of our economy including health care. Mobile medical applications hold incredible promise for patients and health care providers, potentially reducing costs, improving health care delivery and saving lives. That is why we made a significant investment in medical communications, because this is a really important area. We all want to see this exciting innovation continue.

At the same time, we have to be cognizant of the need to protect patient safety. That is why the Food and Drug Administration has released a draft guidance regarding mobile medical applications. So their guidance says if it is a dietary tracking app or a reminder service for medical appointments, they certainly don't need FDA approval for that. But an app that purports to diagnose cancer? Well there ought to be some review and have regulatory scrutiny.

Let me give an example. A group of dermatologists recently published a study of four apps that claim to be able to diagnose melanomas. Well, the dermatologists found that three of the four incorrectly classified 30 percent or more of melanomas as benign when they were actually malignant. Well, we can't tell the American people buyer beware when potentially life-and-death care decisions are at stake.

My Republican colleagues say that FDA is hoping to subject smartphones and tablets to the medical device tax. Well, that doesn't really hold up to scrutiny. I think they have their facts wrong. Allegations that ordinary smartphones and tablets could be subject to added red tape or new taxes under Obamacare are absolute myths. In fact, FDA's draft guidance specifically states that the agency does not intend to regulate distributors of mobile medical apps like the iTunes store or the makers of smartphones or tablets like Apple. Smartphones and tablets are not listed with FDA as medical devices, so they are completely outside the scope of the medical device tax.

Furthermore, it is my understanding that most mobile medical apps would also be exempt from the medical device tax because of the IRS "retail exemption." This provision says that devices are exempt from the tax if they are regularly available for purchase and use by ordinary consumers, including over the Internet, and if they are not primarily intended for use in a medical institution or by a medical professional.

To go back to the case of the dermatologists, those apps would not be subject to the medical device tax, but they would be subject to FDA scrutiny to be sure that the patients are not being harmed.

There are legitimate concerns that we ought to examine, instead of using today's hearing to invent new fallacies to attack the Affordable Care Act. We have already had a number of hearings this year on a tax on Obamacare. Well, my Republican colleagues didn't like it. They all voted against it. They hoped that the Supreme Court would have thrown it out. The Supreme Court upheld it. They hoped the election would replace the President so they could have repealed it. The electorate voted for President Obama. This is all going to go into effect at the end of this year and it will be fully in place by January of 2014. We have already seen a lot of improvements in health care by virtue of the Affordable Care Act.

The Affordable Care Act is going to serve a very important purpose. It is not going to require mobile apps to be regulated or to be taxed. FDA released the draft guidance for mobile medical apps, and we should commend them for this action. Both industry and consumers would benefit from the clarity of final guidance. I hope that FDA is working expeditiously toward that goal.

You have to make distinctions. You don't blur it all to serve the political point of view to attack the Affordable Care Act. We have got to look at the law, draw the distinctions, and make sure that the public is protected while innovation is still encouraged. And I think that we are looking to a lot of very important innovation and we want to see that come into action.

Thank you, Mr. Chairman. Yield back.

Mr. WALDEN. The gentleman yields back the balance of his time. The Chair would ask unanimous consent to enter into the record a letter from the CTIA CEO and former Representative Steve Largent, raising concerns of the wireless industry, and a letter from Keith Brophy, CEO of Ideomed from Grand Rapids, Michigan. It is a medical app device developer, and also has concerns about the uncertainty, which is why we are having this hearing today. Without objection.

[The information appears at the conclusion of the hearing.]

Mr. WAXMAN. Mr. Chairman, I certainly have no objections. I just wanted to point out to the witnesses that there is another hearing going on so I will be back and forth, and I apologize for not being here.

Mr. WALDEN. No problem. Feel free to take the full time in the other hearing if you like. No, I am just—we actually have a little fun together here, so it is fine. Thank you. And we have got other members that are going to be coming and going. It is a good reminder, because there is an Energy and Power Subcommittee meeting as well.

So with that, we welcome our witnesses, and I know Dr. Dagi's plane was a little delayed getting out of Boston, apparently a little snow up there, but he has arrived, and he will be joining us momentarily, but we will go ahead, and again, we thank you all for being here. I have read through your testimony. It is most helpful in our efforts to shine some light on this issue.

So we are going to start with Mr. Robert Jarrin, Senior Director of Government Affairs for Qualcomm. Mr. Jarrin, we are delighted

to have you here this morning and look forward to your testimony, sir.

STATEMENTS OF ROBERT JARRIN, SENIOR DIRECTOR, GOVERNMENT AFFAIRS, QUALCOMM; BRADLEY MERRILL THOMPSON, GENERAL COUNSEL, MHEALTH REGULATORY COALITION; BEN CHODOR, CHIEF EXECUTIVE OFFICER, HAPPTIQUE; JONATHAN SPALTER, CHAIRMAN, MOBILE FUTURE; T. FORCHT DAGI, MD, MPH, DMEDSC, PARTNER, HLM VENTURE PARTNERS; AND DR. GEORGE FORD, CHIEF ECONOMIST, PHOENIX CENTER FOR ADVANCED LEGAL AND ECONOMIC PUBLIC POLICY STUDIES

STATEMENT OF ROBERT JARRIN

Mr. JARRIN. Thank you. Good morning, Chairman Walden, Ranking Member Matsui, and members of the subcommittee. First and foremost, I would like to thank you for having me participate as a witness in today's hearing. I have worked in various capacities over the span of two decades, at times preparing others to sit before you. Today, I am truly honored to be the one sitting here.

I will begin by starting with mobile technology. It is the largest platform in the history of mankind. The population of the world is approximately 7 billion people, and there are nearly 6.6 billion mobile connections. In the United States alone, there are 323 million mobile subscriptions for a population of 315 million people.

Consumer research suggests that two-thirds of people sleep with their mobile device next to them, and one-third interact with their device before they even get out of bed. Those with a mobile phone tend to check it about 150 times per day, roughly about once every 6½ minutes.

Mobile devices are powerful and sophisticated. Today, a typical smartphone has more computing power than Apollo XI did when it landed on the moon. Computing devices are now built around mobile experiences with always-on connectivity, location awareness, augmented reality and powerful processing. Soon there will come a day when virtually everyone and everything in our world will be connected through a ubiquitous wireless technology.

Let me also share some startling statistics of a different nature yet related, chronic disease in America. According to the CDC, about out of every two adults in the United States has at least one chronic illness. Seven out of 10 deaths among Americans are due to chronic disease. Obesity, for example, affects one in three adults as well as one in three children who are either overweight or obese. Although chronic diseases are among the most common, they are also the costliest of all health problems. The CDC states they are also among the most preventable.

This presents an interesting opportunity. Many Americans are sick yet more have access to a personal, powerful, mobile computing device. Hence, it was only a matter of time before the health care technology innovators would take notice of the potential to personalize a mobile platform and facilitate the delivery of affordable health care. Nowhere is this growth more obvious than in the mobile health applications landscape. Quite simply, the growth of mobile health apps has skyrocketed. Approximately 27,000 unique

health apps are available. Over 7,000 health apps are specifically intended for use by students and health care professionals. Five hundred new mobile health apps launch every month. Interestingly, however, a survey conducted by MobiHealthNews shows that to date, FDA has only cleared fewer than 80 mobile medical apps through its 510(k) process. They further estimate that as little as 5 percent of all health-related apps could potentially be considered medical, and possibly subject to FDA regulation.

On July 21, 2011, the FDA issued a draft guidance on mobile medical applications. The agency went on to receive more than 700 pages of comments from over 100 interested stakeholders. They also held a 2-day workshop and engaged the public at large in briefings and events. FDA officials have expressed their views that the final MMA guidance would be deregulatory. In fact, it would delineate how the agency would exercise enforcement discretion to not proactively regulate many low-level-risk mobile medical apps. However, it is now March 19, 2013, and unfortunately, FDA has yet to release a final MMA guidance document. Qualcomm and others are concerned that the failure to release final guidance has created uncertainty among countless budding entrepreneurs and large corporations that fear the prospect of facing FDA regulation. Qualcomm offers the following recommendations for consideration.

First, FDA should promptly finalize the MMA draft guidance document. Second, the final guidance should offer specific examples of low-risk regulated mobile medical devices that FDA, through enforcement discretion, would not regulate. Third, there should be clarity on intended use in light of ambiguous and general health claims and terms. Fourth, for apps that do not warrant listing as low-risk class I medical devices—rather, that do warrant listing as low-risk class I medical devices, the agency should consider how it will assess exemption from Good Manufacturing Practices. Fifth, accessories should be classified according to their individual level of risk and not according to the device with the highest classification level. Sixth, FDA should continue its commitment to consistency, predictability and transparency by coordinating internal and external efforts through a single dedicated office within FDA the agency. Seventh and lastly, the agency would benefit to utilize external facing resources such as CDRH Learn, Device Advice and the Division of Small Manufacturers, International and Consumer Assistance to work with app developers and their communities.

FDA has a proven and successful policy, regulatory, and legal framework, that has been formed from over 100 years of innovation, science and learning, a framework that puts the patient first and ensures the safety and effectiveness of all health and medical products in the U.S. marketplace. We recommend that FDA be given the fullest support it needs to continue doing its fine work while allowing innovation to drive the U.S. healthcare system.

In closing, I would like to say a few words about Qualcomm. Qualcomm, Inc., is the leading supplier of wireless chips, having shipped worldwide well over 11 billion chips to date. Qualcomm is the leading developer of 3G, 4G and other next-generation wireless technologies. In addition, Qualcomm has a wholly owned medical device subsidiary focused on producing medical device data systems. We are committed to the health care space through various

public and private efforts as further described in my written testimony and on Qualcomm's Web site.

Thank you, and I look forward to answering your questions.

[The prepared statement of Mr. Jarrin follows:]

Statement of
Robert Jarrin
Senior Director, Government Affairs
Qualcomm Incorporated

Before the
U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Communications & Technology

Hearing on "Health Information Technologies: Harnessing Wireless Innovation"

March 19, 2013

Summary

Mobile technology is the largest platform in history. Mobile touches every aspect of our society and is at the center of our lives. Mobile devices are powerful and sophisticated – a typical smartphone has more computing power than Apollo 11 did when it landed on the moon. Soon, there will come a day when virtually everyone and everything in our world will be connected through ubiquitous wireless technologies.

Startling statistics on a different, but related topic are those of chronic disease: About one out of every two adults in the U.S. has at least one chronic illness and seven out of ten deaths among Americans are due to chronic disease. This presents an interesting opportunity: Many Americans are sick, yet even more have access to a personal, powerful, mobile computing device.

Hence it was only a matter of time before healthcare technology innovators would take notice of the potential to personalize and take advantage of the mobile platform to facilitate and improve the delivery of affordable healthcare. Nowhere is this growth more obvious than in the mobile health applications landscape, which has, quite simply, skyrocketed.

On July 21, 2011, the FDA issued a Draft Guidance on Mobile Medical Applications (MMA). Officials from FDA have since expressed their views that the final MMA guidance document would be de-regulatory. It is now March 19, 2013, and unfortunately FDA has yet to release a final MMA guidance document.

Although FDA has a proven and successful policy, regulatory and legal framework, Qualcomm and others are concerned that the failure to release final MMA guidance has created uncertainty among countless budding entrepreneurs and large corporations that fear the prospect of facing FDA regulation.

Qualcomm offers the following recommendations for consideration:

1. FDA should promptly finalize the MMA draft guidance document.
2. The final MMA guidance should offer specific examples of low-risk, regulated mobile medical devices that FDA, through enforcement discretion, would not regulate.
3. There should be clarity on "Intended Use" in light of ambiguous and general health claims and terms that are popularly used by the health IT industries.
4. For those apps that warrant listing as low-risk Class I devices, the Agency should consider how it will assess exemption from Good Manufacturing Practices (GMP).
5. Accessories should be classified according to their individual level of risk and not according to the device with the highest classification level.
6. FDA should continue its commitment to consistency, predictability and transparency by coordinating internal and external efforts through a single dedicated office of mobile health within FDA.
7. The agency would benefit to utilize external facing resources such "CDRH Learn", "Device Advice" and the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) to work with app developers and their communities.

Good morning, Chairman Walden, Ranking Member Eshoo, and Members of the Subcommittee. It is an honor for me to testify.

Mobile technology is the largest platform in history. The population of the world is approximately 7 billion people, and there are nearly 6.6 billion mobile connections — 3.2 billion of which are unique users.[1] In the United States alone, there are 323 million mobile subscriptions for a population of 315.5 million.

Mobile touches every aspect of our society and is at the center of our lives. Whether for reasons of health, safety, education, commerce, art, entertainment or sports, at any given moment, all around the world, billions of people are utilizing a mobile device to enrich their lives. Those with a mobile phone tend to check it about 150 times per day — an average of once every six-and-a-half minutes.[2] Consumer research suggests that two-thirds of people sleep with their mobile device next to their bed, and more than one-third of U.S. smartphone users interact with their device before they even get out of bed.[3]

Mobile devices are powerful and sophisticated. A typical smartphone has more computing power than Apollo 11 did when it landed on the moon.[4] Mobile devices have changed how people access the Internet, making it also the most pervasive platform for computing. Today's

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[1] *See* Wireless Intelligence, (Jan. 2013); *see also* U.S. Census Bureau Population Clock http://www.census.gov/main/www/popclock.html.

[2] *See* Tomi T. Ahonen Research, (Feb. 2011).

[3] *See From Apps To Everyday Situations, An Ericsson Consumer Insight Summary*, Ericsson.com http://www.ericsson.com/res/docs/2011/silicon_valley_brochure_letter.pdf, (Consumers were found to check, first thing each morning, apps for social networking, news, weather, and classified ads sites); *see also* 66% of all respondents sleep with their mobile device right next to their bed, TIME Mobility Poll, in cooperation with Qualcomm, (Aug. 2012).

[4] *See Id.*

computing devices are built around mobile experiences, with a focus of always-on connectivity, location awareness, augmented reality and powerful processing. Soon, there will come a day when virtually everyone and everything in our world will be connected through ubiquitous wireless technologies.

Let me also share some startling statistics on a different, but related topic — chronic disease in America. According to the Centers for Disease Control, about one out of every two adults in the U.S. has at least one chronic illness.[5] Seven out of ten deaths among Americans are due to chronic disease.[6] Obesity alone affects one in three adults, and one in three children are either overweight or obese.[7] Although chronic diseases are among the most common and costly health problems, the CDC states they are among the most preventable.

This presents an interesting opportunity: Many Americans are sick, yet even more have access to a personal, powerful, mobile computing device. Hence it was only a matter of time before healthcare technology innovators would take notice of the potential to personalize and take advantage of the mobile platform to facilitate and improve the delivery of affordable healthcare. From the smartphones used by care providers to communicate with patients, to the field laptops utilized by emergency management technicians, to devices like tablet computers that enable doctors to download diagnostic data or remotely monitor patients, mobile devices and ubiquitous

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[5] *See* Chronic Diseases are the Leading Causes of Death and Disability in the U.S., http://www.cdc.gov/chronicdisease/overview/index.htm, (Mar. 2013).
[6] *See Id.*
[7] *See Id.*, *see also* Obesity by the Numbers, http://www.letsmove.gov/learn-facts/epidemic-childhood-obesity, (Mar. 2013).

high-speed 3G and 4G wireless broadband data networks are at the heart of the growing mHealth reality.

Nowhere is this growth more obvious than in the mobile health applications landscape. The development and availability of mobile health apps has, quite simply, skyrocketed. Approximately 27,000 unique health apps are available for consumers and healthcare professionals.[8] About 500 new mobile health apps launch every month, which is up from about 400 health apps that launched every month this time last year.[9] Over 7,000 apps are specifically intended for use by medical students, physicians, nurses, clinicians and other healthcare professionals.[10] The availability of so many mobile health apps begs the question: "Which ones should be regulated as mobile medical devices?"

A survey conducted by Mobihealthnews shows that the Food and Drug Administration (FDA) has cleared fewer than 80 mobile medical apps through its 510(k) process to date, although they estimate that as many as 5 percent of all health-related apps could potentially be considered of a medical nature and, therefore, may be subject to FDA regulation as medical devices. Whether a mobile health app is a medical device or not depends heavily on the "intended use" or public marketing claims of each individual mobile health app — a topic of intense debate among developers, lawyers and industry watchers. This ambiguous area has led to confusion, apprehension and, in some cases, reluctance by mobile health app developers to enter the market for fear of regulation.

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[8] *See* Mobihealthnews, http://mobihealthnews.com/, (Mar. 2013)
[9] *See Id.*
[10] *See Id.*

On July 21, 2011, the FDA issued Draft Guidance for Industry and Food and Drug Administration Staff on Mobile Medical Applications (MMA).[11] This document signaled an important and encouraging first step notifying the public and all interested stakeholders that FDA would firm up and share its "current thinking" on what constitutes a mobile medical app or "device" under section 201(h) of the Food, Drug and Cosmetic Act (FD&C). The issuance of this draft guidance started a 90-day comment period during which FDA accepted more than 700 hundred pages of comments from over 100 organizations and interested parties.

Qualcomm submitted comments for the record, a copy of which is appended to this Statement. As we stated in our comments to FDA in October of 2011, "Although the Draft Guidance states that FDA intends to apply its regulatory requirements solely to a subset of mobile apps that meet the definition of a medical device, enough questions and issues linger that we encourage the Agency to address the entire range of mobile apps to remove any uncertainty as it finalizes the mobile medical apps guidance document."

FDA continued to demonstrate its leadership when, in September 2011, the Agency hosted a two-day workshop where it brought together experts and innovators from around the country to further discuss the MMA draft guidance. FDA used the opportunity to also discuss accessories in a mobile medical context and standalone software that provide clinical decision support.

In addition, FDA officials continued to actively engage the public on this important matter throughout the spring and summer of 2012 by speaking at various meetings and conferences to

[11] *See* Department of Health Human Services, Food and Drug Administration, Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications, http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263280.htm, (Jul. 2011).

discuss the development of the MMA draft guidance. These efforts taken individually and collectively were extremely useful and demonstrated the Agency's commitment to outreach and transparency.

On May 18, 2012, at a public briefing, officials from FDA expressed their views that the final MMA guidance document would be de-regulatory because it would, in effect, delineate how the Agency would exercise enforcement discretion not to regulate many low level risk mobile medical apps — that is, apps with a medical purpose that should be regulated according to FDA regulations but involve such low-risk of harm that they do not merit agency oversight. [12]

Examples given of low-risk apps that would not merit FDA oversight included: Educational tools (apps that provide a list of questions to ask medical professionals), medication reminders for therapy adherence, IV drug dose calculators (e.g., for calculating drip rates), body mass index (BMI) calculators, drug-drug interaction formulae, diabetes management guides (e.g., nutritional guides or pre-diabetes risk assessments), and substance abuse behavior guides.

The officials also stated that FDA would create a website to post generic examples of mobile medical apps that will not be regulated, in addition to serving as a forum to discuss broader policy development issues related to mobile health. These comments were met with approval by large segments of the industry. In fact, Qualcomm and its industry partners found them extremely promising.

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[12] *See* AP-Daybook-Fri-General (Two takes), http://www.krgv.com/news/ap-daybook-fri-general-two-takes-, (May 2012); *see also* Capitol Hill Discussion on the Regulatory Future for Mobile Medical Apps, http://www.himss.org/News/NewsDetail.aspx?ItemNumber=3224, (May 2012).

It is now March 19, 2013, and unfortunately FDA has yet to release a final MMA guidance document. Qualcomm and others are concerned that the failure to do so has created uncertainty about whether to produce richer mobile health apps by countless garage entrepreneurs and large corporations that fear the prospect of facing FDA regulation. Right now, mobile health app developers are left guessing about whether FDA regulatory obligations will impact their products or not. Indeed, comments such as those I describe by FDA officials would suggest that many low-risk apps would not need to pursue listing as a regulated medical device with FDA.

This would change tomorrow if FDA were to release final guidance along the lines discussed above. FDA has a long history of exercising enforcement discretion on products or aspects of products it determines do not warrant regulation. In clarifying its position on certain types of low-risk devices, the Agency would go far to ensure predictability, consistency and transparency.

Qualcomm offers the following recommendations for consideration:

1. FDA should promptly finalize the MMA draft guidance document.
2. The final MMA guidance should offer specific examples of low-risk regulated mobile medical devices that FDA, through enforcement discretion, would not regulate.
3. There should be clarity on "Intended Use" in light of ambiguous and general health claims and terms that are popularly used by the health IT industries.
4. For those apps that warrant listing as low-risk Class I devices, the Agency should consider how it will assess exemption from Good Manufacturing Practices (GMP).
5. Accessories should be classified according to their individual level of risk and not according to the device with the highest classification level.
6. FDA should continue its commitment to consistency, predictability and transparency by coordinating internal and external efforts through a single dedicated office of mobile health within FDA.
7. The agency would benefit to utilize external facing resources such "CDRH Learn", "Device Advice" and the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) to work with app developers and their communities.

FDA has a proven and successful policy, regulatory and legal framework that's been formed from over 100 years of innovation, science and learning—a framework that puts the patient first and ensures the safety and effectiveness of all products in the U.S. market related to health and medicine. We recommend that FDA be given the fullest support it needs to continue doing its fine work while allowing innovation to drive the US healthcare system.

Qualcomm believes that improving healthcare delivery in America should be a national priority of highest order, which can be achieved in large part through the use of mobile broadband technologies. Qualcomm looks forward to working with Congress, the FDA and other public and private stakeholders to ensure that health IT, devices, services, and applications are utilized as extensively as possible to improve the delivery of healthcare in the U.S.

Thank you, and I look forward to answering your questions.

About Qualcomm

Qualcomm Incorporated is the number one global supplier of wireless chips, and the leading inventor of wireless technologies. To date, Qualcomm has shipped over 11 billion chips. Qualcomm is a world leader in 3G, 4G and next-generation wireless technologies. If a person is using a 3G or 4G device today, Qualcomm's technology and ingenuity is being used.

Qualcomm Life (QCL), a wholly-owned subsidiary of Qualcomm Incorporated, is a medical device manufacturer focused on producing medical device data systems. QCL has developed the 2net™ Hub and 2net™ Platform. The 2net Hub, connects medical devices to the 2net Platform's data center and is a compact "plug-and-play" mobile broadband gateway that supports Bluetooth, Bluetooth Low Energy, Wi-Fi, and ANT+ local area radio protocols. The 2net™ Platform reliably captures and delivers medical device data to integrated portals or databases.

The Qualcomm Life Fund was established in 2011 with the amount of $100 million of funding with the goal of accelerating global wireless health services and technology adoption. The Qualcomm Life Fund specifically focuses on investing in venture-backed wireless health start-ups that will help accelerate the 2net™ Platform commercialization.

The Qualcomm Foundation, which Qualcomm established in 2010, is dedicated to developing and strengthening communities worldwide. Specifically, the Qualcomm Foundation focuses it philanthropic efforts on helping create and sustain educated, healthy, culturally vibrant communities in regions around the globe. As sponsor of the Qualcomm Tricorder X PRIZE

competition, the Qualcomm Foundation is proud to support the discovery of innovative mobile solutions that will contribute to the advancement of healthcare and diagnostics.

Qualcomm's Wireless Reach initiative is a strategic program that brings wireless technology to underserved communities globally. Wireless Reach invests in projects that foster entrepreneurship, aid in public safety, enrich teaching and learning, improve environmental sustainability and enhance the delivery of healthcare. Wireless Reach has 73 projects in various stages of development in 31 countries (15 projects are related specifically to healthcare).

Qualcomm includes Qualcomm's licensing business, QTL, and the vast majority of its patent portfolio. Qualcomm Technologies, Inc., a wholly-owned subsidiary of Qualcomm Incorporated, operates, along with its subsidiaries, substantially all of Qualcomm's engineering, research and development functions, and substantially all of its products and services businesses, including its semiconductor business, QMC.

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Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20554

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications	Docket No. FDA-2011-D-0530

COMMENTS OF QUALCOMM INCORPORATED

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INTRODUCTION

Qualcomm Incorporated ("Qualcomm") submits these comments in response to the Food and Drug Administration's ("FDA" or the "Agency") Draft Guidance for Industry and Food and Drug Administration Staff, Mobile Medical Applications (the "Draft Guidance").[1]

Qualcomm greatly appreciates the FDA's preparation of the Draft Guidance to inform all stakeholders, including manufacturers, distributors, the health care community, and even the FDA staff iteslf, of the Agency's current intentions regarding regulation of software applications that meet the legal definition of a medical device and are used on mobile platforms (referred to as mobile applications or "apps"). Such guidance is particularly timely and important given the rapid expansion and broad availability of mobile consumer and professional health apps and the potential of these apps to improve healthcare in so many ways. Consumers are taking full advantage of the many capabilities that are packed into today's mobile broadband-enabled devices, including smartphones and tablets. In contrast to traditional means of accessing information via the Internet on fixed devices, consumers are finding apps to be less time consuming and complex than typical desktop/laptop computer software programs.

Above all, the ability to access apps on mobile devices is highly beneficial for consumers. Apps, by design, provide direct, anywhere/anytime, access to requested information—be it health, news, weather, email, newspapers, books, photos, games, videos, and movies, to name a few. Today's apps turn a smartphone into a GPS guiding system, a book, a celestial viewer, a physical trainer, or an ECG waveform viewer, and the possibilities keep growing. As a result, data usage by smartphone users is exploding. In fact, the average smartphone user now

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[1] See Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications (July 2011), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.

consumes 435 MB per month, which is nearly double the per month amount smartphone users consumed just one year ago.[2]

In essence, smartphones and tablets have become an extension of today's consumer. Indeed, *more than one-third* of U.S. smartphone users interact with non-voice smartphone applications *before they even get out of bed.*[3] In the health, fitness, and medical app space, mobile consumer and professional health apps are estimated to number over 13,000, and it's increasing each day.[4] Over 9,000 consumer health apps are listed in Apple's App Store alone, in addition to more than 3,600 professional medical apps.[5] Interestingly, app innovation has been fueled by an unlikely segment of industry: solo developers and small companies. Solo developers account for 30% of app developers, while small companies (defined as 2-9 employees) represent 34.3% of app developers. The fact that nearly two-thirds of all mobile apps are developed by individuals or small companies is remarkable.

Qualcomm's advanced technologies help enable these wireless health and life sciences applications, including mobile health ("mHealth") products and services. In these Comments, Qualcomm describes the importance of mHealth technologies in the delivery of care in America, given the increasing burden of chronic disease and a shrinking healthcare workforce. We also

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[2] See Ina Fried, "Smartphone Users Continue to Gobble Data At a Staggering Rate," WALL STREET JOURNAL ALLTHINGSD.COM (June 17, 2011) *available at* http://allthingsd.com/20110617/smartphone-users-continue-to-gobble-data-at-a-staggering-rate/. (based on Nielsen's analysis of cellular phone bills for smartphone owners, noting that the growth among the heaviest users has been even more astonishing).

[3] See *From Apps To Everyday Situations, An Ericsson Consumer Insight Summary*, Ericsson.com (2011) *available at* http://www.ericsson.com/res/docs/2011/silicon_valley_brochure_letter.pdf (consumers were found to check, first thing each morning, apps for social networking, news, weather, and classified ads sites).

[4] Estimates provided by Brian Dolan, MobiHealthNews (www.mobihealthnews.com), September 30, 2011, include over 9,000 consumer health apps in the Apple App Store (September 2011) and over 3,600 professional medical apps in the Apple App Store (October 2011). These figures do not take into consideration other mobile app catalogs or markets that include the popular Android Market, BlackBerry App World and Verizon's Media Apps catalog, which may offer duplicate versions or additional unique consumer and professional health apps.

[5] Id.

describe Qualcomm's businesses and interests with respect to mobile health. Finally, we explain how traditional interpretations of medical device regulations should be clarified for mHealth applications by offering practical considerations to FDA about converged medical devices in our increasingly interconnected and highly mobile world.

Although the Draft Guidance states that FDA intends to apply its regulatory requirements solely to a subset of mobile apps that meet the definition of a medical device, enough questions and issues linger that we encourage the Agency to address the entire range of mobile apps to remove any uncertainty as it finalizes the mobile medical app guidance document.

In sum, Qualcomm believes that improving healthcare delivery in America should be a major national priority that can be achieved in large part through the use of mobile broadband technology. Qualcomm looks forward to working with the FDA and with all other public and private sector stakeholders to ensure that mobile broadband technologies, devices, services, and applications are used to improve the delivery of healthcare in the U.S.

M-HEALTH AND HEALTHCARE DELIVERY IN AMERICA

In 2010, total national health expenditures were estimated to be $2.6 trillion dollars or roughly $8,324 dollars per person in the United States.[6] By 2020, national health spending is expected to reach $4.6 trillion and comprise 19.8 percent of the nation's GDP.[7] Many Americans today spend more on healthcare than on housing or food, and if the escalating costs of healthcare continue, the Congressional Budget Office estimates that by 2020, approximately 27 percent of

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[6] See National Health Expenditure Projections 2010-2020, https://www.cms.gov/NationalHealthExpendData/downloads/proj2010.pdf, Centers for Medicare and Medicaid Services, 2010.

[7] Id.

federal spending will be on healthcare. Healthcare spending has become a national concern and has been identified as a top priority by President Obama and Congress.

A large part of the nation's healthcare expenses is accounted for by today's antiquated, inefficient, duplicative, insular, and painstakingly manual system that governs the delivery of care. Incredible as it may seem, in 2011 modern medicine still relies heavily on paper systems, rooted in manila folders and administered through manual entry of patient data. The often forgotten casualty is the patient who continues to have little access, if any, to relevant data, personal electronic medical records, or ongoing instructions from their clinicians, care providers, or hospital.

Passage of the American Recovery and Reinvestment Act of 2009 and the Patient Protection and Affordable Care Act of 2010 have ushered in the most significant changes to America's health care system since the passage of Medicare and Medicaid legislation.[8] These extraordinary measures pave the way for a national focus on implementing and utilizing the most advanced health information technologies to create a modern system of healthcare based on the exchange of electronic health information that will be highly personalized and focused on the most important aspect: the patient.

Today, wireless communications technologies are enabling health products and services that are improving by many measures the delivery and provision of healthcare in the U.S. Health information technologies such as medical devices, health sensors and software applications are increasingly using wireless functionality to transmit raw data, diagnostic health information,

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[8] See American Recovery and Reinvestment Act of 2009, P.L. 111-5 http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf; See also The Patient Protection and Affordable Care Act of 2010, P.L. 111-148 http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf

critical aspects of care, emergency services, and personalized information. These services are at the forefront of a revolution in America—a revolution that collapses time, space, and distance—to more efficiently and effectively monitor patients, develop analytical trends, and save lives. Increasingly, health information technologies utilize broadband technologies over mobile wide area networks or wireless local area networks to seamlessly provide important patient information to healthcare professionals, clinicians, or loved ones at fractional costs and in secure timely formats.

Mobile Broadband Technology And Preventable Disease In The U.S.

The burden of preventable illness in the U.S. is large and growing. Chronic diseases, such as heart disease, cancer, and diabetes, are the leading causes of death and disability in the U.S., according to the Center for Disease Control ("CDC").[9] Chronic diseases account for 7 out of 10 deaths among Americans each year, while also causing major limitations in daily living for 25 percent of people with chronic conditions.[10] In the U.S., the care of chronic illness accounts for almost 75 percent of total healthcare costs.[11] Chronic diseases are generally found among older adults, but they affect people of all ages and are now recognized as a leading health concern of the nation.[12] Although chronic diseases are among the most common and costly health problems, the CDC states that they are also among the most preventable. Thus, the most preventable diseases are of the greatest cost in the U.S. annually.

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[9] See Centers for Disease Control and Prevention, "Chronic Disease Prevention and Health Promotion," http://www.cdc.gov/nccdphp/index.htm.

[10] See Centers for Disease Control and Prevention, "Chronic Disease Overview," http://www.cdc.gov/nccdphp/overview.htm.

[11] See J. Geyman "Disease management: Panacea, another false hope, or something in between?", Annals of Family Medicine 5(3):257-260 (2007).

[12] Chronic Diseases: The Power to Prevent, the Call to Control, at Pages 1-2 (2009).

Today, mobile broadband already plays a role in healthcare. From the cell phones used by care providers to communicate between professionals and their patients, to the field laptops utilized by emergency management responders to keep track of patient information and records, to the handheld devices like tablet PCs, PDAs, or smartphones that specialists use to download diagnostic data or drug information, ubiquitous high-speed 3G wireless broadband data networks are at the heart of the mHealth reality. Mobile medical apps such as Mobile MIM's remote diagnostic imaging tool, AirStrip Technologies various app based mobile solutions (OB, CARDIOLOGY, or PATIENT MONITORING), WellDoc's DiabetesManager / DiabetesManager Rx System, Vocel's PillPhone app or Calgary Scientific's Resolution MD app, are all changing the face of healthcare for doctors and patients alike.[13]

Mobile Broadband And America's Shrinking Healthcare Workforce

While healthcare information technology is growing, America's healthcare resources are shrinking. Hospitals nationwide are beginning to face clinical workforce shortages due to an aging healthcare workforce. Many nurses and physicians are among the baby boomers set to retire in the next few years.[14] Despite a current easing of the nursing shortage due to the recession, the U.S. nursing shortage is projected to grow to 260,000 registered nurses by 2025.[15]

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[13] See http://www.mimsoftware.com/products/mobilemim; See also http://airstriptech.com/Portals/_default/Skins/AirstripSkin/tabid/55/Default.aspx; See also www.welldocinc.com/Products-and-Services.aspx; See also https://www.pillphone.com/PillLogin.htm; See also http://www.calgaryscientific.com/index.php?id=5.

[14] Isgur, Benjamin, "Healing the Health Care Staffing Shortage," Trustee, ABI/INFORM, Health Forum Inc., Pg. 18 (February 2008).

[15] Dr. Peter Buerhaus, July/August 2009 Health Affairs http://www.aacn.nche.edu/media/factsheets/nursingshortage.htm.

A shortage of this magnitude would be twice as large as any nursing shortage experienced in this country since the mid-1960s.[16]

The federal government is predicting that by 2020, nurse and physician retirements will contribute to a shortage of approximately 24,000 doctors and nearly 1 million nurses.[17] While hospital leaders voice concerns over possible shortages, the implications are greater as they extend well into the healthcare delivery system and into the quality of care in America. Furthermore, the expense associated with educating new nurses and doctors is astounding, with taxpayer-funded Medicare spending $8 billion a year for residency training of physicians alone.[18]

While healthcare shortages are on the rise, the U.S. has more physicians and nurses than ever before. Unfortunately these healthcare providers are not distributed or deployed efficiently, underscoring the problems faced with the delivery of quality and timely healthcare in America. Underserved patients are not just those typically found in rural America or in geographic areas of low population density; with an aging baby boomer demographic more and more people will continue to place greater demands on the nation's healthcare infrastructure everywhere. In the U.S. alone, the population of those 65 and older will more than double by 2050, rising from 39 million in 2009 to 89 million.[19] This is a global phenomenon, with the world's 65-and-older

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[16] Id.

[17] See PricewaterhouseCoopers' Health Research Institute, "What works* Healing the healthcare staffing shortage," http://www.wiche.edu/info/agendaBook/nov07/presentations/Carparelli.pdf.

[18] Id.

[19] See U.S. Census Bureau, "Census Bureau Reports World's Older Population Projected to Triple by 2050," (released June 23, 2009), http://www.census.gov/newsroom/releases/archives/international_population/cb09-97.html.

population projected to triple by midcentury, from 516 million in 2009 to 1.53 billion in 2050, according to the US Census Bureau.[20]

Quite simply, the U.S. population is aging. An aging population creates a demand for health services. At the same time, our nation is already facing a shortage of healthcare providers from nurses to primary care providers. The healthcare labor shortage coupled by an increasingly older population will exponentially increase healthcare disparities in urban, suburban, and rural America all the same. Logistical burdens—be it 5 miles or 500 miles—impede access to healthcare by the elderly, infirmed, and chronically ill.

The demand for America to go beyond traditional methods of delivering health services is real. mHealth technologies enabled by powerful mobile broadband networks exist, are growing in number, and will increasingly be relied upon to supplement America's healthcare delivery. This is where companies like Qualcomm can lend a helping hand.

ABOUT QUALCOMM

Qualcomm is a world leader in developing innovative wireless technologies, including Code Division Multiple Access ("CDMA") -based and Orthogonal Frequency Division Multiple Access ("OFDMA") -based cellular technologies used throughout the world for voice and broadband communications as well as countless mobile products and services. Qualcomm's chip division, QCT, is the world's largest provider of wireless chipset technology that is used in cell phones and consumer electronics devices. QCT's multimode chipsets support the full gamut of standardized, globally harmonized wide area mobile broadband and cellular technologies, several

[20] Id.

AGPS location tools, Bluetooth, Wi-Fi, and many operating systems, such as Android, Windows Phone 7, and iOS.

Qualcomm technology powers 3G and 4G cellular networks operated by wireless carriers throughout the U.S. and around the world. These carriers' networks enable hundreds of millions of Americans—in rural, suburban, and urban areas alike—to enjoy ubiquitous and highly advanced mobile voice and broadband data services. Based on the most recently available FCC data, over 95.6% of all Americans live within the coverage of one mobile broadband network, as the FCC has defined mobile broadband, that is 3G EV-DO or HSPA.[21] Patients, doctors, and hospitals all need ubiquitous mobile broadband coverage if wireless health is to deliver on its potential.

Qualcomm has a long track record of investment and innovation. Qualcomm spends billions of dollars annually to develop innovative technologies that extend into every aspect of wireless, especially the healthcare field. Since its inception in 1985, Qualcomm has invested more than $15.5 billion in R & D. In fiscal 2010 alone, Qualcomm spent $2.55 billion, or 23% of its revenues, on R & D. These enormous expenditures have enabled Qualcomm to invent many of the wireless technologies fueling the unprecedented growth in mobile voice and broadband services.

Today, Qualcomm's innovative technologies enable the use of mobile broadband connectivity for chronic disease management, remote patient monitoring, diagnostic care, as well

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[21] See Bringing Broadband to Rural America, Report on a Rural Broadband Strategy, released May 22, 2009, at Pgs. 12-13. At the time of the report, the FCC found, Verizon Wireless, Sprint, Leap Wireless and others provided mobile broadband service to areas in which over 95% of Americans live via EV-DO Revision A, which supported peak data speeds of 3.1 Mbps on the downlink and 1.8 Mbps on the uplink. Likewise, AT&T was concluding its network upgrade to HSUPA, which supported peak data speeds of up to 1.8 Mbps to 5.6 Mbps on the uplink, and was in the midst of upgrading its HSPA network to support peak speeds of 7.2 Mbps. Those technologies have improved dramatically since that report.

as products associated with general health, wellness, fitness, and aging. In addition, Qualcomm has formed partnerships with foundations, health institutions, medical device manufacturers, health alliances, associations, and firms that are involved in numerous facets of the healthcare ecosystem with an interest to leverage wireless technologies and mobile broadband to improve healthcare and maximize the potential of healthcare delivery through these technologies. Not only are Qualcomm and its partners working to bring about an unprecedented convergence of science, medicine, engineering, and technology to effectuate dramatic improvements in the quality of healthcare, but we strive to reduce costs and inefficiencies in the American healthcare system.

One example of the company's many efforts related to healthcare is Qualcomm Labs, Inc. (QL). QL is a wholly owned subsidiary of Qualcomm and serves as an internal wireless product and services incubator, positioned to transform emerging ideas and technologies into viable businesses. QL's areas of focus include context marketing, media enablement, machine-to-machine communication, enhanced wireless access services, and wireless health. In the area of wireless health, fitness, and medical products, QL's investments include Sotera Wireless (mobile rapid response monitoring), Telcare (mobile glucometer), AliveCor (mobile ECG), Work Smart Labs (wireless fitness technology) & Cambridge Temperature Concepts (wireless fertility monitoring).

Qualcomm further demonstrates its commitment to health care through the company's Wireless Reach™ initiative. Qualcomm's Wireless Reach initiative is a strategic program that brings wireless technology to underserved communities globally. By working with partners, Wireless Reach invests in projects that foster entrepreneurship, aid in public safety, enhance the

delivery of health care, enrich teaching and learning and improve environmental sustainability.[22] Wireless Reach began in 2006 and now has 73 projects in various stages of development in 31 countries. Some of these include:

China – 3G Mobile Medicine. Working with partners in China, Wireless Reach is helping to improve the delivery of care in rural health clinics using 3G handsets and 3G-ready PCs, pre-installed with a customized health care application. Through the Wireless Heart Health project, Wireless Reach™ also partnered to provide 3G-enabled electrocardiograph monitors to remotely screen and monitor cardiovascular diseases for underserved communities in China.

Japan – The Wireless_Health_Care@ Home project allows 300 remote local residents to send critical health information to doctors through a 3G wireless network.

Kenya – Wireless Reach™ has teamed with partners to develop a new system that increases efficiency and improves the accuracy of reporting in the supply management of antiretroviral medicines (ARVs) using 3G wireless connectivity.

Peru – Wireless technology enables remote speech therapy and provides critical medical care to rural communities, and has resulted in over 123,000 people receiving treatment and more than 1,300 surgeries performed.

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[22] See Global Citizenship, Healthcare Overview; http://www.qualcomm.com/citizenship/wireless-reach/projects/health-care.

Philippines – Wireless Access for Health uses 3G wireless technology to improve health care in the Philippines by reducing the time required for reporting and by improving access to accurate and relevant patient information.

Portugal – Wireless Reach™ is working with a project that provides 3G solutions for people with severe disabilities so they can communicate and live a more autonomous life using 3G mobile devices specially designed to accommodate their disability.

South Africa – With the help of the Mobile Health Information System (MHIS) – an Internet-capable, commercially available smartphone pre-loaded with a locally relevant and reliable clinical library – nurses can access much-needed information at the point of care.

South Korea – This Wireless Reach project provides health care related support to low-income and/or disabled seniors via a lightweight device called SHOWCare that uses Qualcomm mirasol™ display technology.

Spain – Wireless Reach™ provides the elderly with tools to better communicate and socially integrate themselves with family members and health care providers utilizing a videoconferencing system on the participant's TV set, a wireless HSPA router, a webcam and 3G mobile phones.

Thailand – This project helps improve health care throughout Thailand's rural areas by providing patients at participating clinics with the ability to communicate with doctors in major cities via CAT Telecom's 3G broadband Internet connection.

United States – Wireless Reach™ provided laptops with EV-DO Rev. A data cards to enable trauma surgeons to use a robot to reach patients in need. Additionally, Wireless Reach worked with partners to implement a study that demonstrates how 3G wireless technology can improve health outcomes for hypertensive patients in underserved urban communities, and resulted in patients reporting improved medication adherence rates and increased prescription refill rates with the use of the Pill Phone medication reminder application.

These activities are examples of the many ways in which Qualcomm, and its subsidiaries, are involved in the delivery of healthcare and demonstrates the reason why we are submitting these comments on the FDA's efforts in the wireless and mHealth space.

RECOMMENDATIONS AND COMMENTS

Qualcomm respectfully submits the following recommendations and comments in response to FDA's proposed Draft Guidance for Industry and Food and Drug Administration Staff on Mobile Medical Applications.

I. FDA Should Clarify The Scope And Regulatory Approach Of The Guidance Document

The FDA should clarify the scope and regulatory approach of the Draft Guidance. Although well-intentioned, the Draft Guidance lacks context and specificity that is necessary to help the nascent mHealth industry—many members of which are not traditional medical device companies—understand the FDA's legacy regulations, which were adopted decades ago, and how to apply those regulations to modern science and technology. The scope of the final guidance document should be more than a mere declaration that FDA will regulate certain types of mobile apps that meet the statutory definition of a medical device.[23] The guidance document should explain how to interpret that language for all apps, particularly in light of the mHealth mobile apps that utilize ambiguous terms to describe and market themselves such as focusing on "health", "wellness", "fitness", "sleep", "diet" and "stress."

The final guidance should more clearly describe the regulatory approach that the agency intends to apply to mobile apps. It is not enough to restate the obvious—that in the past, present and future, FDA will regulate medical devices and medical apps. Concepts such as a *intended use* and *level of risk* should be explained and FDA's rationale for applying these concepts to mobile apps disclosed. We suggest further that the document explain how FDA will apply these

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[23] See Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications (July 2011), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf, footnote 4, Page 7.

concepts to mobile medical apps. As written, the guidance mentions those concepts in passing without any meaningful context for how levels of criticality shall be weighed when assessing the potential risk some mobile medical apps pose to public health.

Furthermore, FDA should explain how it will examine the subset of mobile apps that it intends to regulate. For example, we recommend that FDA balance how a product is marketed through claims about its intended use and its functionality with the level of risk that product poses to its users. It is particularly important to understand how FDA weighs those criteria when assessing the regulatory status of mobile medical apps, particularly for stakeholders in the mHealth industry that have never experienced the FDA's regulatory process.

II. FDA Should Provide Clarity On "Intended Use"

The FDA should offer more insight to clarify its current thinking on how claims made by manufacturers about a product's intended use affect how products are regulated. According to the Draft Guidance, FDA deems a "mobile medical app" those apps that 1) meet the definition of a medical "device" as specified in section 201(h) of the FD&C Act and 2) either are used as an accessory to a regulated medical device or transforms a mobile platform into a regulated medical device.[24] The Draft Guidance tries to offer perspective on the definition of a device by way of a footnote, which states:

> Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act. That provision defines a device as "...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent.....", that is "...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in

[24] Id, at Page 7.

> man…" or "…intended to affect the structure or any function of the body of man or other animals…" Thus, software applications that run on a desktop computer, laptop computer, remotely on a website or "cloud," or on a handheld computer may be subject to device regulation if they are intended for use in the diagnosis or the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man. The level of regulatory control necessary to assure safety and effectiveness varies based upon the risk the device presents to public health.' (See Appendix B for examples).[25]

Unfortunately, this reiteration of the statutory definition offers little practical guidance. We are concerned that it may create the impression that the Agency will adopt what could be characterized as a heavy-handed approach towards the regulation of medical devices that could result in over-regulation of some mobile medical apps that should not (depending on interpretation) meet the definition of a mobile medical app. It is also not sufficient to provide a handful of examples representing mobile apps that FDA does not consider to be mobile medical apps for purposes of this guidance.[26] Likewise, providing short examples of mobile apps that FDA considers to be mobile medical apps subject to its regulatory oversight leaves many unanswered questions. Stakeholders in the mHealth industry need a more detailed explanation of the factors that determine whether FDA will regulate a mobile app and at what level of regulation, so that while a mobile app is under development, the app developer, potential investors, and other interested stakeholders can fully appreciate the level of regulatory oversight that applies.

Further, it is unclear whether it is FDA's intent to regulate devices that may not fall neatly within the strict definition of a medical device. Strict interpretation without the benefit of context and guidance may result in all mHealth mobile app products being required to undergo

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[25] Id. footnote 4, Page 7.

[26] Id. at Pages 10-11.

strenuous FDA regulatory requirements that present significant barriers to innovation and market entry. The Agency should appreciate that compliance with its regulations is not easy, even for entities that are traditionally regulated by FDA. Firms that are new to the medical device industry must (at great expense in terms of finances and human resources) institute significant procedural, technical, policy, staffing, and facility controls prior to marketing a medical device. The Agency, in the Final Rule for Medical Device Data Systems (MDDS), reported that costs to manufacturers to comply with FDA's Quality Systems and Medical Device Reporting (MDR) regulations "would likely be less than $20,000 for the manufacturer to bring its quality system into compliance" and could exceed $20,000 if the manufacturer also needed to hire a full time employee to manage the quality system. Many believe these numbers to be significantly underestimated, with some noting that a single employee with regulatory compliance expertise costs $143,000 annually, including salary and benefits.

The impact of compliance with FDA regulations will have a considerable effect, independent of whether the mobile app is created by a sizable firm or a solo developer. In terms of mobile and mHealth apps, many apps are developed by garage entrepreneurs, including individual doctors or clinicians, that work from their home. These mobile app developers should not be underestimated as they represent a significant engine of U.S. innovation. Solo developers account for 30% of app developers, while small companies (defined as 2-9 employees) represent 34.3% of app developers. The fact that nearly two-thirds of all mobile apps are developed by individuals or small companies must not be overlooked because the impact of over-regulation will not only be substantial but will undoubtedly restrict the innovation and growth that the U.S. economy and healthcare system desperately needs.

Taken in context, the number of overall mobile app developers is significant, while the numbers of apps they develop is extraordinary. Apple alone reports that as of August 2010, over 50,000 active app developers contributed to the more than 635,700 mobile apps available at that time on Apple's App Store.[27] The number of total apps continues to grow exponentially, in 2009 to 2010 by as much as 196.1 percent.[28] By 2016, the number of available apps is expected to reach 6.9 million.[29] In 2011, application storefronts are expected to generate approximately $10.51 billion in app sales revenue on an estimated 4.01 billion paid downloads.[30] As stated herein, mobile health apps (including consumer health apps and professional medical apps) account for more than 13,000 of the available apps.[31] The sheer number of mobile apps that will fall within the broad scope of this guidance is overwhelming. Compound that with the fact that two out of three developers of these regulated mobile apps are individuals or small companies that have never worked with the FDA and the demand for Agency resources to educate, review, and enforce regulatory requirements will be astronomical and unprecedented.

It is, therefore, imperative that the final guidance is narrowly-tailored to focus solely on those intended uses that involve significant risk to patients. FDA should explain how intended

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[27] See Analysis Of The Smartphone Application Storefront Market & its Impact On The Smartphone Ecosystem (Frost & Sullivan), pp. 5, 22, September 2011.

[28] Id. at Pages 5, 24.

[29] Id. at Page 24.

[30] Id. at Page 5.

[31] Estimates provided by Brian Dolan, MobiHealthNews (www.mobihealthnews.com), September 30, 2011, include over 9,000 consumer health apps in the Apple App Store (September 2011) and over 3,600 professional medical apps in the Apple App Store (October 2011). These figures do not take into consideration other mobile app catalogs or markets that include the popular Android Market, BlackBerry App World and Verizon's Media Apps catalog, which may offer duplicate versions or additional unique consumer and professional health apps.

use claims made by manufacturers affect how mobile apps are regulated (if at all). We offer below some ways to add this much-needed clarity.

III. FDA Should Exempt Some Low-Level Risk Apps From Regulatory Requirements Or GMP

We believe that the FDA should make a determination and offer guidance as to whether it will require the same degree of regulatory rigor when assessing low-risk mobile medical apps as compared to moderate-higher-risk medical apps and devices. FDA should consider risk-based tiers within Class I to segregate those devices (mobile apps) that pose little risk to users. Those mobile apps that would qualify should be exempted from some, or all, of the general controls that moderate- to higher-risk devices (including higher risk within Class I) are required to perform. We are not advocating for the creation of new regulations, but rather we are looking for guidance on how to treat low-risk mobile medical apps as compared to moderate-higher-risk medical apps and devices.

Ambiguous terms as previously discussed include claims made by developers on topics such as "health", "wellness", "well-being", "fitness", "patient satisfaction", "heart health", "unhealthy", "sleep deprived/deprivation", "stress", "stress management" and "fat." These terms do not seem to trigger section 201(h) of the FD&C Act, but there is no hard guidance to strengthen that assumption. FDA must clarify whether and what regulatory requirements apply if a mobile app involves low risk and is associated with general health claims, but alludes to possibly benefiting known diseases or conditions. Consider the following illustrative mock example:

> An unregulated health and fitness mobile app monitors physical activity and allows for manual input of caloric intake. If such a product included the

> following marketing claim: "Use of this health and fitness mobile app coupled with exercise and a healthy diet may lessen the risk of obesity in some people."

Under current guidance, such a statement would be impermissible and trigger regulatory obligations because it mentions the prevention of disease in man. We believe, however, that this hypothetical mobile app should not trigger regulatory requirements because it is of a particularly low risk to human harm. Rather than regulating low-risk mobile apps under the over-burdensome medical device framework, FDA should consider requiring a disclaimer similar to those used by supplemental vitamin manufacturers, such as "*This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.*"

FDA should also consider focusing its limited resources on enforcing regulations for mobile apps that actually pose a risk of harm to a user, while exempting or excluding those mobile apps that pose little risk to consumers. The Agency has clearly begun to do just that. The Draft Guidance offers examples of products that the Agency does not consider to be a mobile medical app for purposes of the guidance, such as electronic health records (EHRs) and personal health records (PHRs).[32] But it does not offer substantive explanations on how it reached its decisions or how it will exercise its enforcement discretion to exempt such products.[33] The guidance should clarify how FDA intends to exercise its discretion to decline to pursue

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[32] See Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications (July 2011), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf, Page 11.

[33] Id. at Page 12.

enforcement actions for violations of the FD&C Act or applicable regulations.[34] We encourage FDA to contemplate exercising enforcement discretion on mobile medical apps that present little risk to consumers as well as those that stand to benefit the public at large.

Although the Agency prides itself on its focus on innovation, it is also charged with the tremendous responsibility of protecting and promoting the health and well-being of the American people. Those two goals should not be mutually exclusive and it is incumbent upon the FDA to not only ensure the safety and efficacy of FDA-regulated products but to take proactive steps to foster scientific innovation that will lead to tomorrow's new breakthrough products like those found in mHealth.

IV. FDA Should Classify Accessories According To Their Individual Level Of Risk And Not According To The Device With The Highest Classification Level

The Agency's traditional approach of regulating accessory devices should be reconsidered for mHealth systems, mobile apps, and mobile medical apps. Generally, FDA regulates a product as an accessory to a specific medical device when the manufacturer of the initial product intends for it to be used with the medical device or when the medical device manufacturer requires the use of the other product, which is sold separately. Traditionally, products that are deemed accessories to classified medical devices take on the same classification as the "parent" device.[35] For example, an accessory such as software that accepts input from

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[34] Id.

[35] See for example, Content of a 510(k) -- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm) ("Accessories to classified devices take on the same classification as the "parent" device. An accessory such as software that accepts input from multiple devices usually takes on the classification of the "parent" device with the highest risk, i.e., class."); See also Final Rule, Medical Devices, Medical Device Data Systems, 76 Fed. Reg. 8637, 8643-8644 (Feb. 15, 2011).

multiple devices usually takes on the classification of the "parent" device with the highest risk, i.e., class.[36] FDA's rationale is predicated on ensuring that accessories and their parents should share equal risk when it comes to the failure of either the parent or its accessories. Thus, the parent medical device with the higher risk classification rules all.

The scope of the accessory rule is problematic considering the inherent capabilities and functionality of today's interoperable communications systems. Health and mHealth products are only going to become more interrelated and interoperable as medical products, devices, software, and mobile apps will be marketed in the future with broad system claims. The age of traditional independent and insular medical devices is over. The FDA's regulatory approach to mobile apps should establish the framework for these interconnected devices.

In establishing this framework, the Agency should regulate products according to their specific level of risk, independent of those medical devices to which they connect. Therefore, a product that connects to a device with a higher risk classification would be subject to the regulatory requirements that apply to the product based on the risk of the product itself, not based on the risk of its connection to the higher-risk device. Even if the manufacturer of either device claims compatibility with the other device, the regulatory obligations that apply to the other device should remain unchanged. More specifically, where the manufacturer of a medical device claims compatibility with a medical device of lower classification, the claim by the manufacturer of the higher-classified device should not result in heightened regulatory requirements for the lower-classified device.

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[36] Id.

FDA can ensure appropriate risk controls and compatibility between parent devices and accessories by requiring product manufacturers to substantiate accessory claims. Such claims of compatibility should be substantiated through adequate validation to demonstrate that the associated risk is recognized and appropriately tailored to the devices and their functions. Even though a lower-class device is not "up-regulated," substantiation of claims ensures the proper level of oversight for the risk associated with the two products. The substantiation obligation should lie with the manufacturer making the claim of compatibility.

V. Clinical Decision Support Software Is Outside The Scope Of Mobile Medical Apps

Clinical Decision Support ("CDS") software should not be considered as part of the mobile medical apps guidance document. It is simply a separate and distinct issue that confuses the subject of mobile apps and mobile medical apps. The FDA recognized the need for this distinction by stating, "This guidance does not specifically address . . . classification and submission requirements related to clinical decision support . . . software . . . . The FDA intends to address these topics through separate guidance(s)."[37] Given that statement, it is unclear why FDA proceeded to publish the Federal Register Notice of Availability on mobile medical apps with several questions related to CDS functionality and controls. This uncertainty was compounded by the fact that one day of a two-day workshop was devoted to CDS without any discernable tie-in to mobile medical apps.[38]

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[37] See Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications (July 2011), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.

[38] See Public Workshop - Mobile Medical Applications Draft Guidance, September 12-13, 2011, http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm.

We believe that the FDA final guidance on mobile medical apps should not contain definitional discussions on CDS or how to categorize standalone CDS software. Including the seemingly unrelated topic of CDS in the mobile medical apps guidance is likely to cause confusion. We urge FDA to consider CDS software through separate guidance as it is simply not within the scope of this mobile medical apps guidance document. Furthermore, any mention or discussion (including examples) of CDS software should be removed from the guidance.

VI. FDA Should Emphasize Coordination of its Internal Efforts Related To Wireless Health

We respecfully suggest that FDA place more emphasis on coordination of its policy and regulatory efforts related to wireless health and life sciences. The regulation of mobile health and mobile medical products, devices, and apps should be coordinated within the Center for Devices and Radiological Health by one group or in open collaboration within the Agency. Over the past few years, FDA has signaled an increasing interest to better understand this evolving area of science, technology, and medicine. FDA has undertaken the issuance of several draft guidance documents, made public pronouncements, hosted workshops, and launched initiatives that in one way or another discuss wireless and mobile technologies. A cursory sample of those efforts reveals the following:

- 2007 Draft Radio-Frequency Wireless Technology in Medical Devices[39]
- 2010 Medical Device Home Use Initiative Workshop ("Wireless Issues for Home Care Medical Devices")[40]

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[39] Radio-Frequency Wireless Technology in Medical Devices DRAFT GUIDANCE http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm.

[40] Wireless Issues for Home Care Medical Devices (Don Witters, CDRH/OSEL), http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm205804.htm.

- 2010 Memorandum of Understanding between the Federal Communications Commission and the FDA Center for Devices and Radiological Health[41]
- 2010 FDA/FCC Public Workshop: Enabling the Convergence of Communications and Medical Systems[42]
- 2011 Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications[43]
- 2011 Public Workshop: Mobile Medical Applications Draft Guidance[44]
- 2011 Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health ("Emerging Technology Trends")[45]

These efforts, taken individually, are very encouraging because they demonstrate FDA's commitment to the area of wireless health. However, taken together, some of these efforts seem to overlap and to be duplicative. Our concern is that the FDA's recent efforts in wireless health may be causing confusion, which we understand is the exact opposite of the Agency's intention.

Ultimately, FDA should better coordinate its policy and regulatory efforts related to wireless health, including mobile health, and should consider placing these efforts under one organization within CDRH and consolidating public information related to wireless health on one web site.

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[41] Memorandum of Understanding between the Federal Communications Commission and the FDA Center for Devices and Radiological Health, http://transition.fcc.gov/Daily_Releases/Daily_Business/2010/db0726/DOC-300200A2.pdf.

[42] Public Meeting, Converged Communications and Health Care Devices Impact on Regulation, July 26-27, 2010; http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm215046.htm.

[43] Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications; http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm.

[44] Public Workshop - Mobile Medical Applications Draft Guidance, September 12-13, 2011; http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm.

[45] Regulatory Science in FDA's Center for Devices and Radiological Health: A VITAL FRAMEWORK FOR PROTECTING AND PROMOTING PUBLIC HEALTH; http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM274162.pdf.

VII. FDA Should Promote External Resources "CDRH Learn", "Device Advice" And DSMICA

During the Public Workshop on Mobile Medical Applications Draft Guidance, held on September 12-13, 2011 at the FDA White Oak facility, numerous industry stakeholders expressed the need for FDA to improve its method of communication, beyond the need for regulatory clarity on issues and intentions, but more on the order of making documents less confusing and easier to digest. We believe that the FDA should proactively educate its constituency, clearly articulate its intentions, and offer public information in more accessible ways.

In addition, FDA should improve its efforts to promote its internal resources like FDA's Center for Devices and Radiological Health (CDRH) web page for industry education (called "CDRH Learn") or the Agency's comprehensive regulatory assistance page (called "Device Advice"), which offers information on determining how to comply with the federal laws and regulations governing medical devices.[46] Likewise, FDA should enhance the role of the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) for CDRH as a means to educate and respond to industry and consumer questions.[47] More should be done to raise public awareness of FDA's services.

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[46] CDRH Learn http://www.fda.gov/Training/CDRHLearn/default.htm; See also Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

[47] DSMICA for CDRH http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ucm142656.htm.

VIII. FDA Should Adopt The mHealth Regulatory Coalition's Proposed Guidance On The Regulation Of mHealth Technology

The FDA should adopt the mHealth Regulatory Coalition's ("MRC") Proposed Guidance on the Regulation of mHealth Technology under the good guidance practice.[48] The MRC intends to submit the document to the FDA on October 19, 2011 as part of their comments on FDA's Draft Mobile Medical Apps Guidance document. Qualcomm is a founding member of the MRC, a coalition that was formed over one year ago by a diverse group of stakeholders that are representative of industry, public advocacy, and non-governmental representatives. The MRC came together with the goal of answering two questions: 1) what mHealth products should the FDA regulate and 2) if such products are regulated, in what device classification should the FDA place them? The document developed by the MRC specifically addresses those two fundamental questions, as well as other interrelated issues on software that specifically address mobile medical apps. The MRC's proposed document addresses:

1) The types of intended uses that a product may have and associated claims that a manufacturer can make about a product without it being regulated as a medical device;

2) The framework for addressing products that have traditionally been regulated as accessories to other medical devices; and

3) A framework for software in an mHealth system.

The MRC chose to address those questions because its members, including Qualcomm, believe that the interests of the public health and patient safety demand appropriately tailored FDA oversight. Moreover, the MRC sought to help FDA develop a clear, predictable, and

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[48] See Mobile Health Regulatory Coalition, *MRC's Proposed Guidance for Industry and FDA Staff Regulation of mHealth Technology*, http://mhealthregulatorycoalition.org/.

targeted regulatory framework that will promote innovation and discovery of new ways to improve the delivery of care, reduce the cost of health care, facilitate private investment in large and small businesses in the mHealth industry, and stimulate job creation in the United States. Qualcomm believes the FDA could reasonably implement the proposed principles through their good guidance practices and strongly encourages the Agency to do so.

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CONCLUSION

With 5.7 billion global mobile subscribers and the number of wireless devices in the U.S. now outnumbering the U.S. population, it is safe to say that the world is going mobile. Consumers are adopting mobile broadband-enabled smartphones, tablets, e-readers, and other handheld computers faster than any other computing platform in the history of mankind. Deloitte's Technology, Media and Telecommunication Group predicts that this year, the combined sales of smartphones, tablets, and netbooks will exceed 400 million units worldwide, overtaking traditional PC sales by many millions. Indeed, many consumers today own multiple mobile broadband-enabled devices, and it is not at all uncommon to see people carrying a smartphone, a tablet, and an e-reader.

These powerful handheld devices have become integral to the personal and business lives of millions of American consumers who demand anywhere/anytime broadband access to communicate with healthcare professionals, clinicians, and family via videoconference; watch entertainment programming; or store and retrieve from the cloud limitless amounts of data in the form of emails, documents, books, newspapers, magazines, photos, videos, music, and movies.

These technologies, supported by highly integrated chips, enable wireless health and life sciences products as well as converged medical devices to advance the critically important work carried out by America's healthcare community including doctors, nurses, clinicians, emergency medical technicians, critical public safety personnel, and—most importantly—patients and their loved ones.

As a result of the important role that we play in this community, Qualcomm is actively engaged in intensive research and technology development efforts related to mobile health and wireless life sciences. We appreciate the FDA's guidance, and we look forward to working together with FDA and all other stakeholders in this exciting and innovative field.

Respectfully submitted,

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Dated: October 19, 2011

Mr. WALDEN. Mr. Jarrin, thank you for the thought you put into your testimony and for being here today.

We will now go to Mr. Bradley Merrill Thompson, General Counsel, mHealth Regulatory Coalition. Mr. Thompson, thank you for being here today. We look forward to hearing your testimony.

STATEMENT OF BRADLEY MERRILL THOMPSON

Mr. THOMPSON. Well, thank you very much for inviting me. As you can tell from the name of our organization, the topic today is of very great interest to us.

Our coalition is a very diverse coalition, which is both fun and challenging. It is fun, because we have a lot of spirited discussions. It is challenging because it represents a lot of different points of view. We have folks in there from the traditional medical device industry, we have app developers in there, we have the telecommunication firms in there, patient groups and so forth. And frankly, the way I navigate consensus-building in our group is to say, look, we only have one rule, and that is, put the patient first, leave economics at the door and let us figure out what policy puts the patient first.

In that vein, I have three simple points that I want to make this morning in my testimony. The first one is that we would urge FDA to publish its guidance just as soon as possible and indeed expand on that guidance in the future. I cheated a little bit, and I read the testimony of my other fellow witnesses here, and it seems like there is going to be good agreement on that score. What I would offer, as the nerdy lawyer maybe among the panel, is that I think that maybe FDA is delaying because they are going for the complete and final definitive for-all-time answer to these questions, and it is really tough because the industry changes on almost a daily basis. So they write a draft, it goes through a couple of months of review. By that couple months, the environment has changed a bit and they want to go back and erase some of what they wrote previously.

I think what they need to do is get a final version out there and then use the guidance process to update it periodically as the environment changes, as the regulatory issues shift, as the questions shift, simply update the guidance periodically. We have talked about creating a Web site, where they would on a more real-time basis, offer some guidance. There are some tools that are available to them but bottom line is, I think FDA is struggling a bit with how to get hits guidance out, and in our opinion, it needs to get out because there is an awful lot of business that is frozen on the sidelines waiting to see what that guidance says.

The second point I want to make to you is a bit counterintuitive probably for someone from industry to say, and that is, we would like to see more FDA enforcement in this area, and particularly more balanced FDA enforcement in this area. And the way I can make this point is best through an example, and it is an example I read about of a new app just a few weeks ago announced from India where you can do urinalysis with your iPhone, and everyone was talking about it on the Internet because I think a lot of people were trying to figure exactly where you pee on this thing in order to get the reading, and it turns out you do a very traditional tech-

nique: you pee in a cup and put a strip in that cup, it changes color, and then use the camera on the iPhone to more accurately assess what the color changes were.

And they introduced this thing. It hasn't yet hit the U.S. market but they have announced their intention to go through the Apple app store in introducing it. The problem is, FDA has regulated urinalysis for 30-some years. That is a very traditional medical device, and the typical one looks about the size of a cash register, so I got to tell you, doing it on an iPhone, that is cool, that is really cool, but what they did is, on the front page, at the bottom of the front page, they basically said in legalese this is not a medical device. Well, honestly, if it were that simple, I know a lot of other companies that would like to do that same thing, right? If you could avoid FDA by putting a disclaimer at the bottom of your home page and yet the whole rest of the Web site explains how it is used in urinalysis, that is a problem.

So this is in part a competitive issue, right? Because different companies are held to different standards. But it is a public health issue because this is an important app, and if it gets the urinalysis reading wrong, people with diabetes, people with serious conditions could be relying on that app. So either deregulate it, which would take an act of Congress, I believe, because it is clearly a medical device, or more evenly enforce the rules.

The third and final point that I want to make is that we favor sticking with FDA as the regulator for both the traditional device industry and the less traditional mHealth area. There was a rumor circulating, and who knows where these start, that people wanted to move mobile health regulation away from FDA. We couldn't support that. We couldn't support it because it would create two systems where if you do it on an iPhone system, if you do it on a cash registered-sized machine, you have a completely different system. To us, that actually increases the uncertainty and the complexity and the confusion, and so we have found that FDA has the knowledge that they need. This is a new technology. We are all learning the technology, but they have the public health knowledge in order to do this and to do it right, so we favor sticking with the agency.

Those are the three points I wanted to make this morning, and I appreciate the time.

[The prepared statement of Mr. Thompson follows:]

Testimony of Bradley Merrill Thompson

General Counsel

mHealth Regulatory Coalition

Before the House Energy and Commerce Committee

Subcommittee on Communications and Technology

March 19, 2013

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.

Testimony of Bradley Merrill Thompson
General Counsel for the mHealth Regulatory Coalition
Before the House Energy and Commerce Committee
Subcommittee on Communications and Technology
March 19, 2013

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.

Mr. WALDEN. Mr. Thompson, thank you for your testimony. We will now go to Mr. Ben Chodor, who is the Chief Executive Officer of Happtique, like health app boutique.

Mr. CHODOR. Exactly.

Mr. WALDEN. Everybody with me now. All right, Mr. Chodor, you are on.

STATEMENT OF BEN CHODOR

Mr. CHODOR. Good morning, Mr. Chairman Walden and Ranking Member Matsui, and members of the subcommittee. My name is Ben Chodor and I am the CEO of Happtique. It is an honor to testify today on mobile health technology, which Happtique believes can change health care delivery systems. My testimony addresses two important issues in our industry——

Mr. WALDEN. Will you make sure your microphone is on?

Mr. CHODOR. Is that better?

Mr. WALDEN. There we go.

Mr. CHODOR. My testimony addresses two important issues facing our industry: questions about regulations, and the applicability of medical device tax to mobile devices. Happtique is a mobile health solution company whose mission is to integrate mobile health into patient care and daily life. Happtique is owned and operated by GNYHA Ventures, a business arm of Greater New York Hospital Association. GNYHA has a robust family of companies to assist its members in addressing business and operational issues. Happtique, the newest member of the companies, was established in direct response to members' needs to develop comprehensive mobile health strategies to support clinicians, facilitate patient engagement and improve their own operations. Happtique's principle offerings include individually branded, secure, multiplatform applications for hospitals, physician and patient: our MRX, it is our patent pending technology that enables physicians to actually prescribe apps to their patient, a unique system of classifying apps in more than 300 categories, and our brand-new private sector solution to a big problem, we have just launched our certification program for health apps.

Happtique created these solutions to harness the unprecedented potential for mobile health technologies. Think about it: 87 percent of physicians use smartphones or tablets every day. One out of five smartphone users has at least one health app on it. There are over 40,000 health apps on the market and it is growing every day, and there is little to no barrier of entry for these apps. This has incredible opportunity for innovation in health care but comes with certain concerns, namely how credible is this app for myself or for my patient.

So who should monitor the mobile health industry? Clearly, the industry needs to balance three things: innovation, safety and effectiveness. The FDA released its guidelines in 2011, which Mr. Jarrin went over, and Happtique's belief is that the FDA is in the best position of any agency to regulate health apps because of its long health expertise in assuring patient safety, but we have to say from our point of view, the FDA has to release these guidelines sooner than later. It is about time that they come out.

We don't believe the FDA should regulate mHealth products that are not considered medical devices. The FDA's draft guidance addressed which mobile apps the FDA does not anticipate classifying as mobile apps for purpose of regulation. The industry is pleased that the FDA recognizes its own limits.

Complementary to the FDA regulatory framework, Happtique, our company, has created a certification program with industry stakeholders to offer clinicians and patients a way to identify technically and validation of an app. Happtique developed a health app certification standard under the direction of a blue ribbon panel, and we are reviewing operability, privacy, security, and content. In the development of the standards, we consulted with key public-private sector organizations—the FDA, the FTC, the FCC, the AMA, the AAMC and many, many other organization. This conducted the certification process. Again, Happtique is an engaged, well-known security company to ensure operability, privacy and security, and we are engaging specialists, so if it is a cardiology app, cardiologists should review the material. Apps that pass both the technical and testing content review will be awarded the Happtique certification seal. Our goal here is that the users will be reassured that a certified app delivers credible content, safeguards user data and functions as described.

I would like to switch gears for a second and now talk about the medical device tax and how it relates to mobile apps since I know several members of the committee also care a great deal about this issue. Happtique does not believe that Congress intended to impose a device tax on iPhones, iPads, Android phones or tablets, or BlackBerrys, or apps that run on these devices. If congressional intent is ambiguous, we firmly believe the retail exemption applies. If the IRS wants to implement this tax on this technology, Congress needs to pass a law that specifically states that tax applies. Imposing a device tax on apps will undoubtedly stifle innovation, developers and publishers, and frankly, the threat of tax stifles innovation too.

In closing, thank you for my allotted time, and I would like to thank the chairman and ranking member and the subcommittee for asking me to testify today.

[The prepared statement of Mr. Chodor follows:]

Congress of the United States
U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Communications and Technology
Washington, D.C.

Hearing on:

Health Information Technologies: Harnessing Wireless Innovation

March 19, 2013

Testimony of:

Benjamin M. Chodor
Chief Executive Officer
Happtique, Inc.
New York, New York

Testimony of Benjamin M. Chodor, Chief Executive Officer
Happtique, Inc.
Committee on Energy and Commerce Subcommittee on Communications and Technology
March 19, 2013

Summary

Happtique is a mobile health solutions company whose mission is to integrate mobile health into patient care and daily life. Happtique was founded in 2010 and is owned and operated by GNYHA Ventures, Inc., the business arm of the Greater New York Hospital Association (GNYHA). GNYHA represents nearly 250 hospitals and long term care facilities in New York, New Jersey, Connecticut, and Rhode Island, and provides a wide range of membership services to these health care organizations including health information technology.

Happtique believes that the FDA, among the many interested federal agencies, is in the best position to regulate health apps because of its deep expertise on issues of patient safety. Its risk based approach strikes an appropriate balance or guarding against consumer harm, while not chilling technological innovation, and because it is the most prepared to do so. Happtique urges the FDA to release its final guidance on mobile medical apps as soon as possible.

As a complement to the FDA regulatory framework, Happtique has created a certification program with industry stakeholders to offer clinicians and patients a way to identify technically and substantively valid apps. With the cooperation of recognized industry partners, the Happtique Health App Certification Program will provide a valuable tool for the review of health apps.

Happtique does not believe the medical device excise tax should apply to any phones, tablets or mobile health apps. Any application of the tax to these products would be beyond what Congress intended and would serve to slow innovation by placing burdensome costs on app developers in a new and growing market.

Good morning. Chairman Upton and Members of the Subcommittee, my name is Ben Chodor and I am the Chief Executive Officer of Happtique, Inc. It is a distinct honor for me to be here today, and I want to thank you for the opportunity to testify on the very important topic of mobile health technology and applications.

I'd like to begin by telling you about Happtique. Happtique is a mobile health solutions company whose mission is to integrate mobile health into patient care and daily life. Happtique was founded in 2010 and is owned and operated by GNYHA Ventures, Inc., the business arm of the Greater New York Hospital Association (GNYHA). GNYHA represents nearly 250 hospitals and long term care facilities in New York, New Jersey, Connecticut, and Rhode Island, and provides a wide range of membership services to these health care organizations including advocacy; education; emergency preparedness and response; and leadership on key initiatives in such critical areas as health care quality improvement, patient safety, population health management, workforce development and training, and health information technology. GNYHA's businesses, which are national in scope and operated under the umbrella of GNYHA Ventures, Inc., provide group purchasing, consulting, and other valuable products and services to health care organizations across the entire continuum of care with the goal of helping these organizations succeed in delivering high quality health care services in an efficient and cost-effective manner. Today, these businesses serve more than 25,000 customers across the U.S. and are responsible for more than $10 billion in commerce annually.

Happtique, which is the newest member of the GNYHA Ventures' family of companies, was established in direct response to GNYHA members' need for assistance in developing comprehensive mobile health strategies and utilizing mobile health technologies to support their clinicians, facilitate patient engagement, and improve their operations. Happtique's principal offerings include:

- Individually branded, secure, multi-platform application stores for hospitals, continuing care facilities, and physician practices for staff and patient use;
- mRx™, patent-pending technology that enables physicians to "prescribe" apps to their patients;

- a unique system developed by a nationally known medical librarian and a team of physicians and nurses for classifying apps into more than 300 clinically-meaningful categories. This classification system is designed to make the discovery of apps easier and more intuitive to clinicians and consumers; and
- a voluntary certification program for health apps.

I would be happy to discuss any of Happtique's offerings in detail, but in light of the focus of this hearing on the regulation of mobile health technology and applications, I would like to devote the balance of my testimony to a discussion of our certification program and issues related to the mobile health app market and regulation thereof.

Mobile health technology offers unprecedented potential to connect patients and providers—and is coming of age at the perfect time in the history of the American healthcare system. As Americans, we are all cognizant that the costs associated with healthcare management and prevention need to be prioritized. Happtique believes that, in order to move away from individual encounters in the healthcare system toward patient-centered care, greater focus should be placed on connectivity and care management across the continuum. However, before we can fully embrace the necessity for realignment of how healthcare ought to be delivered, we need to recognize that patient engagement is paramount. Fortunately, we have the technological capabilities today (e.g., smartphones, tablets, peripheral devices) that can serve as the ideal vehicles to connect patients and providers remotely and in real time.

Highlights of Market Statistics:

- 87% of adults own a cell phone (Mobile, Pew Internet, January 2013)
- 1 out of 3 cell phone owners has used their phone to look for health information online (Mobile Health 2012, Pew Internet, November 2012)
- 1 out of 5 smartphone owners has at least one health app (Mobile Health 2012, Pew Internet, November 2012)
- 87% of physicians use a smartphone or a tablet in their practice (Screen to Script: The Doctors Digital Path to Treatment, thinkwithgoogle.com, June 2012)

- 78% of consumers believe in the benefits of mHealth (mHealth US end-user research: Beliefs, barriers, success factors and recommendations, GSMA, 2012)
- $200 million in sales for healthcare apps (Frost & Sullivan, 2011)
- 600 million health apps were downloaded in 2012 (Pyramid)

More than 40,000 health apps exist on the market to assist healthcare professionals deliver and improve patient care, in addition to allowing consumers to become educated and manage their own health and wellness. What's driving this proliferation? Unlike other aspects of the healthcare marketplace, there is little to no barrier to entry into the health app market—so basically anyone with an idea and programming skills can build a mobile health app. While this has exposed the healthcare industry to an influx of technologically sophisticated and innovative developers who are eager to make positive transformations, it has simultaneously made the industry vulnerable to a new breed of inventors who are novice to its regulatory landscape. Thus, the easy entry into mHealth offers incredible opportunity for innovation in healthcare; however, the open market comes with certain concerns, namely, "how credible are the apps I am (or my patients are) using?"

Of course, this raises the issue of who should monitor the mobile health industry. The mHealth community is in need of both direction and a level of expectation to foster innovation while assuring safety and effectiveness. Happtique believes that the industry would benefit from a balanced, risk-based approach where regulation and oversight is borne by various appropriate groups and that is clearly conveyed to all stakeholders.

Recognizing the exponential growth and adoption of health apps by healthcare professionals and consumers, the FDA released Draft Guidance in July 2011. The Draft Guidance describes plans to provide oversight with respect to the safety and effectiveness for a subset of mobile apps – mobile medical applications ("mobile medical apps"). These consist of mobile apps that have either already been classified as medical devices themselves or "affect the performance or functionality of a currently regulated medical devices."

The FDA chose to define a "mobile medical app" in the Draft Guidance as:

> *A mobile app that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and either:*

- *is used as an accessory to a regulated medical device; or*
- *transforms a mobile platform into a regulated medical device.*

Examples of "mobile medical apps" that the FDA plans to provide regulatory oversight for include:

- Mobile apps that are an extension of one or more medical device(s) by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data;
- Mobile apps that transform the mobile platform into a medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices; and
- Mobile apps that allow the user to input patient-specific information and – using formulae or processing algorithms – output a patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice or to assist in making clinical decisions.

The FDA also provided the following categories of types of mobile medical apps and their associated classifications:

- Displaying, storing or transmitting patient-specific medical device data in its original format
- Controlling the intended use, function, modes, or energy source of the connected medical device
- Transforming or making the mobile platform into a regulated medical device
- Creating alarms, recommendations or creating new information (data) by analyzing or interpreting medical device data

See Appendix A of the Draft Guidance for examples of each of the above mobile medical app categories/types.

Regulatory Requirements:

In Appendix C of the Draft Guidance, the FDA also provides a "high level description of some select regulatory requirements for medical devices, including mobile medical apps" (e.g., Establishment Registration and Medical Device Listing, Labeling requirements, Premarket submission for approval or clearance, Quality System regulation, Medical Device Reporting, Reporting Corrections and Removals).

Happtique echoes the concerns of the FDA with respect to technologies that pose significant risk and may fall under their surveillance. That said, we don't believe that the FDA should regulate mhealth products that are not considered to be medical devices. The FDA provided clarity in the Draft Guidance as to which mobile apps they do not anticipate classifying as mobile medical apps for purposes of regulation. Happtique agrees with the exclusions, as several significant topics that were excluded from the Draft Guidance are of great importance to the industry.

The following are examples of mobile apps NOT considered "mobile medical apps" by the FDA for purposes of the Draft Guidance:

- Mobile apps that are electronic "copies" of medical textbooks, teaching aids or reference materials, or are solely used to provide clinicians with training or reinforce training previously received
- Mobile apps that are solely used to log, record, track, evaluate, or make decisions or suggestions related to developing or maintaining general health and wellness
- Mobile apps that only automate general office operations with functionalities that include billing, inventory, appointments, or insurance transactions
- Mobile apps that are generic aids that assist users but are not commercially marketed for a specific medical indication
- Mobile apps that perform the functionality of an electronic health record system or personal health record system

Topics that were excluded from Draft Guidance (or to be addressed in a separate piece) include:

- wireless safety considerations
- classification and submission requirements related to clinical decision support software
- application of quality systems to software
- mobile medical apps that are intended to analyze, process, or interpret medical device data (electronically collected or manually entered) from more than one medical device

Due to clarity provided in the Draft Guidance, including these exclusions, Happtique, along with other industry stakeholders, anticipates only a small subset of the health app market (we estimate about 20%) would fall subject to regulatory oversight by the FDA in the event that any final guidance issued by FDA strongly resembles its Draft Guidance. In such event, much of the current health app market would appropriately not be subjected to heighted regulation or

supervision. The majority of health apps would only be subject to regulation and oversight by other government agencies such as the Federal Communications Commission (FCC) and Federal Trade Commission (FTC). The size and expressed concern regarding the expected segment of the health app market not subject to heightened scrutiny by the FDA or other government agencies served as the genesis for Happtique to develop our Health App Certification Program (HACP).

Happtique's Health App Certification Program is a voluntary program borne out of the expressed need by many health care organizations and clinicians for a way to identify technically and substantively valid apps. As previously mentioned, there are currently as many as 40,000 health apps across multiple platforms on the market, with thousands more being added each year. While some app developers have submitted their applications to the FDA and received approval as medical devices, there is no reliable way for app users to readily distinguish credible apps from all others; thus, Happtique saw the need for an objective app assessment and validation process.

As you are aware, much in our health care delivery system is regulated by private sector organizations. For example, The Joint Commission accredits hospitals and other health care organizations and the various medical specialty societies provide physician board certification in their specialties. As a company whose origins are deeply rooted in health care; that is platform, device, and application neutral; has an in-depth understanding of existing regulatory requirements pertaining to medical devices, privacy and security requirements as defined under the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health Act (HITECH), children's online privacy requirements, and other health care-related laws and regulations; and has close ties to many key stakeholders in the health care industry, including hospitals, continuing care facilities, payers, and clinicians, we felt that there was a critical role and need for a private sector-based app certification program and that we were well suited to undertake this role.

Our efforts to develop a voluntary certification program began over a year ago with the formation of a distinguished Blue Ribbon Panel comprised of recognized leaders in mobile health, health care technology, health care certification and accreditation programs, and patient

advocacy. Attached to my written testimony is a list of the members of this Panel, which I am pleased to submit for the record (Attachment A). Under the direction of this Panel, we have developed what we believe are a very rigorous set of standards and associated performance requirements. The standards encompass four areas: Operability, Privacy, Security, and Content. In total, there are nearly 150 standards and performance requirements; of these, 13 individual standards and more than 60 performance requirements focus specifically on privacy and security alone.

In developing the standards, we consulted with key public and private sector organizations, including the FDA, FTC, FCC, Office of the National Coordinator for Health Information Technology (ONC), American Medical Association (AMA) Association of American Medical Colleges (AAMC), Mobile Marketing Association (MMA), GSM Association (GSMA), mobile Healthcare Information and Management Systems Society (mHIMSS), and Association for Competitive Technology (ACT).

In July, 2012, we published the standards in draft form for public comment and received 115 comments from app developers/vendors, hospitals and health systems, trade organizations, information technology organizations, and other entities and individuals. After a thorough analysis of the comments, we made a number of revisions to the standards, and last month published the final set of standards and performance requirements, which we will use to evaluate apps once the certification program is underway. It should be noted that, while our standards are not officially endorsed by any Federal agency, they are explicitly designed to complement the existing regulations and guidelines of the FDA, FTC, FCC, and ONC, and it is our intent to modify them, as necessary, to ensure that they remain in lockstep with any new guidance or rules pertaining to mobile health applications that these agencies may issue in the future. As importantly, however, for the first time, they provide a solid basis for evaluating the thousands of apps that are not currently subject to any public agency regulation or oversight. Attached to my written testimony is a copy of HACP's final Standards and Performance Requirements, which I am also pleased to submit for the record (Attachment B).

HACP is a voluntary certification program that will be available to any publisher or developer of medical, health, and fitness apps intended for sale and/or use in the U.S. and that run on iOS, Android, Blackberry, or Windows smartphones and tablets. Web-based applications (so-called "Web apps"), other mobile health products, and mobile apps intended for sale or use outside the U.S. are not presently included in our certification program, but may be added in the future.

To conduct the certification process, we are engaging key organizations as certification program partners. Intertek, an internationally-recognized leader in the provision of testing, inspection, certification and auditing services to a wide range of industries and in the mobile application space, will test each app submitted for certification for its compliance with our Operability, Privacy, and Security—or so-called "Technical"—standards. Apps that pass the technical assessment will then be reviewed to validate their content. Content reviewers will have credentials relevant and appropriate for the content being reviewed. So, for example, cardiologists will review cardiology apps, nurses will review nursing apps, dieticians will review diet and nutrition apps, certified personal trainers will review fitness apps, and so forth. Presently, we are pleased that the AAMC and CGFNS International have agreed to serve as program partners for the purposes of reviewing medical/patient education apps and nursing apps, respectively, and we expect to finalize agreements shortly with numerous other partner organizations that will provide content experts in the many other clinical specialties and disciplines that we need to conduct this program. Apps that pass both the technical testing and content review will be awarded the Happtique Certification Seal. Certification will be valid for a two-year period and is specifically associated with the version of the app that was submitted for evaluation.

We are currently finalizing numerous other operational details associated with this program, including submission requirements, re-certification requirements, procedures for assuring compliance with our standards between certification reviews, and so forth. We are also forming an Advisory Board that will provide ongoing oversight of the operation of the program. Like any certification or accreditation program, we expect to continuously monitor the standards performance requirements and update them, as necessary. We are currently beta testing all of our systems and processes with a number of apps and expect to formally launch HACP this spring.

We are very excited about our certification program and believe it will play an extremely valuable role and make an important contribution in the mobile health arena by giving health care professionals, consumers, and patients the confidence they deserve to have in the apps they are using or recommending.

Mr. Chairman and members of the Subcommittee, I would now like to make a few remarks about questions regarding the medical device tax and how it relates to mobile health apps.

The Patient Protection and Affordable Care Act (PPACA) imposes an excise tax of 2.3% on certain medical devices in order to generate revenue to help offset the spending created by the law. In general, under the PPACA, a taxable medical device is a device that is listed by the FDA under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 807. There are specific medical devices that are exempt from the PPACA's excise tax, such as eyeglasses, contact lenses, and hearing aids. There is also an exemption, commonly called the retail exemption, for any device of a type that is generally purchased by the general public at retail for individual use.

The final regulations issued by the Internal Revenue Service provide for a "facts and circumstances" approach to determine whether a type of device meets the retail exemption. The regulations enumerate several factors that are relevant, with the determination being based on the overall balance of factors relevant to a particular type of device. A device will be considered exempt if it is regularly available for purchase and use by individual consumers who are not medical professionals, and if the design of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional. One of several factors relevant is whether consumers who are not medical professionals can purchase the device in person, over the telephone, or over the Internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell devices.

Since the passage of PPACA, and increasingly over the last several months, the medical device excise tax has come under broad attack from industry groups, commentators, and legislators. While Happtique does not have a position on the existence of the medical device excise tax as a

general matter, we are opposed to its imposition on the sale of smartphones, tablet devices, and apps used by any type of individual in any setting or circumstance.

We do not believe that it was the intent of Congress to impose an excise tax on iPhones, iPads, Android phones or tablets, or Blackberries. A fair reading of the final regulations implementing the tax should lead one to conclude that the retail exemption applies to all smartphones and tablets that are on the market today. A physician's use of an iPhone app to treat or diagnose a patient that has been regulated by the FDA as a mobile medical app does not change the nature of the iPhone from a consumer device sold to the general public at retail to a medical device subject to the medical device excise tax. As far as we can ascertain, nobody in the Congress, the Congressional Budget Office, or the investor community thought that the PPACA was imposing a 2.3% tax on Apple or RIM. We think that the retail exemption should apply in all circumstances to all smartphones and tablets that are sold the general public, but if for some reason there is confusion, doubt, or the IRS reaches a different conclusion, then changes should be made to the statute as appropriate, to the effectuate such a result.

With respect to mobile health apps, while we believe the FDA is the best suited and most appropriate agency to regulate those apps that fall under their purview for the reasons stated above, we believe that mobile apps, regardless of their intended use, or classification as medical devices or accessories to medical devices under the FDA's existing regulatory framework, should be exempt from the medical device excise tax. We recognize that due to the nature of some apps, the facts and circumstance test and the factors enumerated by the regulations may in some cases lead to the conclusion that the retail exemption does not apply, despite the fact that the app is sold in the App Store. We do not believe it was the intent of Congressto tax any apps sold in the Apple App Store or Google Play. If apps were intended to be taxed, the statute would have expressly stated so, and the tax would have been referred to as the medical device and software tax. Further, the imposition, or even the threat of imposing the medical device excise tax on app will stifle innovation for app developers and publishers, which is a market that was not the intended target of the tax.

In closing, may I again thank the Chairman and members of the Subcommittee for the opportunity to participate in this hearing. I would be happy to answer any questions you might have.

Attachment A

Happtique Health App Certification Program
Blue Ribbon Panel

- David Lee Scher, M.D., Panel Chair – former practicing cardiologist and mHealth authority
- Franklin Schaffer, EdD, RN, FAAN – Chief Executive Officer, CGFNS International
- Shuvo Roy, Ph.D. – Director, Biomedical Microdevices Laboratory and Associate Professor, Department of Bioengineering and Therapeutic Sciences, School of Pharmacy, University of California, San Franciso
- Dave deBronkart ("ePatient Dave") – well-known spokesman for patient engagement

Attachment B

HEALTH APP CERTIFICATION PROGRAM
CERTIFICATION STANDARDS
February 27, 2013

happtique.com @happtique

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App Operability (OP) Standards[1]

Standard OP1
The app installs, launches, and runs consistently[2] on the target device(s) and target operating system(s) for that app.

Performance Requirements for Standard OP1

- OP1.01 The app downloads and installs on the target device(s) and target operating system(s).
- OP1.02 The app consistently launches and runs on the target device(s) that it is installed upon.

Standard OP2
If applicable, the app connects consistently to any and all peripheral or accessory devices (e.g., NFC, Bluetooth), third party mobile application or software, regulated or unregulated, required for operation and/or marketed for use in conjunction with such app.

Performance Requirements for Standard OP2

- OP2.01 The app connects to the peripheral device(s) and operates consistently.
- OP2.02 The app has a mechanism to notify the user in the event that the app fails to connect to any and all peripheral or accessory devices.
- OP2.03 The app connects consistently to any and all third party mobile applications, software, and online user accounts, but such connection shall only occur after: (i) notifying user; (ii) requesting permission; and (iii) receiving consent from the user.
- OP2.04 The app has a mechanism to notify user of any and all updates applicable or necessary for app to connect to any such device, application, software or online user accounts.

Standard OP3
If the app requires that it be connected to a network, the app is able to connect and operates consistently on the intended domestic and global carriers or Local Area Network (LAN).[3]

Performance Requirements for Standard OP3

- OP3.01 The app connects to the network via wireless technology (e.g., CDMA2000 and GSM).
- OP3.02 The app connects to the LAN via well-established standards (e.g., 802.11, 802.15, 802.16).

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[1] These standards are based, in part, on materials from the National Alliance for Health Information Technology, the Mobile Marketing Association's "Mobile Application Privacy Policy Framework" (December, 2011), and GSM Association's "Privacy Design Guidelines for Mobile Application Development" (February, 2012).

[2] To be defined in conjunction with vendors performing Technical Standards testing.

[3] Due to the number of mobile operators (approx. 800), two U.S. operators and WiFi will be used as a proxy for this test.

Standard OP4
If the app connects to the network, the IP addresses and URIs are known or can be determined.

Performance Requirements for Standard OP4

- OP4.01 The list of IP addresses and/or URIs that the app connects to are documented, and the owners of those addresses and domain names are either disclosed or are capable of being determined from testing.
- OP4.02 The app does not connect to any hidden IP addresses that are used behind the firewall of a router or gateway, without user's knowledge, control, or consent.

Standard OP5
A method for contacting the App Publisher and technical support (if different than the App Publisher) is provided.

Performance Requirements for Standard OP5

- OP5.01 The App Publisher's contact information—including but not limited to, mailing address, email address for support and general inquiries, web address and/or DNS address—is provided within the app, or the app provides a link to a webpage that contains the same information.
- OP5.02 The app provides a method for users to submit feedback to the App Publisher for purposes of improving the user experience, including without limitation, any technical issues, bugs, and errors detected by users.

Standard OP6[4]
The app shall be designed to operate in a manner that supports a usable and useful end-user experience.

Performance Requirements for Standard OP6

- OP6.01 App Publisher has a documented process to review, escalate and incorporate, on a timely basis, modifications needed to address suspected errors and other technical issues.
- OP6.02 In designing and maintaining the app, the App Publisher has a documented process for addressing:
    - User feedback regarding efficiency (the speed with which users can complete their tasks), effectiveness (the accuracy and completeness with which users can complete tasks), and satisfaction (the user's satisfaction with how well the app operates); and

[4]This Standard is derived from the mHIMSS report, "Selecting A Mobile App: Evaluating the Usability of Medical Applications" (see http://www.mhimss.org/resource/selecting-mobile-app-evaluating-usability-medical-applications).

- Reasonable requests by users regarding features and functionality not supported by the app (e.g., support in additional languages, audiology assistance, visual impairment support, and other requests specific to the demographic of the app's intended audience).

Standard OP7
Electronic health record (EHR) systems optimized for mobile devices are apps for certified EHRs (EHRs that have been certified by a Federally-designated Authorized Testing and Certification Body). Certified EHRs may consist of complete EHRs or EHR modules.

Performance Requirements for Standard OP7

- OP7.01 The app operates in accordance with the documented functionality provided by the Certified EHR.
- OP7.02 Documentation is provided regarding any relevant EHR certification received.

Standard OP8
An app that is intended to connect to an Electronic Health Record (EHR) or Personal Health Record (PHR) enables users to send and retrieve patient information between a mobile device and the EHR/PHR, and does so in a secure manner.

Performance Requirements for Standard OP8:

- OP8.01 The EHR and/or PHR systems with which the app connects (e.g., Allscripts, Epic, Microsoft HealthVault, etc.) are specifically enumerated and documentation of the interoperability with each specified EHR and PHR is provided.
- OP8.02 The details and description of the data fields that the app saves, sends to, and/or receives from each specified EHR/PHR systems regarding patient information (e.g., medical history, diagnoses, treatment plan, medications, laboratory results, radiology images, etc.) is provided.
- OP8.03 The app maintains (*at rest*) and transmits (*in motion*) patient information in a secure, HIPAA-compliant manner, as applicable (see Standards S2, S3, and S4).

Standard OP9
The App Publisher certifies that the app constitutes a medical device as defined by the U.S. Food and Drug Administration (FDA), has ascertained its correct classification, and either certifies that the app complies with all applicable FDA regulatory requirements[5] or certifies that it is not a medical device.

Performance Requirements for Standard OP9

- OP9.01 The App Publisher has ascertained that the app, including any and all peripheral devices required or intended for operation and/or marketed for

[5] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm

use in conjunction with such peripheral devices, is a Class I, II or III medical device[6].

- OP9.02 The App Publisher provides documentation demonstrating that the app complies with all applicable FDA requirements, including but not limited to: Establishment registration; Medical Device Listing; Premarket Notification 510(k)[7], unless exempt, or Premarket Approval (PMA)[8]; Investigational Device Exemption (IDE) for clinical studies; Quality System (QS) regulation; Labeling requirements; and Medical Device Reporting (MDR).
- OP9.03 The App's Publisher has a mechanism to immediately notify all users and Happtique about an FDA-approved app that is recalled, the subject of an FDA advisory, or similar status that calls the app's safety and/or effectiveness into question.
- OP9.04 If the app does not constitute a medical device as defined by the FDA, the App Publisher certifies that the app is not a medical device by written attestation on the HACP App Submission Form.

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[6] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

[7] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm

[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm

App Privacy (P) Standards[9]

Standard P1
The type(s) of data that the app obtains, and how and by whom that information is used, is disclosed to the user in a Privacy Policy.

Performance Requirements for Standard P1

- P1.01 Prior to downloading, installing, or activating an app, the identity of any entities that will have access to, collect and/or use of the user's personal information, including a company or individual name, country of origin, and related contact information is disclosed to the user.
- P1.02 App Publisher discloses any and all ownership, rights or licenses to any data collected in connection with the app and its usage, including the use of any data for commercial purposes.
- P1.03 The app has a section (tab, button or equivalent) or active link to its Privacy Policy, and owner represents that commercially reasonable efforts are used to notify users of any material changes to its Privacy Policy.
- P1.04 If registration is required to use all or some of the app's features, the user is provided with an explanation as to the uses of the registration information.
- P1.05 User is provided (or has access to) a clear list of all data points collected and/or accessed by the app, including by App Publisher and any and all third parties such as in-app advertisers, pertaining to the usage of the app, including but not limited to browsing history, device (e.g., unique identifiers), operating system, and IP addresses. How and from where such data points are collected is disclosed.
- P1.06 User is provided (or has access to) a clear list of all data points collected and/or accessed by the app pertaining to the specific user, including user-generated data and data that are collected automatically about the user through other means or technologies of the app. This includes data points collected for the purpose of any third-party sharing. How and from where such data points are collected is disclosed.
- P1.07 App Publisher obtains affirmative express consent before using user data in a materially different manner than was previously disclosed when collecting the data or collecting new data, including for the purpose of third-party sharing.
- P1.08 App Publisher obtains affirmative express consent before collecting personal data, in particular information about children, financial and health information, Social Security numbers, and location data.
- P1.09 The Privacy Policy informs users how they can get a copy of their personal information that was collected by the app. The Privacy Policy also informs users how they can correct and update information supplied by, or collected about them, held by or on behalf of the owner, or shared with

[9] In general, these Privacy Standards are intended to be consistent with the principles set forth in "Protecting Consumer Privacy in an Era of Rapid Change: Recommendations for Businesses and Policymakers," Federal Trade Commission, March, 2012.

third parties, including the identity of such third parties, particularly in compliance with the HIPAA Privacy Rule[10], if applicable, and any other laws, rules, or regulations to the extent applicable.

- P1.10 If not otherwise provided by default, the app allows users to control the collection and use of their in-app browsing data by supporting an online Do Not Track mechanism, if applicable.
- P1.11 If not otherwise provided by default, the app allows users to control their receipt of commercial messages from the App Publisher and third parties through an "opt out" option, "do not contact," or substantially similar feature.
- P1.12 Each major component of the Privacy Policy is affirmatively agreed to by the user. Such components include, but are not limited to, entities that will have access to, collect and/or use of the user's personal information; all ownership, rights or licenses to any data collected and its usage; list of all data points collected; and so forth.
- P1.13 Except when expressly disclaimed by App Publisher and the user provides an affirmative consent, App Publisher does not share any user data with third parties, unless App Publisher: (i) has an agreement with such third party that addresses safeguarding any and all such user data; and (ii) takes the necessary measures to anonymize/de-identify all user data. The App Publisher has documented this within the Privacy Policy.

Standard P2

If data are collected, the user is informed about how long the data are retained.

Performance Requirements for Standard P2

- P2.01 The Privacy Policy discloses the retention policy regarding user information. Such statement includes policies with respect to data retention under any third-party data sharing arrangement.
- P2.02 Retention and deletion time periods, which are based on clearly defined business needs or legal obligations, are set. If business needs are defined as "in perpetuity," this is disclosed.

Standard P3

The app user is informed if the app accesses local resources (e.g., device address book, mobile and/or LAN network interface, GPS and other location-based services, contacts, camera, photos, SMS or MMS messaging, and Bluetooth) or resources from and/or for social networking platforms, provided with an explanation by any appropriate means (e.g., the "About" section) as to how and why such resources are used, and prior consent is obtained to access such resources.

[10] http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html

Performance Requirements for Standard P3

- P3.01 If the app uses the mobile network, why the network is being used and a reasonably likely estimate of the average amount of bandwidth consumed per user per month is disclosed to the user.
- P3.02 If the app uses a LAN, why the network is accessed and a likely estimate of the average amount of bandwidth consumed per user per month is disclosed to the user.
- P3.03 If the app or App Publisher uses SMS or MMS messaging, the user is provided with a likely estimate of the average number of messages per month, and a disclosure that data rates will apply.
- P3.04 If the app or App Publisher sends emails, the user is provided with a likely estimate of the number of emails sent per month.
- P3.05 If the app uses Bluetooth, why Bluetooth is being used and which of the Bluetooth profiles are being used is disclosed to the user.
- P3.06 If the app uses the device's camera, why the camera is being used is disclosed to the user.
- P3.07 If the app uses device-available methods to determine location, why the location is being determined is disclosed to the user.
- P3.08 If the app accesses the device's native address book, why the address book is being used is disclosed to the user.
- P3.09 If the app accesses the device's native calendaring or alarm system, why the calendar and/or alarm system is being used is disclosed to the user.
- P3.10 If the app accesses the Public Switched Telephone Network (PSTN), why the PSTN is being accessed is disclosed to the user.
- P3.11 If the app accesses social networking sites, the reason why such sites are being accessed is disclosed to the user.

Standard P4

If the app, on behalf of a Covered Entity or a Business Associate (each as defined by HIPAA and HITECH and the rules thereunder), collects, stores, and/or transmits information that constitutes Protected Health Information (as defined by HIPAA and HITECH and the rules thereunder), it does so in full compliance with HIPAA, HITECH, and all applicable laws, rules and regulations.

Performance Requirements for Standard P4

- P4.01 The user can affirmatively opt in or out (at any time) of information shared with or given access by third parties.
- P4.02 The App Publisher certifies that a Business Associate Agreement (BAA) has been executed pursuant to HIPAA with any and all necessary third parties.
- P4.03 The user has the ability to access or request any of his/her Protected Health Information (PHI) collected, stored and/or transmitted by the app, and has the ability to learn the identity of any person or entity who had or has been granted access to his/her PHI.
- P4.04 The App Publisher uses requisite efforts to limit the use and disclosure of PHI, including ePHI, to the minimum necessary to accomplish the intended purpose (e.g., "need-to-know").

Standard P5
The app has measures in place to protect children in accordance with applicable laws and regulations (e.g., Children's Online Privacy Protection Act[11]).

Performance Requirements for Standard P5

- P5.01 The app provides clear notice of the content that will be made available and its suitability for specific age groups.
- P5.02 The app includes a clear and conspicuous Privacy Policy that addresses use by any child under the age of 13.
- P5.03 The app provides for an age verification process—either automatic or self-reported—to control access to age-restricted content and to minimize the inappropriate collection, use, or disclosure of personal information from a child.
- P5.04 The app does not, without obtaining verifiable parental/legal guardian consent, collect, use, or disclose data from any child under the age of 13.
- P5.05 The app enables a parent/legal guardian who becomes aware that the child has provided information without his/her consent to contact the App Publisher.
- P5.06 The Privacy Policy provides that the App Publisher will delete any child's personal information upon notice, or in the event that the App Publisher becomes aware or has knowledge, that such information was provided without the consent of a parent/legal guardian, including information that was shared with a third party.
- P5.07 Apps that are intended for children must have a location default setting that enables parents/legal guardians to prevent the app from automatically publishing their child's location.

Standard P6
Retroactive or prospective material changes to Privacy Policies require the prior consent of the user.

Performance Requirements for Standard P6

- P6.01 A mechanism is in place to notify users of changes to the Privacy Policy.
- P6.02 A mechanism is provided that enables users to acknowledge and consent to changes to the Privacy Policy.

[11] http://www.ftc.gov/ogc/coppa1.htm

App Security (S) Standards

Standard S1
The app, including without limitation, any advertisement displayed or supported through the app, is free of known malicious code or software such as malware, including, but not limited to, viruses, worms, trojan horses, spyware, adware, rootkits, backdoors, keystroke loggers, and/or botnets.

Performance Requirements for Standard S1

- S1.01 A scan of the app using scanning software does not reveal any known malicious code or software objects.
- S1.02 A scan of any third party code, including advertising networks, incorporated into app for purposes of displaying or supporting advertisements (e.g., banner, interstitial) does not reveal any known malicious code or software.

Standard S2
The App Publisher ensures that the app's security procedures comply at all times with generally recognized best practices and applicable rules and regulations for jurisdiction(s) in which the app is intended to be sold or used and such procedures are explained or made available to users.

Performance Requirements for Standard S2

- S2.01 Administrative, physical, and technical safeguards to protect users' information from unauthorized disclosure or access are provided and employed.
- S2.02 Access to user's information is limited to those authorized employees or contractors who need to know the information in order to operate, maintain, develop, or improve the app.
- S2.03 If the app utilizes unique identifiers, the identifier is linked to the correct user and is not shared with third parties.
- S2.04 Where possible, risk-appropriate authentication methods are used to authenticate users.
- S2.05 A written description of security procedures (in detail sufficient to apprise end users about how their personal information is safeguarded) is provided in a section of the app (tab, button, or equivalent) or through an active link. The security procedures are written in clear, easy-to-understand language and terms and are affirmatively agreed to by the user. Such components include, but are not limited to, how personal information is safeguarded, how unique identifiers are linked to the correct user, and authentication methods used.
- S2.06 The App Publisher has a mechanism in place to review security procedures on an ongoing basis and update security procedures, as necessary, to ensure that they comply at all times with applicable rules and regulations for jurisdiction(s) in which the app is intended to be sold or used.
- S2.07 Cloud-based apps meet Statement on Standards for Attestation Engagements (SSAE) No. 16 requirements and a SSAE No. 16 audit report is provided.

- S2.08 If the app uses SMS or MMS, the user is informed whether messages are encrypted and, if so, the level of encryption.
- S2.09 The App Publisher has a formal and documented secure software development lifecycle (SDLC) process that has been implemented throughout the inception, testing, implementation, deployment, and maintenance of the app.

Standard S3
If the app collects, stores or transmits any personal information, including, but not limited to, usernames and passwords, such information is collected, stored, and transmitted using encryption.

Performance Requirements for Standard S3

- S3.01 Passwords are stored using a random length, one-way salted hash, SHA-1 or better.
- S3.02 Usernames and passwords are collected and transmitted only when using encryption between the client app and the server.
- S3.03 Other personal information while at rest and/or in motion is encrypted using a generally recognized, industry-accepted encryption method (e.g., FIPS 140-2[12], ISO/IEC) for such information and the encryption level is disclosed.
- S3.04 App contains security safeguards to verify the identity of intended user in the event of forgotten, lost or unknown user name, password and/or passcode ("unique identifiers"), for purposes of reminders, re-linking, or creation of new unique identifiers.

Standard S4
If the app collects, stores and/or transmits information that constitutes PHI as defined by HIPAA, HITECH, and the rules thereunder (e.g., App Publisher constitutes a Business Associate pursuant to HIPAA and HITECH), it uses requisite efforts to maintain and protect the confidentiality, integrity, and availability of individually identifiable health information that is in electronic form (e.g., ePHI).

Performance Requirements for Standard S4

- S4.01 If the app, or through its use, subjects the user or any party to HIPAA or HITECH, the App Publisher has implemented administrative, physical and technical safeguards, and developed policies and procedures, pursuant to the HIPAA Security Rule[13], as applicable. For purposes of the technical safeguards/security controls, only certain certified encryption technologies are permissible for compliance with HIPAA and HITECH.
- S4.02 If the app is, or through its use becomes, subject to HIPAA or HITECH, all PHI collected and/or stored is encrypted at all times and is otherwise protected in accordance with HIPAA and HITECH.

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[12] http://csrc.nist.gov/groups/STM/cmvp/standards.html#02
[13] http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html

- S4.03 If the app is or becomes subject to HIPAA or HITECH, all data transmission to and/or from the app through any network with any server, system, software, application and third party is encrypted at all times.
- S4.04 If applicable, the app or the App Publisher has safeguards in place and/or uses requisite efforts to comply with any and all obligations pursuant to any BAA, including capabilities to assist a covered entity in curing any breach, and address all other requirements of HITECH in the event of a breach.
- S4.05 The App Publisher has the capabilities to enable compliance, and shall comply with any and all applicable notification requirements to its users in the event that users' PHI is or is suspected to be compromised (e.g., Breach Notification Rule pursuant to HIPAA and HITECH including the capability to support and execute notification requirements[14]).

Standard S5
If the app collects, stores and/or transmits personal information, the app offers one or more industry-accepted methods for guarding against identity theft.

Performance Requirements for Standard S5

- S5.01 The app provides a method for securely authenticating the user at a session level (e.g., password, pass phrase, PIN, challenge phrase) and also utilizes additional methods or techniques[15] to further secure the identity of the users whenever the system is initially establishing identity or the system has indications that the identity might have been compromised (e.g., multiple password failures).

Standard S6
The App Publisher has a mechanism to notify end users about apps that are banned or recalled by the App Publisher or any regulatory entity (e.g., FDA, FTC, FCC).

Performance Requirements for Standard S6

- S6.01 In the event that an app is banned or recalled, a mechanism or process is in place to notify all users about the ban or recall and render the app inoperable.
- S6.02 In the event that the app constitutes a medical device (e.g., 510(k)) or is regulated by the FDA in any other capacity, the App Publisher has a policy and a mechanism in place to comply with any and all applicable rules and regulations for purposes of handling all aspects of a product notification or recall, including all corrections and removals.

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[14] http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html

[15] Examples of additional methods or techniques might be the use of certificates signed by recognized certificate authorities, two-factor authentication methods, static knowledge based authentication methods, and/or dynamic knowledge-based authentications.

Standard S7[16]

The app implements reasonable and requisite security measures to safeguard user financial data in accordance with any and all applicable laws, regulations, industry best practices, and standards.

Performance Requirements for Standard S7

- S7.01 Any app that collects, stores and/or transmits user financial data for any purpose, including payment processing, or the app directs to any website for the purpose of collecting and/or processing of financial information, including any third party website, shall comply with any and all applicable Federal and state laws, rules and regulations, and private sector regulatory best practices guidelines and initiatives regarding data security requirements (e.g., Section 5 of the FTC Act, Fair Credit Reporting Act, Gramm-Leach-Bliley Act, Payment Card Institute Data Security Standards, the SANS Institute's security policy templates, and standards and best practices guidelines for the financial services industry provided by BITS, the technology policy division of the Financial Services Roundtable).

[16] FTC Act, Section 5, available at: http://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf

PCI Security Standards Council, PCI SSC Data Security Standards Overview, available at: https://www.pcisecuritystandards.org/security_standards/

SANS Institute, Information Security Policy Templates, available at: http://www.sans.org/security-resources/policies/

BITS, Financial Services Roundtable BITS Publications, available at: http://www.bits.org/publications/index.php

App Content (C) Standards[17]

Standard C1
The app is based on one or more credible information sources such as an accepted protocol, published guidelines, evidence-based practice, peer-reviewed journal, etc.

Performance Requirements for Standard C1

- C1.01 If the app is based on content from a recognized source (e.g., guidelines from a public or private entity), documentation (e.g., link to journal article, medical textbook citation) about the information source and copyright compliance is provided.
- C1.02 If the app is based on content other than from a recognized source, documentation about how the content was formulated is provided, including information regarding its relevancy and reliability.

Standard C2
The app's content reflects up-to-date information (as of the date that the app is submitted for certification).

Performance Requirements for Standard C2

- C2.01 Documentation about the source of the app's content and explanation as to why it is deemed to be up-to-date is provided.
- C2.02 The date(s)/source(s) of the app's content is provided through an "About" section (tab, button or equivalent).
- C2.03 The App Publisher has a method or protocol for determining if an app's content requires updating in order to remain up-to-date.
- C2.04 The App Publisher has a method or protocol for updating the app's content when new or changing information warrants. Updates should include a description of and documentation for each change.

Standard C3
For any app that contains content that is derived from a third-party source (e.g., accepted protocol, published guidelines, evidence-based practice, peer-reviewed journal), any significant deviations in an app's content from the original source (e.g., excerpts, abbreviated versions) are indicated and explained. Any such app shall also provide a method or citation to enable the user to locate to the complete content.

Performance Requirements for Standard C3

- C3.01 For any app derived from a third-party source that does not contain the original source's complete content, such app's description or "About"

[17] These standards are based, in part, on materials from the Association of American Medical Colleges (AAMC), including AAMC's MedEdPORTAL Submission Standards and Scholarly Criteria (https://www.mededportal.org/download/262700/data/mepsubmissionstandards.pdf).

section shall indicate the specific portion(s) absent and contain an explanation as to why each portion(s) is not included.

- C3.02 For any app derived from a third-party source that does not contain the original source's complete content, the app provides a link, reference, or other appropriate method to enable the user to locate the complete content.

Standard C4[18]

The app's description and content are truthful, fair, and not misleading.

Performance Requirements for Standard C4

- C4.01 Backup documentation is provided to substantiate any claims made in the description and/or content.
- C4.02 Disclosures are provided, as needed, to prevent deception. Such disclosures shall be presented in a clear and conspicuous manner.
- C4.03 Disclosures are provided, as needed, if the app requires an additional fee(s) (e.g., subscription fee) in order to fully access the app, its associated functionality, and/or content.

Standard C5

An app that contains tools that perform user or patient management functions, including but not limited to, mathematical formulae, calculations, data tracking, reminders, timers, measurements, or other such functions, does so with consistent accuracy and reliability to the degree specified in the app.

Performance Requirements for Standard C5

- C5.01 When operated, the app produces consistent and accurate results that are independently verifiable.

Standard C6

Reference apps (e.g., apps that are used for reference purposes to inform clinical decision-making, etc.) derive their content from one or more authoritative sources.

Performance Requirements for Standard C6

- C6.01 The app's content is based on authoritative sources as recognized by the field or discipline that is the subject of the app.
- C6.02 As appropriate, prior accepted work (e.g., published, peer reviewed) is used to derive the content of the app.
- C6.03 The source(s) and date(s) (e.g., published, last modified) of the app's content are cited.

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[18] For further information and guidance, refer to "Dot Com Disclosures: Information about Online Advertising," Federal Trade Commission. (http://www.ftc.gov/os/2000/05/0005dotcomstaffreport.pdf)

Standard C7
Instructional, educational assessment, and other such apps (e.g., apps used in educational settings for physicians, nurses, students, etc.) derive their content from one or more authoritative sources and are based on accepted pedagogy and/or learning strategies or techniques that are appropriate for the intended audience(s).

Performance Requirements for Standard C7

- C7.01 The app's content is based on authoritative sources as recognized by the field or discipline that is the subject of the app (e.g., recognized textbook and/or peer-reviewed journals in an applicable field or discipline).
- C7.02 As appropriate, prior accepted work (e.g., published, peer reviewed) is used to derive the content of the app.
- C7.03 The source(s) and date(s) (e.g., published, last modified date) of the app's content are cited.
- C7.04 The app's learning goals and objectives are clearly stated.
- C7.05 The app uses suitable teaching and/or learning approaches to meet its stated objectives.
- C7.06 A process or method for assessing and documenting improvements in knowledge or skills is provided.

Standard C8
Apps that constitute clinical decision support (CDS) software and apps that integrate or work in conjunction with CDS software, comply with current rules and regulations, if applicable (e.g., for CDS software that is regulated by the FDA), and evidence-based/accepted practice guidelines.

Performance Requirements for Standard C8

- C8.01 Documentation is provided regarding the regulations and any applicable evidence-based/accepted practice guidelines that the app operates in accordance with.
- C8.02 App has a process and mechanism to deliver all applicable updates pursuant to any relevant guidelines when such guidelines are issued or made available.

Standard C9
For a multi-purpose app (e.g., apps that have reference, instructional, or educational assessment content, integrate or work with CDS software, etc.),where each element of the app can be separated for testing, each element of the app meets the requirements of the relevant Content Standard(s) herein.

Performance Requirements for Standard C9

- C9.01 Each separate function and/or content area is defined, documented, and operates in accordance with relevant Content Standards described herein.

Standard C10
An app that contains advertisements clearly identifies the advertising and complies with any and all applicable regulatory requirements, particularly advertisements that involve or relate to products or services that are clinical or related to health.

Performance Requirements for Standard C10

- C10.01 Information in any app that constitutes advertising is denoted by the message "This is an advertisement" or equivalent.
- C10.02 Information in any app that constitutes advertising will at all times comply with all applicable regulatory requirements related to the marketing of any product or service, including, but not limited to those of the FDA, FTC, FCC, and any laws, rules, regulations and policies of other regulatory entities in all jurisdictions that app's owner makes its app available.
- C10.03 App Publisher takes commercially reasonable efforts to clearly and prominently indicate (e.g., in the "About" section) that any advertisement, which may be perceived as health care or medical advice or treatment, is being displayed for the sole purpose of advertising and should not be construed as a substitute for medical or clinical advice.

Standard C11
The content of apps should be written and presented in a manner that is appropriate for the intended audience.

Performance Requirements for Standard C11

- C11.01 The content of an app is designed and written in a way that is appropriate for the target audience (e.g., age, educational background, healthcare professional versus patient or consumer, caregiver, and so forth).

Appendix 1. Acronyms

A number of acronyms are used in this document. The following table provides the full term for each acronym.

Acronym	Full Term
AAMC	Association of American Medical Colleges
BA	Business Associate refers to a person/entity that requires disclosure of ePHI in order to deliver their product/service to or on behalf of a Covered Entity.
BAA	Business Associate Agreement (required in certain circumstances under HIPAA and HITECH [defined below])
CDMA2000	Refers to a family of 3G standards providing high-quality voice and broadband data services over wireless networks
CDS	Clinical Decision Support software
DNS	Domain Name System
EHR	Electronic Health Record (also referred to as EMR – Electronic Medical Record)
FCC	Federal Communications Commission
FDA	U.S. Food and Drug Administration
FTC	Federal Trade Commission
GPS	Global Positioning System (a satellite-based navigation system)
GSM	Global System for Mobile Communications (originally, Groupe Spécial Mobile)
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health
LAN	Local Area Network
MMS	Multimedia Messaging Service
NFC	Near Field Communication
PHI	Protected Health Information
PSTN	Public Switched Telephone Network
SMS	Short Message Service
URI	Uniform Resource Identifier

Mr. WALDEN. Mr. Chodor, thank you for your very good testimony, and that is why we are having this hearing is to try and shine some light and bring some clarity.

Mr. Jonathan Spalter is next. He is the Chairman of Mobile Future. Mr. Spalter, thank you for being here.

STATEMENT OF JONATHAN SPALTER

Mr. SPALTER. And thank you, Chairman Walden, and members of the subcommittee for giving me the opportunity to testify on behalf of Mobile Future and our member companies. My name is Jonathan Spalter and I am Chairman of Mobile Future. We represent innovators across the wireless ecosystem, and I sit before you, I think, at a very, very hopeful time for our community.

It is now believed by many scientists that there has already been a child born in the world who will live to 150 years old. What an exciting notion for our children and our grandchildren. These leaps and bounds in the quantity and the quantity of our lives are in no small part due to the astounding progress we are all witnessing at the nexus that we are talking about today of health care and mobile innovation.

This morning I would like to very focus very practically my comments on what mobile innovators need from government to help us all advance our health. We know that the virtuous cycle of investment in the mobile ecosystem from networks to devices to applications provides an unparalleled foundation for health innovation, and I believe government can help build on it by providing our mobile health innovators four key and achievable certainties. First, a clear understanding of where regulation begins and where it ends. The mobile medical app guidance now has been pending for 2 years. Clear guidelines and regulatory certainty are needed now, commonsense and affordable approval processes that are measured in months, not in years, timely decisions across government that of course encourages a careful balance to safeguard patient safety and privacy on the one hand, which we all care about, without inhibiting the development and use of mobile medical apps, and finally, basic fairness when it comes to the taxes we pay, all consumers pay, on wireless services and applications. Bottom line: Americans would benefit from clear guidelines on when applications go to which government agency and for what set of approvals.

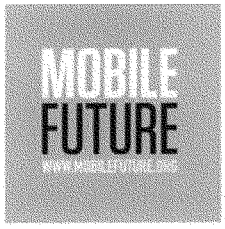
But let us also not forget that none of this progress would be possible without spectrum and without investment, and therefore it is imperative that the incentive auctions, which are being designed now at the FCC, are open and inclusive so that all Americans can take advantage of wireless health applications, and it is also worth noting that the needed spectrum is held by government agencies, significantly held by government agencies, so all of our eyes, all of America's eyes are on the federal agencies who hold much of this underutilized spectrum hoping they will make a meaningful contribution.

I know that all of us can personalize this progress that we are talking about today. My daughter Willa was diagnosed 2 years ago at age 8 with type 1 diabetes. She has been extremely fortunate that from her very first week with the disease to have been in a clinical trial at Stanford University that is pursuing the holy grail

of diabetes research: the artificial pancreas. Even having worked in mobile innovation and technology myself for years, I wasn't prepared, my family wasn't prepared, for just how personally and profoundly relevant mobile innovation would become so quickly to my daughter. On the first day of her trial, there was her endocrinologist, Bruce Buckingham, and her research nurse, Jen Block, explaining the research and the hope that it holds for 3 million Americans who are dealing with this disease. And then Dr. Buckingham, not really knowing what I do for a living, spoke about the importance of spectrum as he explained the wireless sensors that were all around my daughter's hospital room and the wireless glucose monitor that she now wears in her body. The medical team included software coders, application developers, algorithm writers, network engineers, all pushing together towards what could be and I indeed hope will be nothing short of a revolution in diabetes management, and this is the future of American health care. We all have a personal stake in speeding its process, and ultimately this is not about government stepping away, rather it is a profound opportunity for government to lean in and demonstrate that it too can innovate, that it can act flexibly, that it can move quickly with common sense and with the understanding that innovation is born of many, many things including a healthy dose of humility and restraint when it comes to regulation.

So on behalf of application developers and wireless innovators across our country, on behalf of my little girl and the millions of Americans who are managing chronic diseases, I really thank you for the opportunity to testify about our Nation's promising mobile future, and I really look forward to your questions.

[The prepared statement of Mr. Spalter follows:]



TESTIMONY OF JONATHAN SPALTER

CHAIRMAN, MOBILE FUTURE

on

"HEALTH INFORMATION TECHNOLOGIES: HARNESSING WIRELESS INNOVATION"

before the

Subcommittee on Communications and Technology
Committee on Energy and Commerce

UNITED STATES HOUSE OF REPRESENTATIVES
WASHINGTON, D.C.

March 19, 2013

TESTIMONY OF JONATHAN SPALTER

Chairman Walden, Ranking Member Eshoo and members of the subcommittee, thank you for this opportunity to testify on behalf of Mobile Future and its member companies.

My name is Jonathan Spalter, and I am Chairman of Mobile Future, which represents innovators across the wireless ecosystem—from applications developers to device makers to service providers—as well as a range of non-profit organizations which depend on them. We are united in our commitment to advancing a policy environment that encourages the profound mobile investment and innovation we see all around us today.

* * *

Summary

The subject of this hearing—and mobile health generally—is one very close to Mobile Future's mission of fostering a policy environment that supports continued investment and innovation in the nation's mobile ecosystem and the next generation of wireless broadband networks and services. We are very focused on how we as a nation can ensure that innovators and entrepreneurs have the opportunity and incentives they need to develop new services, new applications, and new technologies, and in so doing, create new jobs, grow our economy, and sustain American competitive leadership globally. It is also critical that American citizens can reap the benefits of this innovation.

With respect to mHealth initiatives specifically, we have the additional promise of improving the effectiveness of patient care, empowering Americans to better manage and control their own and their loved ones' health, and radically reducing the cost and increasing the effectiveness of health care delivery in the United States.

My message today is simple:

1. Though still in their infancy, mHealth applications and services already are helping to save lives and improve health care delivery. If properly fostered, mobile entrepreneurs and innovators can help re-invent health care delivery in the years to come as Americans benefit from a more connected life. The virtuous cycle of investment in the mobile ecosystem—from networks, to handsets and tablets, to applications—provides an unparalleled foundation for innovation and advancement in mHealth. First and foremost, we need to ensure our nation's innovators, businesses and consumers will have the wireless spectrum required – now and in the future – to support these powerful and promising new applications.

2. We must find the best way to advance the nation's health and wellness and protect our citizens' safety and privacy without stifling innovation and investment. mHealth innovators – and the millions of Americans they serve – need a clear understanding of where regulation begins and ends, common-sense approval and review processes, low economic barriers to entry, timely decisions reflective of the short development cycle

for mobile applications, and a coherent and cohesive approach across government agencies. In order to succeed, mHealth entrepreneurs also need advanced networks and the regulatory restraint, certainty and speed, that is essential to support the substantial annual private capital investment needed to keep the nation's wireless infrastructure state-of-the-art and capable of keeping pace with fast-rising demand for mobile Internet—driven by consumers, by businesses and the rapidly expanding machine-to-machine connectivity that is certainly a key component of the mHealth renaissance we are enjoying today.

Our World is Going Wireless

Wireless connectivity is increasingly a central part of our everyday lives – from how we work and learn, to how we stay connected to friends and family, and increasingly how we take care of our health, diet and fitness. Overall, wireless innovation supports nearly 3.8 million American jobs today and contributes nearly $200 billion to the economy. One-third of smartphone users in the U.S. already use their mobile device to keep track of things like diet and exercise. For Americans under the age of 35, that number rises to 60 percent. By some estimates there are already 40,000 apps and counting in the broad mHealth category. Venture capitalists so far have invested three-quarters of a billion dollars in early-stage mHealth apps and devices.

These are the early signs of anytime, anywhere healthcare taking hold and this has the significant potential to improve the outcomes of the nation's health care system especially at a time when the U.S. ranks 36th globally in terms of overall health care outcomes, though first in all categories for per capita health care costs and spending. Popular demand for mobile medical applications underscores a market-driven explosion in the use of health information technology in ways that engage consumers and health care providers to enhance care outcomes, promote self-management, improve safety, and lower health costs.

Looking more broadly, it took Apple nine months after its App Store was established five years ago to reach 1 billion total app downloads. By the end of this year, it is estimated that 2 billion apps will be downloaded every single week. This "virtuous cycle" of wireless innovation is the great American success story: app developers from the smallest start-up to now Fortune 500 companies riding on the U.S.'s world-class wireless infrastructure utilizing the best mobile handsets, tablets, and operating systems. The average mobile user today has over 100 mobile apps on smartphones and other devices, and by one estimate, the number of consumer devices with mHealth apps doubled just last year.

Overall, wireless innovation is transforming each facet of our daily lives from education and energy to public safety and civic engagement. Smart Grid, mCommerce, and digital textbooks allow us to re-imagine entire sectors of the economy – with improved efficiencies and exciting opportunities. In the years to come, the Internet of Things – with machine-to-machine connectivity – promises even more advanced mobile functionalities.

mHealth: The Future is Now

Nowhere is that promise of future innovation and opportunity greater than mobile health: from wearable mobile devices that track your activity levels, to using your smartphone to measure your blood sugar and transmit the results to a doctor, parent, or caregiver, and the frontiers of nanotechnology where tiny microchips and digestible antennas can confirm an elderly parent has taken their pills. I could keep going — walking canes that can do everything from provide turn-by-turn directions to alerting your caregiver to an irregular heartbeat, and just this week MIT's Technology Review announced that researchers have found a way to directly print wireless sensors on to our skin — as we could spend days discussing these exciting mHealth advances alone. Our message today is that the innovation and vision exist now in both the medical and technology communities working together collaboratively. This progress will proceed, in many respects, as rapidly as government allows.

And I'm quite certain that each of us can personalize this progress. I have a daughter who two years ago at age 8 was diagnosed with Type 1 diabetes. We are fortunate that she was accepted in her first week with the disease into a NIH-supported clinical trial at Stanford University's Lucile Packard Children's Hospital that is working to pursue the 'holy grail' of diabetes research—the artificial pancreas. Even having worked in the field of mobile innovation for years, I was not prepared for just how personally relevant mHealth – and mobile technology in general – would so quickly become. On the first day of her trial, there was her

endocrinologist, Dr. Bruce Buckingham, and her research nurse, Jen Block, explaining the research and the hope it holds out to the nearly three million Americans living with type 1 diabetes. And then the very same medical researchers began talking about the importance of wireless spectrum, as they explained the mobile sensors and other wireless technologies all around the hospital room.

Their team includes software coders, application developers, algorithm writers, network engineers and other mobile innovators—all pushing together for what could be—indeed I hope will be—nothing short of a revolution in diabetes management. As for my daughter today, and many millions of Americans who courageously will be managing chronic diseases tomorrow, their health – and for many quite literally their lives – will depend on continued innovation in mobile health applications and services.

This is the future of American health care, and we all have a strong, personal stake in supporting it. This is not about the government stepping away. Rather mHealth presents an extraordinary opportunity for our government to instead 'lean in' and demonstrate decisively to our citizens that our lawmakers and our regulators can move judiciously and quickly when it comes to the medical needs of our families – and they can do so with the understanding that innovation is born of many things, including a healthy dose of humility about the role of regulation. In short, when it comes to mobile innovation, our government now has a real moment of opportunity to prove that regulation will never be an "app killer," but a fierce

exponent of and catalyst to the next "killer app" – an app which may well improve our health, prolong our lives, and enhance our wellness.

Indeed, across virtually every metric, mHealth applications hold such great promise to help improve our nation's health care system. By one estimate, connected devices reduce intensive care stays by 17 percent and cut mortality rates by 25 percent. Similar studies have found that the cost of elderly care in rural areas could be reduced by as much as 25 percent with remote wireless monitoring and other mHealth efforts. The cost savings projected can be staggering—$200 billion from remote monitoring alone in the next 25 years.

The FCC's mHealth Task Force found similar savings in health care administration: 30 percent cost savings due to wireless and remote access to health records, and electronic prescriptions could save $29 billion over the next decade. Not surprisingly, given the magnitude of opportunities, the market for mHealth apps is expected to grow by 23 percent annually over the next five years, reaching $26 billion by 2017. This does not even necessarily include countless mHealth apps and services that are available for free to consumers.

Among the tens of thousands of mHealth services and apps available today, I wanted to highlight a handful of start-up companies, and Mobile Future members, that are leveraging technology to improve patient outcomes:

InfieldHealth offers a range of text-based solutions to help patients transition from hospital to home and follow doctors' orders. The delivery of care information straight to a patient's wireless device has been found to result in a 50 percent improvement in reported outcomes.

HealthCrowd provides an individualized messaging service to reduce hospital readmissions and improve daily self-care. Solutions are geared to pulmonary rehabilitation, diabetes management and other chronic illnesses. These solutions have been found to double the likelihood that a patient completes a six month outpatient care program.

Supermechanical's Twine personal home wireless sensors – entirely financed by a crowd-funded Kickstarter initiative – allows, among other things, the families and caregivers of the elderly or infirm to be aware that those under care remain ambulatory in their homes with email or text alerts provided when refrigerators, doors, or even medications are opened.

Voxiva sends regular text-based messages to expectant mothers via its Text4Baby program.

Still other companies are pursuing a host of different solutions: remote monitoring applications, wearable sensors, smart bandages, and video telemedicine solutions. Importantly, solutions are not just for consumers, they are also for clinical professionals. There

is significant ongoing investment in cloud-based secure enterprise services that help provide more integrated clinical solutions. All share the promise of improving the quality of care, reducing costs, and improving citizens' overall experience.

These applications provide the tools Americans need to more actively engage and take control of their own care, and better utilize preventive care solutions. In rural America, mHealth also expands the reach of health care facilities and access to specialists hundreds of miles away. Too many communities do not have the medical care they need, and doctor shortages in underserved communities are an increasing national challenge. mHealth can help patients reduce travel times, improve health outcomes, and substantially reduce the cost of care, both in terms of time and money.

A Balanced Regulatory Framework

We appreciate the subcommittee's commitment – both in holding this hearing as well as its long-standing efforts to advocate on behalf of greater regulatory certainty and clarity. It is essential that our nation have the world's most effective and nimble regulatory framework for mHealth services and applications that protects patient safety and privacy while facilitating continued progress in applying mobile innovation to advancing the nation's health and wellness.

Any discussion of the apps economy and government should begin with the broader mobile ecosystem and the critical role government plays in ensuring there is sufficient spectrum available for mobile broadband use. Here too, the subcommittee has shown great leadership and we thank you for the Spectrum Act and related efforts to help unlock additional spectrum for commercial use.

The ability of mHealth applications to deliver on their promise is entirely reliant on continued investment in – and advancement of – our nation's wireless networks. Thus, as wireless providers seek to invest in more and faster wireless broadband infrastructure (last year alone brought $25 billion in capital investment), Mobile Future shares your view that additional spectrum is critically needed to aid in these efforts.

Mobile data traffic is expected to grow 100-fold over the next 10 years, and all of the mHealth initiatives we discuss today will require strong and scalable broadband networks to keep up this explosion in demand. As this subcommittee understands, strong broadband networks require adequate wireless spectrum capacity. This is an issue that has the government's attention—both in the Administration and at the FCC. We have to move forward in a timely way to achieve the goal set forth in the National Broadband Plan to make significantly more spectrum available to consumers and to the millions of Americans who are turning to their mobile devices to help improve their health.

The FCC is hard at work advancing innovative incentive auctions that aim to make significantly more spectrum available to expand mobile broadband, and we fully support those efforts. It is imperative that these auctions are open and inclusive so all Americans have access to the mobile capacity needed to empower these mHealth innovations. Additionally, much of the spectrum necessary to achieve our objectives is controlled today by the federal government. I applaud the efforts of the Administration and NTIA to transition under-utilized federal spectrum to commercial use, and urge action to move forward quickly to deliver on that promise. It is also imperative that we have a vibrant, flexible and fully functioning secondary market and an efficient and quick-paced regulatory review process supporting it to ensure that already available commercial spectrum is put to consumer use.

It is equally important that health care facilities themselves are connected and we support the FCC's recent effort to expand telehealth networks across the nation through much-needed reform of the Rural Health Care funding program. For mHealth to succeed, doctors and medical professionals themselves cannot be dependent upon dial-up or slow connections at clinics and hospitals. In addition, the FCC has also taken important steps to allow greater use of spectrum for Mobile Body Area Network devices, and has remained vigilant regarding the spectrum needs of other health care services.

With respect to mobile medical applications, my member companies – and hundreds, if not thousands, more potential developers and innovators – have the technological tools to harness 4G networks to improve patients' lives. But they do not always know if their new service or

application will be regulated. Assuring patient safety and privacy is critical, and the government's approach should be tailored to meet those core objectives without stifling innovation.

We can all agree there is a clear cut need for some degree of oversight over clinical treatment, and housing that functionality on a mobile device does not eliminate the need for thoughtful review. All parties in the ecosystem would, however, benefit from a clearer set of guidance on when they go to which government agency and for what set of approvals. The dynamic nature of innovation in mHealth requires a predictable, rapid and transparent approach.

First, we are hopeful that there is limited regulatory duplication and the government will speak with one voice to the greatest extent practicable. The risk of confusion, duplication and jurisdictional overlap is heightened here as old regulatory silos – medical devices regulated at the FDA and communications devices at the FCC – have been blurred, if not eliminated altogether. mHealth solutions also face potential scrutiny from the Federal Trade Commission (FTC), Centers for Medicare and Medicaid Services (CMS), and the HHS Office of the National Controller (ONC). Congress' mandate for a strategic Health IT plan by January 2014, including both the FDA and FCC, is promising. As are efforts within the FCC and FDA to improve collaboration and coordination like the FCC's call for its own health care director, and the FCC mHealth Task Force's recommendation for expanded inter-agency collaboration. We urge clear delineation of regulatory jurisdiction between agencies to help preserve the incentive to innovate.

Second, we hope the FDA will provide much-needed clarity to application providers and developers as to how and when mHealth applications will be regulated and the applicable approval process. The line between medical devices and wellness application is not always clear: When does a health and wellness app become a regulated clinical tool? The Mobile Medical Act (MMA) guidance has been pending since 2011 at the FDA. A clear, predictable, and appropriately tailored regulatory framework for mHealth applications is critical. The MMA was an important first-step to establishing regulations for mobile medical apps, but more work needs to be done to promote greater regulatory certainty. Specifically, the MMA guidance lacks clarity on how the FDA intends to apply its regulatory authority over particular elements and functions of mHealth products and services.

We urge a careful balance to safeguard patient safety and privacy without inhibiting the development and use of mobile medical apps. We are also hopeful that any necessary approval processes are measured in months, not years. It is critical for policymakers to put in place a process to modernize regulations so that health information technologies can keep pace with emerging technology and meet consumer demand. The continued absence of clear and unequivocal guidance on mobile medical applications could jeopardize health IT providers' ability to promptly and flexibly bring innovative products to market

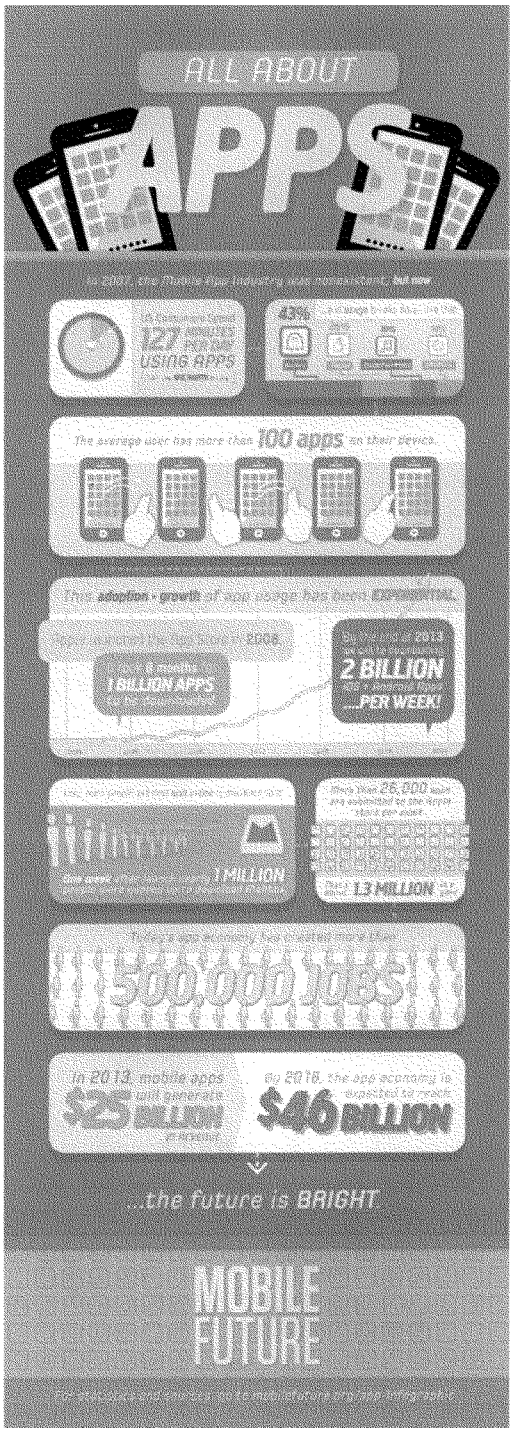
Entrepreneurs and app developers – and the capital markets, financial institutions and venture capitalists supporting them – need predictability and certainty to invest. Added costs – in the

form of onerous and lengthy regulatory review and approval processes, as well as uncertainty or delay – could mean some applications that provide tangible benefits to patients may never be developed, negatively impacting patient welfare. Capital that could otherwise be invested in mHealth may well be diverted to other opportunities in the mobile ecosystem. It is useful to remember that at a time when the average pre-approval clinical trial costs for a medical device range from anywhere from $1 million to $10 million or more, and take from months to years to complete, most applications are offered to consumers for free or at very low cost. I am hopeful we can all work together collaboratively to develop a sensible regulatory framework that best serves patient welfare, keeps barriers to entry low, and helps jump start greater investment in these mHealth solutions that hold so much promise. To put it simply – our government has a real opportunity to provide a constructive policy environment and clear guidelines, so app developers can focus their innovation and genius on improving the health our nation.

I would like to close with a very brief note on the continued excessive and unfair taxation of wireless consumers that hits low-income Americans hardest and frustrates our collective efforts to drive mobile broadband adoption efforts. As has been reported broadly, the average wireless customer is charged a tax rate two and a half times higher than other goods and services. We support bipartisan efforts to curb actions by states and localities to add even additional discriminatory taxes on to wireless consumers, and we urge Congress to watch closely any actions that could result in increased tax burdens at any level on wireless consumers that could limit usage or adoption of innovative mobile services, devices or applications – including for new mobile medical devices.

* * *

Thank you again for the opportunity to testify this morning, and I look forward to your questions and the continued opportunity to work together to help promote innovation and opportunity in the mobile broadband ecosystem.


ALL ABOUT
APPS
127 MINUTES USING APPS
43%
The average user has more than 100 apps on their device.
2 BILLION
...PER WEEK!
1 MILLION
1.3 MILLION
500,000 JOBS
in 2013, mobile apps will generate
$25 BILLION
by 2018, the app economy is expected to reach
$46 BILLION
...the future is BRIGHT.
MOBILE FUTURE

Mr. WALDEN. Mr. Spalter, thank you for sharing your very powerful story with us. It really sheds clear light on our task here, and of course, it also shows that we are the most important subcommittee in the Congress because we did make available new spectrum and we are continuing to pursue the government excess spectrum as we might find.

Mr. SPALTER. And that has the added advantage of being true, Mr. Chairman.

Mr. WALDEN. Thank you. You are welcome to come back on a weekly basis. Seriously, thank you very much and thanks for the work you are doing.

We will now go to Dr. T. Forcht Dagi, I believe, MD, MPH, DmedSC—I will let you explain all of those things—Partner at HLM Venture Partners. We are delighted you were able to get another flight and get down here from Boston. Thank you very much. Go ahead and push that button in front of you there.

STATEMENT OF T. FORCHT DAGI

Dr. DAGI. Thank you, Mr. Chairman. Chairman Walden, Ranking Member Eshoo, members of the subcommittee, I am Dr. T. Forcht Dagi. I am a Partner of HLM Venture Partners based in Boston, Massachusetts, and San Francisco, California. I am a board-certified neurosurgeon trained at Johns Hopkins and the Massachusetts General Hospital and hold or have held leadership positions in clinical and academic medicine for over 20 years. I am Chair of the Committee on Perioperative care of the American College of Surgeons at present, and I hold a professorial appointment at Harvard Medical School.

On behalf of HLM Venture Partners, the venture industry and the entrepreneurial community, and also as a physician devoted to the betterment of health care, it is my privilege to testify before this committee on the subject of mobile medical apps, MMAs.

Venture capitalists are committed to the funding of American's best and most innovative entrepreneurs. They work closely to transform breakthrough ideas and to emerging growth companies that drive job creation and economic growth in the United States.

One of the top priorities for health care and life science investors is to work and discover innovative solutions that address unmet medical needs, enhance health care outcomes and lower overall health care costs while preserving the safety and the quality of the American health care system.

For investment to grow in the formative stages of emerging medical mobile applications, there need to be well-defined regulatory pathways to market. Uncertainties in the regulatory environment create significant risk for innovative companies and deter investment in many promising ideas. We believe that regulatory pathways should be risk based, transparent, consistent, predictable, and above all, balance the problem of patient safety and its protection against innovation.

I believe that medical mobile applications will prove to be a central, important, and potentially critical tool in optimizing communications among clinicians, and especially between clinicians and patients. Also, they will help broaden and sustain shared decision making, which is a critical part of any type of health care reform.

I believe that MMAs will prove invaluable for patient engagement in education. They can materially enhance integrated strategies for health care, help coordinate the management of chronic disease and promote patient safety while lowering health care costs. Here are some examples of the critical roles they already play. They are used to help diabetics follow and refine insulin regimens. Mr. Spalter, I didn't know you were going to speak to that. Thank you. They are used to screen for diseases of the retina, for telemedical consultations, to help patients with congestive heart failure avoid readmission, to diagnose moles and screen for cancer, and to coordinate across groups of physicians in different institutions. They provide a means for sending sentinel emergency alerts to providers. They also facilitate home health care and remote monitoring of patients in other settings like the intensive care unit. They hold tremendous promise in patient care, and I emphasize, safety.

I would also like to emphasize my concern about the 2.3 percent medical device tax with regard to medical innovation and U.S. job creation. We also believe Congress did not intend to burden the emerging MMA companies with this new tax. Their products are not included in the traditional medical devices. The 2.3 percent tax on revenue has already started to have detrimental effects on early-stage medical device companies. They are regressive and repressive. It creates a major market inefficiency by increasing the capital intensity of innovation and discourages venture capitalists from investing in these companies now and in the future. The tax would be even more devastating for companies developing MMAs because of their revenue structure.

The tax of 2.3 percent sounds modest but it is not. This is a tax on revenue. It is not a tax on profits. The vast majority of entrepreneurial ventures developing MMAs are very small and very early. Some of the companies in which we invest may in fact generate some revenue but very unlikely to generate profit. Revenues are plowed back into the company for growth, and therefore the 2.3 percent tax on small startup companies delays their ability to reach profitability and increases the amount that must be invested before a company can become cash flow positive.

Venture capitalists and entrepreneurs stand ready to participate, along with other public and private stakeholders, to find solutions that will help move these important innovations into the health care system. We would like to offer the following recommendations to help stimulate investment in this very important sector.

First, promote a regulatory framework that is predictable, consistent, transparent and risk based. The Food and Drug Administration issued draft guidance for mobile medical applications on the 21st of July 2011. This guidance addresses some regulatory concerns and reduces some regulatory uncertainty but leaves open questions around enforcement discretion decisions. The uncertainty must be resolved. Second, the FDA and other stakeholders are encouraged to collaborate and formulate alternative oversight frameworks that meet the goals of patient safety and mobile medical applications, but also encourage and foster innovation and invention. Third, we would ask that the FDA solicit very broad input in evaluating new regulatory frameworks, especially from those at the forefront of the innovation that promotes health care transformation.

And finally, we would ask that mobile medical applications that are defined as medical devices be exempted from the 2.3 percent medical device tax.

Mr. Chairman, Member Eshoo, members of the subcommittee, thank you for the opportunity to testify. I look forward to working with you to address these critical issues.

[The prepared statement of Dr. Dagi follows:]

Testimony of

T. Forcht Dagi, MD, MPH, DmedSc
HLM Venture Partners

on the

Health Information Technologies: Harnessing Wireless Innovation

before the

U.S. House of Representatives
Committee on Energy & Commerce
Subcommittee on Communications and Technology

March 19, 2013

Introduction

Chairman Walden, Ranking Member Eshoo and members of the Subcommittee, I am Dr. Teo Forcht Dagi, Partner of HLM Venture Partners, based in Boston, MA. I am a board certified neurosurgeon trained at Johns Hopkins and the Massachusetts General Hospital. I hold a professorial appointment at Harvard Medical School and served as President of the Georgia Neurosurgical Society and as a Director of the American Association of Neurological Surgeons. I also sit on the steering committee of the Harvard-MIT Program in Biomedical Entrepreneurship, and was a director of the Goergen Institute for Entrepreneurship at the Wharton School of the University of Pennsylvania. I also chair the Committee on Perioperative Care for the American College of Surgeons and serve as a director and officer of the Council for Surgical and Perioperative Safety and a director of the Anesthesia Patient Safety Foundation.

Prior to joining HLM, I raised a venture capital fund focused on very early stage ventures in the Southeast. By investing $17 million in 11 early stage companies focused on healthcare and the life sciences, the fund yielded over a 300-fold increase in value. It participated in the development of drugs and devices that benefit millions of patients world-wide and created numerous new jobs.

HLM Venture Partners is a leading dedicated health care venture capital firm providing over $400 million in capital to some of the most dynamic, innovative companies nationwide. HLM is focused on building sustainable, profitable companies to the advantage of patients, healthcare professionals, entrepreneurs and investors in the Health Care Information Technology, Health Care Services and Medical Device sectors. HLM was established in 1983 and qualifies as one of the most experienced healthcare funds in the industry. Because of its experience and its focus, it is uniquely positioned to provide insightful guidance on a range of health care industry issues. We take pride in partnering with exceptionally talented entrepreneurs and with strategic partners from the industry to develop emerging companies. Over the course of my 15 year venture capital career, which overlaps with over 30 years in the practice of clinical and academic surgery, I have worked side-by-side with entrepreneurs to create and finance many start-ups.

In addition to representing HLM Partners and its portfolio companies, I also am testifying on behalf of the National Venture Capital Association (NVCA) based in Arlington, Virginia. NVCA represents nearly 400 U.S. venture capital firms and empowers its members and the entrepreneurs they fund by advocating for policies that encourage innovation and reward long-term investment.

On behalf of HLM Venture Partners, the venture industry and entrepreneurs, it is my privilege to share our perspective on the current state of investment in the Health Information Technologies and Health Care Services Sectors and how emerging technologies are positioned to improve patients' access to better

health care, achieve improvements in patient outcomes, provide greater efficiencies and drive down costs in the overall healthcare system.

Venture Capital Plays a Key Role in Innovation

According to a 2011 IHS Global Insight report, companies that were founded as small start-ups with venture capital accounted for 12 million jobs and $3.2 trillion in revenues in the United States. These figures equate to 11 percent of private U.S. employment and 21 percent of our country's GDP.

Venture-backed companies are responsible for the creation of entire industry sectors here in the United States including semiconductors, biotechnology, Internet content and software. Today, we are creating the companies that will serve as cornerstones for cloud-based computing, internet security, healthcare, social media and new energy. Many companies founded with venture capital are household names today, including Apple, Genentech, Starbucks, Facebook, Home Depot and FedEx. With more than 18,000 companies having received venture funding in the last five years, the next generation of successful companies innovating in healthcare, the life sciences, high technology, and new energy are poised to follow in their footsteps.

The Healthcare and Life Sciences sectors account for 25 percent of all venture capital (VC) dollars invested. The majority of dollars are invested in the biopharma (60%) and medical devices (26%) sectors. A smaller portion is invested in the Health Care Services and Health Care Information Technology (4%). (PwC/NVCA Money Tree Report based on Thomson Reuters)

Venture capitalists are committed to funding America's best and most innovative entrepreneurs. They work with them closely to transform breakthrough ideas into emerging growth companies that drive job creation and economic growth in the United States. One of the top priorities for healthcare and life sciences investors such as myself is to work with healthcare focused entrepreneurs to develop new treatments and technologies for patients and discover innovative solutions that address unmet medical needs, enhance healthcare outcomes, and lower overall healthcare costs without compromising the safety and the quality of the American healthcare system.

For investment to grow in the formative stages of emerging medical mobile applications, which, as a group, stand to make a significant contribution to these goals, there need to be well defined pathways to market that balance patient safety and efficacy with rewards for undertaking investment risk in healthcare innovation. Uncertainties in the regulatory environment create significant risk for investors and deter investment in many promising ideas. We believe that regulatory pathways should be risk-based, transparent, consistent and predictable.

Bringing Promise to our Healthcare System

I believe that medical mobile applications (MMAs) will prove to be a central, important and potentially critical tool in optimizing and integrating communications among clinicians and between clinicians and patients, and will help broaden and sustain shared decision making. MMAs will prove invaluable for patient engagement and education and have the potential to materially enhance integrated strategies for patient care, coordination of the management of chronic disease, improve healthcare outcomes, promote patient safety, and lower healthcare costs. In fact, MMAs are already playing a critical role in patient care. MMAs are in development and in use to help diabetics follow and refine their insulin regimens; to screen for diabetic disease of the retina; for telemedical consultations in remote areas; to help patients with congestive heart failure avoid readmission; to diagnose moles and screen for melanoma; to exchange diagnostic images and obtain consultations; and to coordinate and integrate care across groups of physicians in different institutions. MMAs also provide a means for sending sentinel alerts to providers. They help patients adhere to medication protocols. They facilitate home health care as well as remote patient monitoring in other settings, like the intensive care unit. All in all, MMAs hold tremendous promise with respect to improving patient safety, increasing the quality of care and helping to contain the costs of delivering effective healthcare.

The Medical Device Tax is Impacting Investment in Health Care Innovation

I would like to also express my concerns about the medical device tax is having regarding medical innovation and U.S. job creation. MMAs that are listed as a device with the FDA under section 510(j) of the Federal Food, Drug and Cosmetic Act, and 21 CFR part 807, pursuant to FDA requirements are subject, under the provision of the Accountable Care Act (ACA), to a 2.3% medical device excise tax on revenues. The tax is intended to raise approximately $30 billion to help pay for the implementation of the ACA.

As you know, there was a lengthy debate during the ACA legislative deliberations regarding which products should pay the 2.3% tax. We believe Congress did not intend to burden emerging MMA companies with this new tax since their products aren't included in "traditional" medical devices. The 2.3% tax on revenue has already started to have a detrimental effect on early stage medical device companies. It creates a major market inefficiency by increasing the capital intensity of innovation, and affects the ability of venture capitalists to invest in these companies in the future. This tax would be even more devastating for companies developing MMAs.

The tax of 2.3% sounds modest, but is it not. This is a tax on revenue, not profits. The vast majority of entrepreneurial ventures developing MMAs are very small and very early start-up companies. Most of the

companies in which we invest may generate some revenue, but likely not profit. Revenues are plowed back into the company for development and for growth. Therefore, the 2.3% tax on small start-up companies delays their ability to reach profitability and increases the amount that must be invested before a company can become cash flow positive.

Even when profitability is attained, a company in this space might deliver profits of no more than 10% of revenue. A tax of 2.3% on revenue at that stage is the equivalent of a 23% tax on profits, over and above the corporate state and federal income tax companies are already obligated to pay. The effect on after-tax profits is material and severe. This tax dramatically reduces after tax profits. Correspondingly, it chokes the company, and can be expected to reduce the value of the company to prospective acquirers or public market investors. Thus, as you can see, more has to be invested for a smaller return, reducing the incentive for investors to support high risk, early stage companies working to bring important and innovative solutions to patients with unmet medical needs, and depriving the healthcare system of valuable tools and expedients. Rather than growing and creating new jobs, companies will be increasingly and unreasonably constrained. To pay the tax, they must cut R&D budgets and cut jobs.

As we have noted, these early-stage companies form the core of the ecosystem that has resulted in leading and sustainable medical innovation and in a brilliant American success story for patients and the economy alike.

We believe MMAs that are defined as medical devices should be exempted from the medical device tax. And more generally, we believe that Congress should repeal the entire tax because of the impact it is having on emerging growth companies that are focused on fueling medical innovation and job creation.

Recommendations to help drive investment in Health Care Services

Venture capitalists and entrepreneurs stand ready to participate, along with other public and private stakeholders, to find solutions that will help move these important innovations into the health care system. We would like to offer the following recommendations to help stimulate investment in this important sector.

- Promote a regulatory framework that is predictable, consistent, transparent and risk-based. The Food and Drug Administration (FDA) issued draft guidance for mobile medical applications on July 21, 2011 that addresses some regulatory concerns and reduces some regulatory uncertainty, but leaves open questions around enforcement discretion decisions. FDA's delay in finalizing this guidance document has had deleterious effects on the industry. It has prolonged ambiguity, impaired the ability of investors and innovators to evaluate regulatory risk, and discouraged investment. The lack of definitive guidance has

also affected the consistency of decisions made within the FDA by its reviewers. We also note that the FDA has broad discretion with respect to enforcement decisions that determine the regulatory status of MMAs--whether they are listed as medical devices and whether they are subject to the 2.3% excise tax. The FDA should publish final guidance documents regarding MMAs in order to shrink the grey area into which many of these applications fall. Publication will serve to reduce the current state of procedural and regulatory ambiguity, and relieve at least some of the burden of liability for the medical device excise tax. We believe there should be a risk-based approach to regulating mobile medical devices that balances protecting patient safety with fostering innovation. The regulatory environment should be rational, transparent, consistent and predictable.

- FDA and other stakeholders should collaborate and formulate alternative oversight frameworks that meet the goals of patient safety in mobile medical applications, but also encourage and foster innovation and invention. While the FDA remains the gold standard in the protection of patient interests, with unique credibility and expertise, it is essential that the pace of regulation keep up with the pace of innovation. Both are critical. Nevertheless, in order to address the healthcare challenges facing our nation, we must ensure that proposed alternatives to regulation of mobile medical devices by the FDA are feasible in today's resource-constrained environment, that they do not lead to duplicative or increased regulation, and that they neither slow innovation and nor create confusion through the implementation process.

- Solicit broad input, in evaluating new regulatory frameworks, especially from those at the forefront of innovation that promotes healthcare transformation. We are pleased that a working group is being convened to aid the Secretary of Health and Human Services in formulating a strategy and recommendations for an appropriate, risk-based regulatory framework pertaining to health information technology, including MMAs. Given the importance of this task and the need to optimize future applications of health IT, we encourage the Secretary to gather input through public forums beyond this working group so that all stakeholders might be heard.

- Medical mobile applications that are defined as medical devices should be exempted from the 2.3% medical device tax.

Thank you for the opportunity to testify. I look forward to working with you to address these critical issues.

Mr. WALDEN. Dr. Dagi, thank you very much for your very learned testimony.

We will now go to Dr. George Ford, who is the Chief Economist, Phoenix Center for Advanced and Legal Economic Public Policy Studies. Dr. Ford, we are delighted to have you. Please go ahead with your testimony.

STATEMENT OF GEORGE FORD

Mr. FORD. Chairman Walden, Ranking Member Matsui and members of the committee, thank you for the invitation to speak today and appear before this committee again.

At issue in this hearing is the role of FDA oversight in health-related applications for mobile devices and the platforms on which they run. MHealth applications are believed to have great potential to promote better health and improve the efficiency of the health care system. MHealth can also help address the documented health in lower-income segments of the population where the provision of health services and treatment compliance can be challenging. In my testimony today, I touch upon a couple of thoughts about the possible regulation of mobile applications and platforms as medical devices by the FDA.

First, by its very nature, regulatory intervention into mHealth by the FDA will have direct implications for the Nation's mobile communications industry. Mobile applications, mobile devices and mobile networks are all part of the mobile communications ecosystem. In a greater or lesser degree, to touch one, is to touch them all. United States mobile industry is a true American success story, and the mobile app economy is said to employ about a half a million persons. Many believe that the continued growth in the mobile sector, both in size and innovative capacity, is critical for the U.S. economy. One study suggests that the diffusion of new technology and mobile wireless communications supports about 400,000 jobs annually, and the billions invested annually in mobile and fixed networks supports and creates hundreds of thousands of jobs.

Accordingly, regulating mobile applications is not only a health care issue but a much broader economic one. The difference between a good decision and a bad decision regarding the FDA's regulation of the mobile sector may have significant economic impacts. Indeed, economic theory and ample literature demonstrate that the inevitable and arguably intended effect of FDA involvement is to raise the cost of innovation, to alter the trajectory of innovation, to reduce competition and to favor larger firms that can afford the overhead of dealing with a federal regulatory agency. In a tradeoff with efficiency and efficacy and safety, these negative effects may be acceptable. Gains from improvements in safety and quality may be sufficient to offset the lost innovation and higher prices from less competition. Normally, the cost-benefit tradeoff is limited to the health sectors, but in the mobile ecosystem, the FDA's intervention could spill over into the entire mobile broadband industry. The dangers are significant, and I applaud this committee for taking this matter seriously.

Second, while the scope of the FDA's regulation of mHealth is a complex issue on its own, the decision is made ever more complex by the Affordable Health Act's medical device excise tax. Regula-

tion and taxation are completely different questions, and there is no reason to believe, and every reason to suppose, that the proper methodologies for choosing when is appropriate or not will be quite different in scope and severity. Taxes may or may not raise revenues, but taxes always discourage the activity being taxed and play no apparent role in ensuring the safety of the product being sold. Yet the role of the FDA in assessing mobile health applications cannot be treated today as independent of the tax question since defining applications medical devices may very well lead to the taxation of such applications under the Affordable Health Act.

In addition, given health disparities for low-income Americans and given the expectation that mHealth will be particularly effective with low-income Americans, the medical device tax may prove to be a regressive tax.

Moreover, the medical device can be described, or what I describe as, a virtue tax. Normally, the government applies taxes to items it wants people to consume less of, that is, sin taxes. The medical device tax, in contrast, applies to items a government agency has declared to be good for people. If we want innovation to drive a healthier America, then why tax such innovation? It doesn't seem to be very good policy, perhaps doing more harm than good.

Finally, and perhaps most significantly, I believe the FDA's draft guidance leaves the door wide open for inserting the FDA into the innovation flow of mobile handsets, tablets and other devices, or what we refer to as platforms. There are good reasons to believe that formal role for the FDA in the mobile handsets and tablets would significantly curtail the pace of innovation in that sector, an innovative pace that is rapid and highly beneficial. My written testimony discusses this concern in detail.

A critical question is: could a regulator or tax collector, or even an overzealous regulator or tax collector, make a legally defensible argument that these general purpose devices, or even the entire mobile network, are medical devices and thus subject to regulation or the medical device tax? In an ecosystem like the wireless industry where all the components are tightly intertwined, where does the line get drawn on what is and what is not a medical device? Obviously, clarity is needed, and there needs to be some limitations on the scope of the FDA's reach, lest regulation and taxation become very broad in a mobile ecosystem and do significant damage to innovation in the sector.

Mr. Chairman, thank you again for the invitation to testify today. I welcome any questions.

[The prepared statement of Mr. Ford follows:]

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Written Statement of

George S. Ford, PhD

Chief Economist

Phoenix Center for Advanced Legal & Economic Public Policy Studies

Before the

House of Representatives

Committee on Energy and Commerce

Subcommittee Communications and Technology

Hearing on

"Health Information Technologies:

Harnessing Wireless Innovation"

March 19, 2013

Testimony of George S. Ford, PhD

Chief Economist, Phoenix Center for Advanced Legal & Economic Public Policy Studies

House Committee on Commerce and Energy Subcommittee on Communications and Technology

Hearing on "Health Information Technologies: Harnessing Wireless Innovation"

March 19, 2013

I. Introduction

Mr. Chairman, Ranking Member Eshoo, and members of the Subcommittee, good morning and thank you for inviting me to testify once again before the Committee today.

My name is George S. Ford, and I am the Chief Economist of the Phoenix Center for Advanced Legal and Economic Public Policy Studies. I hold a Ph.D. in Economics from Auburn University, and the economics of the communications industry has been the focus of my career. Prior to joining the Phoenix Center full-time, I worked at the Federal Communications Commission as well as for several companies in the telecommunications industry. I have written numerous research studies that explore this industry, and many of these studies were subsequently published in peer-reviewed academic journals, books and other academic outlets. Recently, my work has evaluated

the effect of Internet use on health outcomes, and the results reveal the potential for the Internet to improve the health of Americans and reduce healthcare expenses.[1] I am pleased that the Sub-Committee has asked for my insight on the issue of health information technologies.

By means of introduction, the Phoenix Center is a non-profit 501(c)(3) organization that studies broad public policy issues related to governance, social and economic conditions, with a particular emphasis on publishing academic-quality research about the law and economics of regulated industries. Among other activities, the Phoenix Center publishes a PUBLIC POLICY PAPER SERIES, a POLICY BULLETIN SERIES, a POLICY PERSPECTIVES SERIES, and our blog @LAWANDECONOMICS, where we provide real-time comment on current events, as well as to highlight market examples of the relevancy of our research. We also sponsor Congressional briefings, Policy Roundtables, educational retreats, as well as our Annual U.S. Telecoms Symposium. The Phoenix Center makes it a policy not to endorse or support any particular piece of federal or state legislation or proposed rule. Our primary mission is not to tell you *what* to think about an issue but *how to think* about it. As such, our contributions to communications policy are decidedly more analytical than most, and we refuse to ignore the institutional realities and economic constraints of the communications business and related sectors

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[1] *See, e.g.*, George S. Ford and Sherry G. Ford, *Internet Use and Depression Among the Elderly*, 23 PHOENIX CENTER POLICY PAPER NO. 38 (October 2009) (available at: http://www.phoenix-center.org/pcpp/PCPP38Final.pdf) and published as 28 COMPUTERS IN HUMAN BEHAVIOR 496 (2012).

including the health care industry. I have attached to my testimony a bibliography of our work, all of which is available at www.phoenix-center.org.

II. Summary of Testimony

My testimony today consists of three basic parts: First, I point out that in any discussion of regulatory intervention by the FDA into mHealth, we must remember that this intervention will have a direct effect on the broader U.S. mobile industry. Second, I explain that not only could regulation of mHealth slow down the rate of innovation and growth of the wireless industry, but mHealth regulation of mobile devices could also trigger the 2.3% medical excise tax required by the Affordable Care Act, which could also slow innovation and, worse yet, impose a regressive tax on those Americans who could most benefit from the efficiencies and breakthroughs created by mHealth. Given the nature of regulation, the costs to innovation and competition may not be offset by improvements in safety and efficacy. Finally, I would like to highlight some of the specific language in the FDA's 2011 *Draft Guidance* that I believe an over-zealous regulator or tax collector could use to make a legally-defensible argument that mobile handsets, tablets and other devices, or even the entire mobile network, was a medical device and thus subject to regulation or the medical device tax.

III. Background

At issue in this hearing is the role of FDA oversight of health-related applications for mobile devices, commonly referred to as (or included in the class of) "mobile-Health" or "mHealth." Mobile health applications are believed to have great potential to promote better heath care through improved communications between doctors and

patients, better decision-making by health professionals and patients, the encouragement of active and healthy lifestyles, and better access to medical and health information. mHealth also promises to improve the efficiency of health care operations and thus reduce the costs of providing health care to Americans. While much attention is directed at the benefits of mHealth in less advanced economies,[2] the use of mobile telecommunications in health care is rapidly growing in advanced economies. Patient monitoring systems alone are expected to be a $21 billion market by 2016.[3] Even in advanced economies, mHealth can help address the documented health disparities in lower-income segments of the population where the provision of health services and treatment compliance can be challenging.[4]

In this set of hearings, I am certain you will hear of the many actual and potential benefits of mHealth technologies. Suffice it to say that the present and future benefits derived of mHealth are (for now) not much disputed and potentially large, though there are challenges in widespread and effective implementation.

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[2] World Health Organization, *eHealth Tools and Services: Needs of Member States* (2005) (available at: http://www.who.int/kms/initiatives/tools_and_services_final.pdf); Vital Wave Consulting, *mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World* (2009) (available at: http://www.unfoundation.org/news-and-media/publications-and-speeches/mhealth-for-development-mobile-technology-for-healthcare.html).

[3] N. Versel, Wireless patient monitoring to be $20.9B business in U.S. by 2016, MOBIHEALTHNEWS (July 18, 2012) (available at: http://mobihealthnews.com/17951/wireless-patient-monitoring-to-be-20-9b-business-in-u-s-by-2016).

[4] *CDC Health Disparities and Inequalities Report – United States, 2011*, Center for Disease Control and Prevention, 60 MORBIDITY AND MORTALITY WEEKLY REPORT (January 14, 2011) (available at: http://www.cdc.gov/mmwr/pdf/other/su6001.pdf); B.D. Smedley, *Addressing Racial and Ethnic Health Care Disparities*, Testimony to the House Energy and Commerce Committee, Health Subcommittee (March 2009) (available at: http://www.jointcenter.org/hpi/sites/all/files/Smedley%20testimony.pdf).

By its very nature, a discussion of the regulatory intervention into mHealth by the FDA has direct implications for the nation's mobile communications industry. Mobile applications, mobile devices, and mobile networks are all part of the mobile communications ecosystem. The United States mobile wireless industry is a true American success story. As FCC Chairman Julius Genachowski just testified before your colleagues in the Senate Commerce Committee earlier this month, the United States has as many LTE subscribers as the rest of the world combined.[5] Moreover, Mr. Genachowski further testified that while mobile infrastructure investment in Europe and Asia has been roughly flat since 2009, annual mobile investment in the U.S. is up 40% over this period.[6] And, according to statistics compiled by CTIA—The Wireless Association, not only does the U.S. wireless industry directly/indirectly employ more than 3.8 million Americans, which accounts for 2.6% of all U.S. employment, but these wireless employees are paid 65% higher than the national average for other workers. Finally, and particularly germane to my testimony today, CTIA reports that the "mobile app" economy employs 519,000 developers and related jobs, and grew from almost zero to nearly $10 billion in four years.[7]

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[5] Prepared Statement of FCC Chairman Julius Genachowski Before the United States Senate Committee on Commerce, Science, and Transportation, "Oversight of the Federal Communications Commission" (March 12, 2013) at 1 (available at http://transition.fcc.gov/Daily_Releases/Daily_Business/2013/db0312/DOC-319476A1.pdf).

[6] *Id.*

[7] CTIA, *50 Wireless Quick Facts* (available at: http://www.ctia.org/media/industry_info/index.cfm/AID/10377); M. Mandel, *Where the Jobs Are: The App Economy,* TECHNET (February 7, 2012) (available at: http://www.technet.org/wp-

Footnote Continued...

Many believe that the continued growth in the mobile sector, both in size and innovative capacity, is critical for the U.S. economy. The deployment of new mobile technologies brings significant benefits. For example, last year a study—*The Employment Effects of Advances in Internet and Wireless Technology: Evaluating the Transitions from 2G to 3G and from 3G to 4G*—considered the impact of progress in mobile technology on jobs.[8] This study reports that the investment in mobile network upgrades, and the resulting adoption of smarter devices and the apps that ride on them, have stimulated significant job creation in the US. Indeed, the authors of the study conclude, the "shift from 2G to 3G Internet and wireless network technologies led to the creation of nearly 1.6 million new jobs across the United States, between April 2007 and June 2011—even as total private sector employment fell by nearly 5.3 million positions." Based on computations using their estimated relationship between employment and wireless technology diffusion, the authors conclude that the advancement of wireless technology created

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content/uploads/2012/02/TechNet-App-Economy-Jobs-Study.pdf); M. Mandel and J. Scherer, *The Geography of the App Economy*, CTIA: The Wireless Association (September 20, 2012) (available at: http://files.ctia.org/pdf/The_Geography_of_the_App_Economy.pdf); *Creating Jobs Through Innovation*, Apple (available at: http://www.apple.com/about/job-creation); *but c.f.*, D. Streitfeld, *As Boom Lures App Creators, Tough Part is Making a Living*, NEW YORK TIMES (November 17, 2012) (available at: http://www.nytimes.com/2012/11/18/business/as-boom-lures-app-creators-tough-part-is-making-a-living.html?pagewanted=2&hp&_r=0).

[8] R. Shapiro and K. Hasset, The Employment Effects of Advances in Internet and Wireless Technology: Evaluating the Transitions from 2G to 3G and from 3G to 4G (January 2012) (available at: http://ndn.org/sites/default/files/blog_files/The%20Employment%20Effects%20of%20Advances%20In%20Internet%20and%20Wireless%20Technology_1.pdf.

about 400,000 jobs annually (1.585 million jobs over about four years). This is a big number, which is a good thing given current economic conditions.[9]

Accordingly, regulating mobile applications is not only a healthcare issue but a much broader economic one. Healthcare and information technology, as well as related industries such as retail and manufacturing, are significant economic sectors upon which the growth of the U.S. economy depends. The difference between a good decision and a bad decision regarding the FDA's regulation of the mobile sector may have significant economic impacts. I commend this Committee for taking this issue seriously.

IV. Discussion

A. *The Law of Unintended Consequences*

The "app economy" is a fast growing segment of the U.S. economy. Health-related applications are a significant part of this growth and offer significant promise for improved health care. Perhaps billions of dollars are at stake. In some cases, these medical applications can directly and materially influence health outcomes. Naturally, concerns have arisen regarding the largely unregulated nature of these mobile health applications. In July 2011, the FDA issued a *Draft Guidance* on how the agency plans to

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[9] Similar results are found in T.R. Beard, G.S. Ford, and H. Kim, *Jobs, Jobs, Jobs: Communications Policy and Employment Effects in the Information Sector*, PHOENIX CENTER POLICY BULLETIN No. 25 (October 2010) (available at: http://phoenix-center.org/PolicyBulletin/PCPB25Final.pdf). Mobile Internet use has also been shown to have a large and statistically significant effect on sustaining active job search, cutting in half the probability an unemployed person abandons efforts to find new employment due to discouragement about labor market prospects. In fact, mobile use reduces labor market discouragement even more than broadband use at home. G. Ford, *Mobile Broadband and Job Search: An Empirical Test*, PHOENIX CENTER POLICY PERSPECTIVE NO. 11-05 (2011) (available at: http://www.phoenix-center.org/perspectives/Perspective11-05Final.pdf).

regulate, or not, mobile medical applications as medical devices.[10] Many praised the effort as a solid first step, but many questions remain as the guidance lacked specificity and clarity. It appears the industry is ready for further guidance. As noted in the Federal Communications Commission's *National Broadband Plan*, the "[p]otential lack of clarity about the appropriate regulatory approach to these convergent technologies threatens to stifle innovation, slow application approval processes and deter adoption."[11]

Without doubt, the scope of the FDA's regulation of mobile health applications is a complex issue on its own. Unfortunately, the regulatory decision is made even more complex by an important side effect of the regulation: specifically, the proper definition of a "medical device" for purposes of FDA regulation also affects the taxation of such devices under the Affordable Care Act ("ACA"), which levies a 2.3% excise tax on medical devices (subject to some exclusions). It is tempting to assume that a single operative definition of a medical device will do for both regulation and taxation. I urge Congress to resist this temptation. Regulation and taxation are completely different questions, and there is no reason to believe, and every reason to suppose, that the proper methodologies will be quite different in scope and severity. The taxation requirements are not insignificant, and economists would broadly agree that such taxes will reduce

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[10] U.S. Department of Health and Human Services, Food and Drug Administration, *Draft Guidance for Industry and Food and Drug Administration Staff, Mobile Medical Applications* (June 11, 2011) (available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)

[11] *National Broadband Plan: Connecting America*, Federal Communications Commission (March 2010) (available at: http://www.broadband.gov/download-plan) at 207.

the introductions of new devices by lowering the returns the innovator can expect from them. Taxes may (or may not) raise revenues, and they always discourage the activity being taxed, but they are not very useful means of assuring the safety of the product being sold. Yet, the role of the FDA in assessing mobile health applications cannot be treated today as independent of the tax question, since defining applications as "medical devices" may very well lead to the taxation of such applications under the ACA. I examine the distinct issues of regulation and taxation on the mobile industry next.

1. *The Potential Effects of FDA Regulation on the Mobile Industry*

Many (but not all) believe that the regulation by the FDA of medical devices lies squarely within the sphere of FDA's traditional function of assuring the safety and efficacy of medical goods. Agreement on the specifics of the regulatory approach is not, however, universal. Some believe that the FDA should play no role in regulating medical applications, while others believe a balanced, risk-based framework is better for both consumers and the industry. Whichever side one takes, most agree that FDA regulation has implications not only for safety, but also for innovation and competition.

An inevitable and arguably intended effect of FDA involvement is to raise the cost of innovation and to alter the trajectory of innovation. Uncertainty, delays and the fixed costs related to the regulatory process reduce expected returns, and thus

discourage firms from participating in the healthcare industry.[12] As such, we must expect FDA review of mobile applications to slow innovation and to reduce competition. Also, the fixed cost of compliance will likely reduce participation in the market by small firms that cannot afford the overhead of dealing with a federal regulatory agency. As such, the regulations will likely favor large, incumbent firms that already have such apparatus in place. Given the nature of the app economy, where small firms are common, FDA oversight could materially alter the structure of the industry.

In a trade-off with efficacy and safety, these negative side effects may be acceptable. Improvements in safety and quality have benefits, and these gains may be sufficient to offset the lost innovation and higher prices from less competition. This trade-off is affected by the nature of the regulation. A risk-based approach to the problem, which is what is outlined in the *Draft Guidance*, is arguably a sensible approach. The devil is in the details, however, and those details remain unspecified. Regardless of the level of intervention, the industry will evolve into something different.

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[12] In one case, the FDA approval of a mobile application took two-and-one-half years and costs the applicant hundreds of thousands of dollars. J. Stossel, *The FDA Kills: How Government Regulations Raise Prices and Stifle Medical Innovations*, REASON (November 10, 2011) (available at: http://reason.com/archives/2011/11/10/the-fda-kills); *VCs Take Their Case For FDA Reform To Capitol Hill*, WALL STREET JOURNAL (October 6, 2011)(available at: http://blogs.wsj.com/venturecapital/2011/10/06/vcs-take-their-case-for-fda-reform-to-capitol-hill/); T. Hay, *Frustrated Investors Swap FDA War Stories, Share Advice*, WALL STREET JOURNAL (April 25, 2011)(available at: http://blogs.wsj.com/venturecapital/2011/04/25/frustrated-investors-swap-fda-war-stories-share-advice).

Merely determining whether regulations do or do not apply can be a complex problem,[13] and this alone may discourage participation in the industry.

These theoretical risks of intervention are understood by most persons familiar with the effects of regulation. In fact, the risk-based framework for determining what applications are to be regulated arises out of the desire to minimize the cost and maximize the benefit of regulatory intervention. There is, however, a fundamental error in the typical evaluation of the FDA's role in mHealth. For the health industry, the FDA's role is, put simply, to regulate private sector innovation, and the necessity for such intervention is based on the idea that the private sector may have inadequate incentives for safety and effectiveness. It is frequently argued that the FDA is needed to offset the incentive problem and by doing so the health products that hit the shelves in America are safer and more effective. However, to some extent, the argument is guilty of what economists refer to as the Nirvana fallacy.[14] The Nirvana fallacy is described by noted economist Harold Demsetz as follows:

> The view that now pervades much public policy economics implicitly presents the relevant choice as between an ideal norm and an existing 'imperfect' institutional arrangement. This nirvana approach differs considerably from a comparative institution approach in which the relevant choice is between alternative real institutional arrangements. In practice, those who adopt the nirvana viewpoint seek to discover

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[13] B.M. Thompson, *FDA Regulation of Mobile Health, 2010 Report*, MOBIHEALTHNEWS (June 2010) (available at: http://mobihealthnews.com/wp-content/pdf/FDA_Regulation_of_Mobile_Health.pdf).

[14] H. Demsetz, *Information and Efficiency: Another Viewpoint*, 12 JOURNAL OF LAW AND ECONOMICS 1 (1969), p. 2 (emphasis in original).

> discrepancies between the ideal and the real and if discrepancies are found, they deduce that the real is inefficient. Users of the comparative institution approach attempt to assess which alternative real institutional arrangement seems best able to cope with the economic problem; practitioners of this approach may use an ideal norm to provide standards from which divergences are assessed for all practical alternatives of interest and select as efficient that alternative which seems to most likely to minimize the divergence. The nirvana approach is much more susceptible than is the comparative institutional approach to committing three logical fallacies – *the grass is always greener fallacy, the fallacy of the free lunch, and the people could be different fallacy.*

The Nirvana fallacy points to the error of an unqualified belief that a regulated outcome will be superior to an unregulated outcome simply because the unregulated outcome is not to your liking. The grass is not always greener, and regulation has costs of its own. Instead, the proper comparison involves the economic well-being across the regulated and unregulated states as they can actually be expected to exist, rather than treating the regulated state as some perfection (i.e., nirvana) that solves the static defects of the market outcome. While it is true that market outcomes – which are simply the outcomes of interactions among buyers and sellers (that is, human beings) – sometimes may be sensibly labeled as inadequate in some regard, particularly when lives are at stake, the FDA is an institution run by human beings with their own incentives and limitations. Regulatory agencies, including the FDA, are imperfect, and the problems it attempts to solve are very complex. In some instances, the FDA's oversight may render positive outcomes, while in others the costs of its action may well exceed the benefits. As a life-saving treatment awaits approval, people die; when a dangerous treatment is rejected, people live. There are costs and benefits inherent in the process; there is no free lunch.

Research on the FDA, which is extensive, presents widely different assessments of the agency, many highly critical of the agency.[15] The Government Accountability Office ("GAO") has pointed to a number of shortfalls in the FDA's regulatory efforts.[16] Some economic research suggests that the lives lost from delay in approval may significantly overwhelm the lives saved from the FDA approval process.[17] Some studies say otherwise.[18] Recently, the FDA's own scientists and leadership describe the agency as "fundamentally broken" and "failing to fulfill its mission,"[19] and lament the agency's tendency to consider the "political consequences"[20] of its decisions. Some refer to the FDA as "government's most dysfunctional agency."[21]

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15 *See, e.g.*, S. Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 JOURNAL OF POLITICAL ECONOMY 1049–1091 (1973); F. Hawthorne, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT (2005); P. Hilts, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION (2004); B. Richards, FIGHT FOR YOUR HEALTH: EXPOSING THE FDA'S BETRAYAL OF AMERICA (2006); R. Higgs, HAZARDOUS TO OUR HEALTH? FDA REGULATION OF HEALTH CARE PRODUCTS (1995).

16 *FDA Has Met Most Performance Goals but Device Reviews are Taking Longer*, GOVERNMENT ACCOUNTABILITY OFFICE, GAO-12-418 (February 2012) (available at: http://www.gao.gov/assets/590/588970.pdf).

17 D. Gieringer, *The Safety and Efficacy of New Drug Approval*, 5 CATO JOURNAL 177-201 (1985).

18 T. J. Philipson, E. R. Berndt, A. H. B. Gottschalk, M. W. Strobeck, *Assessing the Safety and Efficacy of the FDA: The Case of the Prescription Drug User Fee Acts*, NBER Working Paper 11724 (2005) (available at: http://www.nber.org/papers/w11724).

19 A. Mundy and J. Favole, *FDA Scientists Ask Obama to Restructure Drug Agency*, WALL STREET JOURNAL (January 8, 2009) (available at: http://online.wsj.com/article/SB123142562104564381.html).

20 *Lamictal Efficacy Comparable to Carbamazepine in First-Line Epilepsy, Glasgow Study; Lamotrigine in Phase III for Monotherapy, Pediatrics*, PHARMACEUTICAL APPROVALS MONTHLY, F-D-C REPORTS (January 1996), at p. 29.

21 *See, e.g.*, J. Entine, *FDA SpyGate – New Revelations Challenge The New York Times Investigation of Agency "Enemies List," Raise More Questions About the "Government's Most Dysfunctional Agency,* FORBES (August 20, 2012) (available at: http://www.forbes.com/sites/jonentine/2012/08/20/fda-spygate-new-revelations-challenge-the-new-york-times-investigation-of-agency-enemies-list-raise-more-questions-about-the-governments-most-dysfunctional-agency); *Medical Device VCs Link FDA Dysfunction With Company*

Footnote Continued…

Put simply, some question whether the cost-benefit tradeoff for FDA involvement is favorable on average, and clearly the tradeoff could be net negative for any specific drug or device. It is possible that FDA intervention may do more harm than good due to the nature of the problems its tries to solve or to its alleged dysfunction. Even a well intentioned, perfectly functioning FDA may not improve matters through its regulation given the inherent uncertainty and complexity of its tasks.

Legislation and regulation would be easy if all one had to do was to vote for a policy of "safer products," but this is not possible. "Safety" is not a policy; it is an idea, or a goal. Too often the debate over regulation centers on ideas rather than policies. A policy is a set of legally-defensible and specific rules telling people what to and not to do. The policy is about how and when to move the box from pallet A to pallet B and who is to do it. Human implementation of a complex set of human-designed rules aimed at improving safety may, in the end, increase danger. We have made personal decisions that we thought wise, yet turned out be to otherwise; regulators are people too. Recognizing that regulation has shortcomings need not imply the regulators necessarily behave badly; rather, in my experience, regulatory solutions to even simple problems are hard enough to construct, implement, and enforce even under the best of intentions, and the FDA hardly ever deals with simple problems. Certainly, the FDA is not dealing in "safety." Rather, the FDA establishes very specific rules that firms must

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Shutdowns, VENTURE WIRE (June 23, 2011) (available at: http://www.atvcapital.com/technology-news/medical-device-vcs-link-fda-dysfunction-with-company-shutdowns).

follow in the hope that the rules will increase safety (or possibly serve some political end). Success is a probability; not a certainty.

On the issue of mobile health applications, even those that believe the FDA has an important role to play in the regulation of mobile health applications contend that the FDA has failed in the sense that it has acted too slowly or has failed in that it has provided too little guidance. "More action" or "more guidance" seems to flow naturally from such thoughts. In the course of these hearings, the testifying experts and some members of the Committee will likely say things like "the FDA should be doing" something it is not. But it is also important to recognize that the "should be doing it" implies necessarily that the FDA is not doing what it should be doing. Embedded in a call for "more" is the recognition of "failure." It is important to keep in mind we are not dealing the FDA we wish existed, but the FDA we have, including all of its warts. As we contemplate the role of the FDA in regulating mHealth applications and devices, we must not only consider the inevitable negative consequences on innovation and competition (and hopefully the benefits of safety and efficacy), but it is important to keep in mind that the actions of the agency may or may improve safety, efficacy or quality.[22] It is sensible to guard against letting hope overcome experience.

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[22] For example, the GAO has identified a wide variety of concerns related to FDA's ability to fulfill its mission of protecting the public health. *FDA's Premarket Review and Postmarket Safety Efforts*, GOVERNMENT ACCOUNTABILITY OFFICE, GAO-11-556T (April 13, 2011) (available at: http://www.gao.gov/products/GAO-11-556T); *FDA Should Expand Its Consideration of Information Security for Certain Types of Devices*, GOVERNMENT ACCOUNTABILITY OFFICE, GAO-12-816 (August 31, 2012) (available at: http://gao.gov/products/GAO-12-816). Also see M. Carey, *Medical Research, FDA and Mental Health Programs Face Budget Bite*, KAISER HEALTH

Footnote Continued...

2. *Medical Device Taxation: Is it a Regressive Tax?*

The Affordable Care Act levies a 2.3% excise tax on medical devices, and the FDA's regulation of mobile apps is likely to label such apps as medical devices. Whether or not these applications are taxed is an important consideration naturally flowing from the FDA's activity in this area. Economists would broadly agree that such taxes will reduce the rate of innovation and the introductions of new mobile applications and devices by lowering the returns on such innovations. Taxes may (or may not) raise revenues, but they always discourage the activity being taxed (other things constant). Taxes do nothing to improve safety or efficacy. Is it important that Congress and the FDA consider the implications of such taxation on the mHealth sector, the health sector broadly, and the mobile communications sector that is a perfect complement to these applications.[23] Clear guidance is needed to avoid unnecessary loss of innovative capacity in this sector.

Another significant concern with taxes on medical devices, particularly those in the mHealth space, is that such taxes could be regressive in nature. Government studies regularly document the health disparities in lower-income segments of the population.[24]

NEWS (March 1, 2013) (available at: http://www.kaiserhealthnews.org/Stories/2013/March/01/health-programs-budget-cuts-sequester.aspx).

[23] D. Furchtgott-Roth and H. Furchtgott-Roth, *Employment Effects of the New Excise Tax on the Medical Device Industry*, Furchtgott-Roth Economic Enterprises (September 2011) (available at: http://www.chi.org/uploadedFiles/Industry_at_a_glance/090711EmploymentEffectofTaxonMedicalDeviceIndustryFINAL.pdf).

[24] *See supra* n. 4.

Studies also show that lower-income residents are also more likely to access the Internet using a mobile device, suggesting that mHealth will be particularly beneficial in improving health care for poorer Americans.[25] Indeed, mHealth is frequently targeted at lower income populations, whether in less-developed economies or within advanced economies. The combination of health disparities and use of mobile technology in lower-income populations suggests that the medical device tax could be regressive, with lower income Americans shouldering a relatively high tax burden. More research on this topic is obviously needed, particularly in light of universal health care, but the conditions appear suitable for such an outcome.

3. *The Odd Case of the Medical Device Tax*

Without dispute, taxes reduce the production and consumption of goods and services. "Sin taxes" are a clear manifestation of this fact, where goods that are deemed socially undesirable are taxed more heavily in order to curb their consumption (e.g., tobacco). With that in mind, it is interesting to consider the implication of taxing regulated medical devices, including mobile medical applications.

In order to market a "regulated medical device," the device must be reviewed or certified by the FDA. This "certification" by the FDA indicates that the medical device is a "good one," or one that is efficacious and safe and will improve the general well being

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[25] A. Smith, *35% of American Adults Own a Smartphone*, PEW INTERNET & AMERICAN LIFE PROJECT, Pew Research Center (July 11, 2011) (available at: http://pewinternet.org/~/media//Files/Reports/2011/PIP_Smartphones.pdf).

and health of society. If the device is not efficacious and safe, then it will not be certified; it is a "bad" device. It is only after receiving the FDA's stamp-of-approval as a "good" and "health improving" device is the ACA's excise tax applied. Oddly, the tax, which necessarily discourages the consumption of the "good" medical device, applies only to those medical devices which improve the well being of society. The ACA's medical device tax may thus be labeled a "virtue" tax, as opposed to a "sin" tax. Only those things society deems as desirable are targeted by the tax, thereby reducing the use of the desirable devices. By reducing the consumption of the "good" medical device, the tax reduces the social value of the FDA by reducing the benefits of the agency's efforts without affecting its costs.

When the medical device tax is contemplated within the context of its relationship to FDA approval, the ACA's medical device tax is a particularly odd form of taxation. I am not surprised that there is bipartisan support for a repeal of this "virtue" tax; there appears to be good reason to do so.[26]

V. Is the iPhone a Medical Device?

All of the mobile applications in question are running on mobile platforms like iPhones, Android phones, iPads, and so forth. Technological innovation in these

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[26] P. Kasperowicz, *GOP, Dems Call for Repeal of $30 Billion Medical Device Tax*, THE HILL (February 7, 2013)(available at: http://thehill.com/blogs/floor-action/house/281691-gop-dems-call-for-end-to-30-billion-medical-device-tax)("A bipartisan group of 180 House members – consisting of about 40 percent of the House – has reintroduced a bill to end the 2.3 percent tax on medical devices that was imposed under President Obama's healthcare law.")

platforms is rapid and provides substantial benefits to consumers. The ubiquity of such devices is amazing considering that the first iPhone was released in 2007. The most troubling (to me) about the FDA's *Draft Guidance* on the regulation of mHealth is the potential for inserting the FDA into the innovation flow of mobile handsets, tablets, and other devices. I suspect many would find a requirement for FDA approval on each new mobile device a scary thought. It would certainly curtail the pace of innovation. While many do not believe the FDA will regulate mobile platforms as a regulated medical device, some do, and I believe the *Draft Guidance* plainly leaves that door wide open.

In the FDA's *Draft Guidance,* it defines a "mobile platform" as "as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as the iPhone, BlackBerry phones, Android phones, tablet computers, or other computers that are typically used as smart phones or personal digital assistants (PDAs)."[27] As such, we can equilibrate the iPhone (for example) with the "mobile platform." The same document defines a mobile application as "as a software application that can be executed (run) on a mobile platform, or a web-based software application that is tailored to a mobile platform but is executed on a server."[28] In turn, the "mobile medical application" that is to be subject to FDA regulation is a "mobile application" is defined as an application "that meets the definition of 'device' in Section

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[27] FDA *Draft Guidance, supra* n. 10 at p. 7.

[28] *Id.*

201(1) of the Federal Food, Drug and Cosmetic Act (FD&C Act); and either (a) used as an accessory to a regulated medical device; or (b) transforms a mobile platform into a regulated medical device."[29] Per the *Draft Guidance*, the application would meet the definition of a "device" when "the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man."[30]

My initial concern about the treatment of handsets and tablets as regulated medical devices subject to FDA jurisdiction should be immediately apparent from these definitions. Specifically, a "mobile medical application" is one that "transforms a mobile platform into a regulated medical device," which (by substitution) could be read as saying it "transforms [an iPhone] into a regulated medical device." This language is troubling, and it may be that the specific words do not accurately reflect the intent of the FDA or could be interpreted differently. Nevertheless, the plain language suggests, at least to me, that the mobile platform can be a "regulated medical device" by implication of its complementary use with a mobile health application.[31]

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[29] *Id.*

[30] *Id.* at p. 8. For the full definition of a device, *see* http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm.

[31] Such language appears elsewhere in the *Draft Guidance* ("Mobile apps that transform the mobile platform into a medical devices by using attachments, display screens or sensors or by including funcationalities similar to those of currently regulated medical devices (*Draft Guidance, supra* n. 10 at p. 15).")

There is more to demand concern. In an attempt to clarify the guidance on mobile platform regulation, the FDA's *Draft Guidance* provides an example, stating "if it is possible to run mobile medical apps on BrandNamePhone but BrandNamePhone is not marketed by BrandNameCompany with a medical device intended use, then BrandNameCompany would not be a medical device manufacturer."[32] Clearly, the example addresses the treatment of the "phone." The example reveals that whether the "phone" qualifies as a "medical device" depends on "intended use." Thus, the *Guidance* leaves open the question of whether the "phone" is a "medical device," which takes us back to the question of a "transformation" of the platform into a *regulated* medical device.

What is meant by "intended use" is obviously an important concept. Is it possible, for example, for a manufacturer of blood glucose meters to avoid FDA by describing its product as a paperweight? No. The term "intended use," as applicable to the FDA, "refer[s] to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives."[33] Intent, therefore, may be

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[32] *Id.* at p. 10.

[33] 21 CFR § 801.4 (available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=801.4).

reflected not in specific labeling, but in other materials and actions. To clarify, consider the discussion provided in a paper written by my co-panelist Bradley Thompson[34],

> Figuring out the actual intended use of the article depends entirely on the facts. I teach this topic at Columbia Law School, and I generally begin the session by taking out a popsicle stick. To employ a case study, I tell the students that I'm the CEO of a company that makes these sticks, and I want to know whether I have to comply with FDA regulations. At that point I encourage them to ask questions of me in my hypothetical role as CEO, and then ultimately to advise me.
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> If they have done their homework, they will start to ask me how I promote the stick. In my answers, I'm pretty coy at first, simply explaining that I sell sticks and what my customers do with them is their business. I explain that my labeling for the product merely identifies the product as a stick without going into its possible uses.
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> Hopefully my students have read enough to know that the regulations define "intended use" as: "the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. ..." So what I say in my labeling is not the last word, but ultimately what matters is the totality of what I have done to promote the article and to some extent what I know about how my customers are using it.
>
> Eventually my students start asking me about what trade shows I attend, what types of magazines I use to advertise the sticks, what my salesmen say to customers, and what I know about the actual usages of the sticks. And it turns out, in my hypothetical, I know that many of my customers are using them as pediatric tongue depressors, I promote them in advertisements in hospital journals, and at least some of my salesmen might encourage their use as tongue depressors. So eventually my

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[34] Thompson, *supra* n. 13.

> students come to the view that my simple popsicle sticks might in fact qualify as medical devices and be subject to FDA regulation.

As this discussion reveals, and the regulatory language infers, the term "intended use" is not the same as "stated use." Mobile platforms are typically sold as just that: general-purpose handsets, tablets, phones, and so forth. Yet, the manufacturers of such platforms frequently advertise the use of their products as health devices. For example, Apple's "iPhone in Business" and "iPad in Business" series describes the benefits of its handsets and tablets in healthcare systems, with the apparent intent of promoting its devices to healthcare organizations. These reports state, for example, the "iPhone is clearly helping to improve health care"[35] and is "helping doctors treat patients" and "take care of [] patients."[36] Apple has also made corporate announcements about its devices use for medical care with demonstrations from major medical companies.[37] (Many of the claimed usages are for records management, however, which is a largely unregulated field today.) Nor is it clear that such representations rise to the level of "intended use." Perhaps the critical question is could an over-zealous regulator or tax collector make a legally-defensible argument that devices or even the entire mobile network was a medical device and thus subject to regulation or the medical device tax?[38]

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[35] http://www.apple.com/iphone/business/profiles/memorial-hermann.

[36] http://www.apple.com/iphone/business/profiles/mt-sinai; also http://www.apple.com/ipad/business/profiles/dr-ferencz; http://www.apple.com/ipad/business/profiles/rehabcare/#video-rehabcare; http://www.apple.com/ipad/business/profiles/medtronic/#video-medtronic.

[37] http://mobihealthnews.com/949/iphone-30-all-about-mhealth.

[38] The platforms, as general purpose devices purchased by consumers, may qualify under the retail

Footnote Continued...

In an ecosystem, where all components are intertwined, where does the line get drawn on what is and what is not a medical device? Obviously, clarity is needed, and there needs to be some limitations on the scope of FDA's reach lest regulation taxation become very broad in the mobile ecosystem and due significant damage to innovation in the sector.

VI. Conclusion

Mr. Chairman, thank you again for the invitation to testify today. I would welcome any questions the Subcommittee might have.

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exemption.

Mr. WALDEN. Dr. Ford, thank you very much for your testimony and that of all of our witnesses today. I think it has helped explain why we are doing this hearing to begin with because we kept hearing that there is a lot of uncertainty in the marketplace that may indeed be slowing down, stifling investment, innovation and new U.S. job growth and technologies, so that is why we are doing this hearing, and I know Mr. Waxman, who had to leave, and I understand that we all have to juggle here, thinks the law is very clear. Obviously, you all don't, especially when it comes to the FDA's lack of a final rule in this area. Look, we are all for patient safety, and there is no separation here. We are all patients eventually. We want patient safety. We don't want fraudulent devices on the market. We recognize the importance of appropriate regulation.

But Dr. Ford, you reminded me of something I always was told, that if you want less of something, tax it more, and you really summed it up and basically said, look, you are taking innovation in health care, don't we want more of that. Is that not what you were——

Mr. FORD. Yes.

Mr. WALDEN. And a gross-receipts tax, which could completely stifle innovation.

Mr. FORD. The gross-receipts tax will significantly deter involvement of companies in this space. It is a fairly severe tax, particularly when we are dealing with innovation, new products, new companies and even hospitals and doctors themselves have entered into the business to design their own applications. This virtue-tax issue is an interesting one, and I think it is weird when you have a government agency say OK, here is the good stuff and now we want you not to use it so much.

Mr. WALDEN. We have run into that in my own State of Oregon. There was a medical device manufacturer who for various reasons, but they said including the new gross-receipts tax, I believe laid off, what a couple hundred people already, and I am hearing about it around the country.

Dr. Dagi, are you seeing a move to take this offshore in terms of innovation and development and offshore these jobs and all that now, or not?

Dr. DAGI. I am, sir, seeing two things. We are seeing that many companies attempted to take this offshore, and they are also attempting—they are also thinking about launching offshore where profits will not be taxed and where the regulatory path is both simpler and more direct.

Mr. WALDEN. So is it accurate to say that Obamacare is driving this sort of medical technology and innovation to other countries because of this tax?

Mr. FORD. I am not expert enough to say that it is Obamacare specifically.

Mr. WALDEN. Well, but the 2.3 percent tax is part of the President's health care law.

Mr. FORD. Yes, sir.

Mr. WALDEN. All right. And so Mr. Spalter, what does that mean, people like your daughter and the innovation that could come from that? Are you concerned about a reduction in innovation in this area and that these really smart people who are probably,

I don't know, 14 sitting in a garage somewhere creating apps, are going to create another Angry Birds as opposed to something in this area? And I would open that up to anybody here. That is my concern is that public policy has an impact. Is it going to have a negative impact here, which is not what we want.

Mr. SPALTER. America's wireless consumers, all of are actually paying roughly 17 percent of our monthly bill of our wireless services to taxes. Wireless services are taxed at two and a half times other goods and services on average across our country. We are very concerned, Mr. Chairman, that these types of taxes, if they are applied to mobile medical applications and devices, will stifle innovation, will tempt entrepreneurs to pursue, as you suggested, other types of innovation and apply their genius and their efforts to other parts of the mobile ecosystem rather than efforts to make our children, our families, our parents healthier. So there is an impact and we need to be very, very vigilant and cautious about going down this path.

Mr. WALDEN. Mr. Jarrin, in your testimony you mentioned that as many 5 percent of the 27,000 health-related apps could be subject to regulation, yet as our data would indicate, fewer than 80 medical apps have gone through the FDA process. I was a journalism major, not a math major, but I think that leaves 1,200 apps in a state of regulatory uncertainty, roughly.

Mr. JARRIN. Correct.

Mr. WALDEN. Is that accurate, and are you concerned about the time delays and all of that?

Mr. JARRIN. Yes, we are very concerned about the fact that we haven't found any clear guidance. The draft guidance document needs to be finalized, and we were hoping that through that finalized document we would have a better understanding of whether or not these apps that are on the market should be regulated or the agency will use their enforcement discretion to not regulate them. That is a very important thing, because when you are talking about a device, a medical device will always be a medical device. It is up to the agency whether or not they are going to proactively regulate that medical device, and I am speaking about the very low risk end of devices, not medium risk or higher risk devices, which I think we all agree are not the ones that we are discussing. But when we are talking about a mobile application, a health application, there is a lot of ambiguity. For example, if I were to use some of the terms like "well being" in my marketing claims or "heart health" or "sleep deprivation" or "patient satisfaction", "stress", even mentioning——

Mr. WALDEN. Do those trigger FDA?

Mr. JARRIN. Unsure, and that is the kind of clarity that we are looking for from the agency, and they seemingly were ready to deliver that clarity. I believe in this very building, less than a year ago, Dr. Jeffrey Shuren, the center director, spoke about some of the things they were contemplating to take off the table, and they spoke about some of the things like medication adherence software potentially could be off the table, BMI calculators, I mean body mass index calculators, drug-drug formula, drug dosing calculators. That would have been very helpful for the industry.

Mr. CHODOR. Can I add something?

Mr. WALDEN. If you are real quick, because I am over my time.

Mr. CHODOR. Well, we are hearing from developers and hospitals and docs that a lot of them are waiting on the sidelines until there is final—when are the guidelines going to come out, is there going to be a tax until they start developing in the space.

Mr. WALDEN. And those are separate issues?

Mr. CHODOR. Separate issues, but they are not going forward because they are waiting.

Mr. WALDEN. All right. Thank you all, and I thank the courtesy of the committee, we went over, but we will turn now to Ms. Matsui for 5 minutes.

Ms. MATSUI. Thank you, Mr. Chairman.

Let me just go through this. You know, the Affordable Care Act was carefully drafted so not to add to the deficit. It imposes a small tax on a wide range of industries that will benefit from expansion of health insurance coverage for nearly 30 million Americans under the reform. Now, one such levy is the 2.3 percent excise tax on medical devices. Now, let me just—without getting into the merits of the device tax, I would like to ask some questions to clarify quickly the applicability to smartphones, tablets and app stores.

Mr. Thompson, is FDA proposing to regulate devices like smartphones and iPads or app stores like the iTunes store?

Mr. THOMPSON. I think in the draft guidance, they did about the best they could to explain no, that they don't want to regulate those articles if they can avoid it. Admittedly, it is not the model of crafting but I think their intent came through.

Ms. MATSUI. OK. So if the FDA is not regulating smartphones, tablets or app stores, would they be subject to the medical device tax?

Mr. THOMPSON. So if they are not medical devices, they would not be subject to the medical device tax.

Ms. MATSUI. So Mr. Thompson, it is also my understanding that IRS looks at something called the retail exemption when examining the applicability of medical device devices.

Mr. THOMPSON. Right.

Ms. MATSUI. Could you explain that exemption?

Mr. THOMPSON. Well, the exemption is meant to cover medical devices that are basically sold at retail for use by laypeople in managing their health, and so those are exempt from the tax, and it covers most things other than, for example, the professional use apps that we have referred to a few times. So whether it is for reading an ultrasound image for a doctor or whatever, those apps would be subject to the tax. But stuff sold to consumers through the app store would not, as I understand it.

Ms. MATSUI. OK. Mr. Chodor, you state in your testimony that a fair reading of the final regulations implementing the tax should lead one to conclude that the retail exemption applies to all smartphones and tablets that are on the market today. So do you agree with Mr. Thompson that based on current IRS rules, smartphones and iPads are not subject to the medical device tax?

Mr. CHODOR. Absolutely, Happtique agrees with that.

Ms. MATSUI. OK. So from all you have stated then, smartphones and tablets will not be taxed as medical devices.

Now, I understand the frustration here, and I am frustrated too regarding the draft of 2011, and I agree the FDA needs to move swiftly to finalize the mobile medical app guidance. I understand that. The clarity of the final guidance can improve confidence for investment and bringing new innovative applications to the consumer, and I wholly agree with you there, and I think we really need to encourage that in a very expeditious manner.

I want to move on to something else here. Spectrum is something that I am very much involved in, and we are all involved on this committee. We understand how important that is and how important it is to free up the federal spectrum. Mr. Spalter, your testimony discusses the importance of making more spectrum available to expand mobile broadband, and I couldn't agree more. Do mHealth applications have particular spectrum needs? Are hospitals and other health care providers going to be affected if we do not address the looming spectrum crunch?

Mr. SPALTER. I believe profoundly yes. Mobile health applications are at their nascent stage now. We are expecting there are going to be extraordinary levels of adoption, innovation, new products, new services, new applications brought to the market, and we need to have a predictable and reliable continuum of access to spectrum for enabling and deploying these innovations. Similarly, for hospitals, patient communities, professional health care providers, the need for secure, reliable, profoundly strong and scalable networks, is only going to become more important, and that is based on the availability of spectrum.

Ms. MATSUI. Right, exactly, but the unlicensed spectrum is also necessary for you too, correct?

Mr. SPALTER. Both unlicensed and licensed spectrum are going to be critical to advancing the prospect and the promise of innovation in America's health care.

Ms. MATSUI. So you think that this is going to be the future, and in essence, as fast as we can do this, the better it is going to be?

Mr. SPALTER. The President has spoken about the fierce urgency of now for the sake of our patients, for the sake of our families. Nowhere is that urgency more important than in the health care of our citizens, and mobile innovation based and built on spectrum assets and reliable networks is what will get us there.

Ms. MATSUI. Well, thank you very much. I see my time is exceeded. I yield back. Thank you.

Mrs. ELLMERS [presiding]. Thank you. I now turn to Vice Chairwoman Blackburn for her questions.

Mrs. BLACKBURN. Thank you, Madam Chairman, and thank you all again for being here with us.

You know, listening to you all and listening to some of the questions, I think that we are kind of walking through a period of the what-ifs, and some of the what-ifs are, well, if it is light touch, if they stay out of our business, we are going to do this, and if it is overregulating, talk to me. If the FDA says we are going to go after all of our mobile devices as well as go after some of these 80,000 apps, what is that going to do? Because we are talking about a gross-receipts tax, not a tax on your profits. So talk to me. If they go heavy-handed on this, does it stifle all the innovation? Does it

shut it off? Anybody that wants to speak, raise your hand and then I will recognize you. Go right ahead.

Dr. DAGI. The problem is that there is a risk to developing any kind of a medical application or medical device. For investors to come in and to provide the investment capital, they have to see a reward. Sooner or later, reward is going to be based on profits, but in the early stages it is going to be based on gross revenues. If you cut the gross revenues, first of all, you cut the valuations of the company. They become less valuable and less likely to be——

Mrs. BLACKBURN. So it is like anything else? The money is going to find an easier path?

Dr. DAGI. It will find an easier path.

Mrs. BLACKBURN. OK. I appreciate that.

Anybody, anything else to add to that? No? OK. I want to—Mr. Chodor, I think that probably you are the one to go to on this. I saw the national coordinator's Patient Safety Action Plan, and of course, with all of your health information management systems, a lot of that work is done down in my district in Tennessee, and we appreciate that they are there, and I know that for the HIMS members, many times with meaningful use, you have got the private certifications that are working in that space. Do you think a similar model would work for the mobile medical apps and have it go through that process as opposed to a more lengthy regulatory process?

Mr. CHODOR. From Happtique's point of view, we don't think it would be the same because when you take an app, as we were mentioning earlier today, where it takes a mole and takes a picture of it and says is it a melanoma or not, and someone is going to make a clinical decision based on an app, we believe that is something that should go in the hands of the FDA, an organization that has done that, and that should be done by the government as opposed to private sector. Just like Happtique's certification program, we aren't covering apps that should be FDA. We think those apps that are really making clinical decisions should be regulated.

Mrs. BLACKBURN. OK. Anybody else want to add to that? No? Nothing else?

OK, Mr. Jarrin. The IOM recommendations, when did you suggest FDA move forward with its draft guidance?

Mr. JARRIN. When did we suggest?

Mrs. BLACKBURN. Yes.

Mr. JARRIN. We suggested when we offered comments to the agency back in October of 2011. The agency released their draft guidance document in July. They opened up a 90-day comment period, and I believe they accepted over 700 pages of comments from over 100 stakeholders in the industry and the public, et cetera, and we were one of those, meaning Qualcomm Incorporated. We submitted a document, which I actually appended to my written statement, so you will find it at the back of my written statement.

Mrs. BLACKBURN. OK, then. You and Mr. Thompson, let me ask you this. Do you think the FDA or Congress should set the policy on how we move forward with IMS regulation?

Mr. JARRIN. IMS regulation?

Mrs. BLACKBURN. Yes, with the management systems, health management systems, the mobile apps. Do you think it should be us or FDA?

Mr. JARRIN. I think FDA is squarely within its jurisdiction right now to move and to act, and that is what they had begun to do. We took a lot of their initial actions as a very promising indication to the industry at large that they were willing to work with all of us.

Mrs. BLACKBURN. OK. Let me get Mr. Thompson in.

Mr. THOMPSON. I agree with Mr. Jarrin. I think FDA is taking a fairly measured look at health information technology and is trying to do in some ways the least that they can do in the hopes of allowing innovation to flourish as much as possible, so I am optimistic now. Having said that, I want to see the document because——

Mrs. BLACKBURN. Yes, kind of back to Dr. Dagi's point that if the overreach is there, the money, the VC, the funding stops.

Mr. THOMPSON. Right. We need to see the document.

Ms. BLACKBURN. Thank you. Yield back.

Mrs. ELLMERS. I now turn to Mr. Waxman.

Mr. WAXMAN. Thank you very much, Madam Chair.

First of all, let me say that I agree that innovation is important, that overregulation can harm public health just as underregulation can. I think there can be great value in discussing how to determine the correct balance and how to achieve it. But when I read the Republican memo for today's hearing, I got the impression that the only two issues of interest to my colleagues on the other side of the aisle with respect to health IT whether the FDA will inhibit innovation and whether all of our smartphones will be subject to a device excise tax. I understand Mr. Walden agreed with my earlier statement that there is a federal interest in ensuring patient safety, and I very much appreciate that.

I would like to hear from our expert witnesses whether you think there is a need for any FDA oversight of any mobile medical apps. In my opening statement, I mentioned the example of the apps that claim to be able to educate the consumers as to whether a mole is a sign of a melanoma. Clearly, if such an app is accurate, it could lower health care costs by minimizing unnecessary trips to the doctor for the nine moles and could save lives by encouraging people to go to a doctor when they might otherwise have ignored a mole that could kill them. On the other hand, an app that is inaccurate can do just the opposite.

So Mr. Chodor, do you think such an app warrants going through an FDA premarket clearance process just as it would have to do if it were a conventional standalone medical device?

Mr. CHODOR. Yes, we believe that any app that is going to make clinical decisions should go through a FDA type of program.

Mr. WAXMAN. Thank you. Mr. Thompson, what do you think?

Mr. THOMPSON. I agree with that. I think if you look at the 80 apps, for example, that have already been submitted to FDA, they represent fairly high-risk technologies that should be reviewed by FDA.

Mr. WAXMAN. And Mr. Jarrin?

Mr. JARRIN. Yes, I would agree with that assessment as well.

Mr. WAXMAN. Mr. Spalter, do you agree?

Mr. SPALTER. I do agree. I think that the important issue, in addition to whether there should be preapproval is, we also need to keep our eyes and our minds focused on the costs to application developers who are going through those approval processes, the time it takes, and the importance of having a precedential document finally that will set forth the clear guidance and outline and suggest what the real balance is between assuring, as we need to, patient privacy and security at the same time not inhibiting innovation.

Mr. WAXMAN. Good points. Dr. Dagi, do you agree that there ought to be an FDA premarket clearance for some of these devices?

Dr. DAGI. Absolutely. There is a balance between innovation and patient safety. Patient safety comes first, and the balance has to be there as well.

Mr. WAXMAN. And Dr. Ford, do you agree or disagree?

Mr. FORD. Sure. There is a balance that has to be maintained. I think it depends on perhaps what representations are made by a particular application, things like that.

Mr. WAXMAN. To Mr. Thompson, in Mr. Jarrin's testimony, he stated that 500 new mobile health apps are being launched every month compared to 400 apps that were being launched every month just a year ago. Those statistics indicate to me that the mobile medical app industry is growing at a healthy rate. We all want to see this pace of innovation in the mobile medical app market continue and accelerate. Do you think that the certainty of final guidance from FDA would help the mobile medical app industry continue to attract investment?

Mr. THOMPSON. Absolutely. Getting a document out there in final form will relieve a lot of the uncertainty, and I think folks who have been sitting on the sidelines will be encouraged to jump in at that point.

Mr. WAXMAN. Are the members of your coalition concerned that FDA has plans to aggressively regulate this industry or do they just want certainty?

Mr. THOMPSON. It is a little bit of both, in all honesty. For the most part, we want certainty. We always live in some fear of overregulation but we haven't seen any evidence of that, so as of right now, we feel pretty good about it.

Mr. WAXMAN. Good. Mr. Chodor, you discussed Happtique's app certification program and the need for an objective validation process for mobile medical apps. Do you see Happtique's certification as a substitute of any and all regulation of mobile medical apps?

Mr. CHODOR. Absolutely not. It is an add-on.

Mr. WAXMAN. And what types of mobile medical apps should be subject to FDA oversight?

Mr. CHODOR. I think anything that is going to make a clinical decision, anything a doctor is going to use or patient is going to use that can lead to surgery or a clinical decision.

Mr. WAXMAN. Do you believe an unfettered market creates incentives to ensure patient safety, and if not, who should step in to ensure patient safety?

Mr. CHODOR. That is a great question. I think it is a combination. I mean, in that case there is a place for the government and the federal agencies to participate in that, and for the public.

Mr. WAXMAN. Of course, if a patient and a doctor can't trust the efficacy of a product, that is not going to do much good.

Mr. CHODOR. Exactly.

Mr. WAXMAN. Thank you very much. I yield back my time.

Mrs. ELLMERS. Thank you. I now turn to Mr. Latta for his questions.

Mr. LATTA. Thank you very much, and just following on. I think that as Chairman Walden said earlier, we want to make sure that there is a clear line out there for patient safety, and we also agree that there is the need out there for FDA to ensure that patients are safe, and we also have to make sure there is a clear line to make sure that those apps that are out there that need to be regulated and those that don't have to be delineated, and I think that is what we are hearing from our panel today, and I just want to again, as I had mentioned earlier, thank you all for being here today because again I think it is an excellent panel and excellent information that we are receiving here today, and if I can just start, Mr. Chodor—I would like to go back to what you said a little bit earlier, saying that there is a clear need for the FDA to be reviewing these regs sooner than later. Would you want to just go into that a little bit?

Mr. CHODOR. Well, it has been July 2011 that they came out with their draft guidelines, comment period came back. The public needs to know, the developers need to know, hospitals need to know, doctors need to know what is going to be regulated and what is not going to be regulated. Right now, we are just sitting in this middle ground and no one knows, and I think that is the scariest part because the longer it takes, more apps are going to be developed, and should they be FDA approved or shouldn't they be FDA approved, nobody knows.

Mr. LATTA. Let me go to Dr. Dagi, and thank you very much for your effort. Many of us know what it is like to be on planes that are delayed or canceled, so we appreciate you making the effort to be here today. You know, just following on to that, when you are looking at the venture capitalist side, if folks don't have that line out there knowing how fast these things are going to be approved, what is that going to do for folks wanting to invest into these apps into the future?

Dr. DAGI. It is going to increase the risk of investment and venture capitalists will put their money elsewhere.

Mr. LATTA. OK. And when you say putting their money elsewhere, does that mean taking that money offshore to have these apps developed?

Mr. DAGI. They might.

Mr. LATTA. And in your testimony, you were giving some numbers. How much money are we talking about, do you think, that these medical device apps would be bringing in for venture capitalist and they would be investing into in a year's time?

Dr. DAGI. That is a hard number to get a hold of right now because there are a number of things that may or may not be medical apps. We don't know whether the extension, for example, of patient engagement is a communication or whether it is a medical device. But probably I am sure we are talking about hundreds of millions of dollars, but I can't give you a specific number at this point.

Mr. LATTA. Well, following up a little bit when you were just talking about folks wanting to make an investment in this, what about when they have to look at that 2.3 percent medical device tax and they have to add that in to the equation? What does that do to an investor?

Dr. DAGI. If 2.3 percent is taken off the top, you have a regressive and repressive tax that is going to tell the venture capitalist the return that you can get investing in this area will be curtailed at the very early stage, at the very vulnerable stage of company development. That is the fear: the risk increases.

Mr. LATTA. And Mr. Jarrin, again, thanks for your testimony today too, and also, I think that Chairman Walden had brought this up, but it is really looking at, again, on the FDA side, not getting these things done quickly and slowing down that development, and we used to talk about slowing down development, again, as you just have heard from Dr. Dagi and Mr. Chodor, what does that tell people out there if they want to get into this or not? I think the chairman had mentioned a little bit earlier about, does that mean somebody doesn't get into the mobile medical app side and they go and develop some type of a game or something like that, what does that mean to the industry?

Mr. JARRIN. Well, it is really tough on the industry. I have got a great example. There is a company out in California called MedCell, which changed to Vocel, that had an application called the Pill Phone, and they brought it to market, and in construction with the FDA, they actually pushed the FDA and said we are thinking about making this app and we hope that you can help us make this app, and they ended up being a regulated app. The CEO of that company claims that that was very helpful to them because it made them make a better product. However, the FDA has mentioned that those apps potentially may not even have to undergo regulation. So he ended up spending several thousands of dollars going into the hundreds of thousands of dollars, to go through all of the Good Manufacturing Practices and quality systems to actually ensure that it would really fall under the FDA guidelines and regulations, and if in fact, he wouldn't have had to go through that, then that is a major capital expense that he incurred technically for nothing, so we can also argue that it was actually better because his product came out better in the long run. So you would have to weigh both sides, but I think that is very hard on the industry not knowing whether or not you are or are not going to be regulated because you have to take that into consideration.

Mr. LATTA. Thank you very much, and Madam Chair, I see my time is expired and I yield back.

Mrs. ELLMERS. Thank you. I now turn to Mr. Luján for his questions.

Mr. LUJÁN. Thank you very much, Madam Chair, and to everyone that is here today, we really appreciate your time today.

Mr. Chodor, I think the questions have been asked but I think just for clarification because of the memo that we received about today's hearing, I think that is why you are getting a lot of similar questions just to make sure that we are able to get answers to these questions. Do you think that some types of mobile medical apps deserve different levels of scrutiny than others?

Mr. CHODOR. Yes, I do.

Mr. LUJÁN. And is there anyone on the panel that disagrees with that? I don't hear anyone. That is good to hear.

For example, some apps might not need any premarket oversight as you have described. For some apps, consumers and health professionals might expect a version of a voluntary Good Housekeeping seal that is adequate like your organization is providing, and some apps might warrant a little more mandatory federal oversight. Do you think the FDA's draft guidance recognizes these distinctions?

Mr. CHODOR. I think they do. We can't wait to see the final guidelines.

Mr. LUJÁN. Well, and I appreciate the testimony today because one area where I have seen agreement by the entire committee today is that we want to push the FDA, we want the certainty associated with this document to be put into final form, so that way we are able to move on and work together.

With that being said, Mr. Thompson, you mentioned in your testimony that there is already 40,000 apps available on smartphones and tablets under the broad mHealth category, and we saw them double just last year. Have you seen any slowdown in mHealth innovation since the passage of the Affordable Care Act?

Mr. THOMPSON. I haven't seen any slowdown. I am not in the best position. I think actually Mr. Jarrin follows those statistics better than I do, but my impression is that it is growing quite rapidly.

Mr. LUJÁN. With that being said, Mr. Jarrin, have you seen a slowdown?

Mr. JARRIN. No, no slowdown at all. As a matter of fact, it is almost like a hockey stick. Two years ago when I formed our comments to the agency, I believe that the figures I was using were about 13,000 apps in one of the app stores and 10,000 in the other, and those were not unique apps. When you hear the current statistics of 40,000 apps, I think it is even higher. It might be actually 45,000 apps, but some of those are the same company, just different types of the same app in essence, so you can't really count them as unique. My understanding from MobiHealthNews, which is one of the sources for the industry right now, is that there are 27,000 unique apps, so in 2 years it has basically doubled, and that is just unique apps, so I see no slowdown at all. I think that this is a very dynamic, vibrant space.

Mr. LUJÁN. I appreciate that, Mr. Jarrin. The memo that we received today said that the Food and Drug Administration could potentially classify smartphones and tablets that run the apps as medical devices. I think that is one of the reasons that we are here today, and when you look at the FFDCA section 201(h), it states that if a device addresses the diagnosis of a disease or other conditions or in the care and mitigation, treatment or prevention of disease, that it could be subject to one of these classifications. I just bought these really great pair of Nikes that have this little chip in them that communicates to my phone, so do we need to provide clarification that that shoe is not going to be classified as a medical device?

Mr. JARRIN. Are you speaking to me, sir?

Mr. LUJÁN. Yes, Mr. Jarrin.

Mr. JARRIN. No, because that is a general health and fitness type of device.

Mr. LUJÁN. I appreciate that, and that is the point that I wanted to make today is, when I ride my mountain bike and I have a Bluetooth connection to it and it sends some information to my doctor and he says Ben, you have gotten a little bit chubby since you have gone to Congress, you need to start watching what you are eating, you need to start running a little bit more, and so these other devices that are communicating to a mobile device, I think what has been clear today is that there is no evidence even in what the FDA has put out when we talk about a difference between component manufacturers and device manufacturers, that there is a concern there, but we can all agree again that we need to put the FDA together.

And lastly, Madam Chair, as my time expires, I hope that there is agreement with the committee and we work with the chairman and Ranking Member Waxman that we put as much pressure as we can on the FDA to get this document out, that I heard a lot of concerns from my Republican colleagues about the 2.3 percent tax, and I completely hear their opposition to this. I am hoping that they can join me in voting against the Paul Ryan budget this week because the Republican budget released last week relies on the revenue generated by the medical device excise tax to achieve its revenue targets. So, look there are some ways to talk about this today and some ways to show opposition, but when it is included in the blueprints associated with the future of what we are looking at here, there has to be a better way to do this.

The only good thing I can say today, Madam Chair, is that I think we have seen some clear agreement in this area, and just one last thing. When we talk about the apps even in the startup companies and the concerns associated with the 2.3 percent excise tax that was included in the Affordable Care Act, there is one other thing that startups making retail mobile applications have an explicit retail exemption in the law that excludes these types of apps along with products like contact lenses and hearing aids. That is the truth. So we as Members of Congress also need to be careful with how we create uncertainty when we are out saying things that sometimes mislead the public, and I hope that we can work together and make sure I can join with some of my friends and use those new Nike shoes and go for a little jog. Thanks, Madam Chair.

Mrs. ELLMERS. Thank you, Mr. Luján, and I would like to say as far as clarity and factual information, the Ryan budget does not in fact do that.

I now turn to Mr. Shimkus.

Mr. SHIMKUS. Yes, it is a nice attempt. We just think it is important to balance your budget by 10 years and start paying down debt, so I guess if balancing the budget in 10 years and not paying down debt is not important to you, then I guess you go to your processes.

Mr. LUJÁN. Would the gentleman yield?

Mr. SHIMKUS. No, actually not. I was going to try to ask for time, but I think I will use mine on this debate.

Mr. Dagi and Mr. Ford, in follow-up to my colleague's other questions, talk about that chip in the phone. Does it—I mean, he is assuming that the whole panel agrees. Where do you stand on what could happen, Mr. Dagi first and Mr. Ford, with that example that my colleague just expressed?

Dr. DAGI. It depends on the application, sir. If you have, for example, chips in shoes that can be used for a runner but can also be used to look at a child with cerebral palsy and use it to treat them——

Mr. SHIMKUS. My colleague is not paying attention to your answer, and since I would hope that he would do that, go ahead.

Dr. DAGI. The same chip can have multiple applications, and traditionally, the FDA has regulated applications and clings as well as devices themselves, so the safety piece of it and the efficacy is one part. The second part is the application. We would ask for clarity on the way these are going to be regulated, and we would ask that the goalpost not be moved in the process of bringing devices to the market.

Mr. SHIMKUS. Mr. Ford?

Mr. FORD. Well, I think it is interesting that we keep asking the FDA for certainty about things and then we make certain claims about what they will or will not do. It has got to be one or the other. We either need certainty or we don't. The other issue with uncertainty that I think is important to clarify, resolving the uncertainty is not helpful in itself. What if we become very certain that they intend to regulate everything very heavily as class III devices and tax mobile phones and everything else? I don't think that would be very helpful for innovation. So resolving the certainty/uncertainty issue depends on what we become certain about and what we remain uncertain about. So resolving uncertainty is not really that helpful if we become more certain that the regulation is going to be very heavy-handed.

Mr. SHIMKUS. And that is a great segue. Mr. Jarrin, you talked about the hockey stick, all these new apps. How many of you actually have apps right now? And what is the approval process to have an app right now?

Mr. CHODOR. None.

Mr. SHIMKUS. Why do you think we have so many apps? Now, I have got my iPad here. I have got 21 updates, map updates. If you had go through—let me ask another question. How often do you update an app, Mr. Chodor?

Mr. CHODOR. I mean, all developers do it differently. Some developers update it three, four, five times a year. Some developers are only updating once a year.

Mr. SHIMKUS. So if you have to go through the same regulatory regime on approval of the original app and then all the updates, doesn't that segue back into the uncertainty of the risk the raising of capital? That is a problem. Would you agree?

Mr. CHODOR. If the app is going to make clinical decisions, then that is the cost of being in a heavily regulated industry called health care where we are dealing with patients and physicians.

Mr. SHIMKUS. But you are living I a world right now where you don't have it, right?

Mr. CHODOR. Well, we——

Mr. SHIMKUS. We are in a new world, a new, brave world of health care delivery that everyone is going to be happy with. But health apps developed in the absence of Obamacare and they are plentiful throughout the system, and our concern is, as the federal government gets involved, it creates uncertainty, it raises the cost of capital, it slows up the delivery process, and it could be very problematic for delivering the same care that we are all espousing.

Mr. Dagi, you are nodding yes. Do you agree with that?

Dr. DAGI. Absolutely. I believe that the medical application can be seen as a provider extender in some cases, so we don't have enough primary care physicians, we don't have enough specialty physicians. This is a way of getting to the patient.

Mr. SHIMKUS. So we are all saying FDA should publish final guidance to clear up confusion. However, Mr. Dagi, you noted that we should be looking at alternatives to the FDA framework. I mean, there are some of us that realize government is big, costly, bureaucratic, slow, the Telecommunications Subcommittee. The great thing about this sector is it moves faster than we can regulate, and this is a concern that we are going to slow it down.

Mr. Dagi, do you believe that the FDA framework is the best way to balance patient safety and innovation in this space?

Dr. DAGI. They have the credibility and the experience. They need to take information outside the FDA. It can't be positivist. It can't be only from the inside. But with the appropriate inputs, yes.

Mr. SHIMKUS. And you can bring the technology community in and be tech savvy, and that would be helpful.

Dr. DAGI. That is correct.

Mr. SHIMKUS. Thank you, Madam Chairman. I yield back my time.

Mrs. ELLMERS. Thank you. I now turn to my colleague, Mr. Gardner, for his questions.

Mr. GARDNER. Thank you, Madam Chair, and thank you to the witnesses for joining us today at this hearing.

A couple weeks ago I met with a constituent of mine in Colorado. He was a software developer in his earlier life, earlier years, and since has focused his attention on developing applications for a variety of uses, and one of the things he was talking about was a recent health care scare that he had. He had a conversation with a doctor in Colorado where the doctor was showing him some of the new technologies that he is able to use today when it comes to medical applications, apps, software apps, things like that, but also in the near future things that we will be using, and he described a scenario where you could walk into your bedroom and you would have a scale and you would get on the scale and you would check your weight. That scale would have a Bluetooth connection to it, to the iPad, and it would send your weight to the iPad, and then you could actually use the iPad for as little as 100 bucks, I think you said, with a device that was attached to it where you could check your blood pressure, your heartbeat, your heart rate, oxygen levels, and that that would be collected through the iPad as well. There may be some other things in the room that you could have that would also check your health status, and then that would send it through Bluetooth to the iPad, it would collect it and then send it directly to the doctor's office. At what point then are any of those

things an app that could be subject to regulation, subject to a device tax? Would the scale qualify at that point as a device, Mr. Jarrin?

Mr. JARRIN. The scale would qualify as a device if it is a medical device, if that is the intended use of the device. There are medical-grade weight scales and there are non-medical-grade weight scales on the market.

Mr. GARDNER. So but just if you had just a scale that was attached to Bluetooth, then that scale would become a regulated medical device?

Mr. JARRIN. Not necessarily. You need the intended use from the manufacturer.

Mr. GARDNER. So the intended use would be just you go buy a scale and the intended use is to check your weight. That is what a scale is.

Mr. JARRIN. Right.

Mr. GARDNER. That weight then gets sent. Is that a medical device?

Mr. JARRIN. Not necessarily. It depends again on the intended use by the manufacturer.

Mr. GARDNER. So not necessarily but it could be?

Mr. JARRIN. Correct. It could be.

Mr. GARDNER. OK. So there is no clarity there.

Mr. JARRIN. Well, it really—what we would need is more information about what the manufacturer intends with——

Mr. GARDNER. Well, it is intended as a scale. It is intended to check your weight.

Mr. JARRIN. But there are some scales that are just for informational purposes and there are others that are——

Mr. GARDNER. Well, all scales are for informational purposes.

Mr. JARRIN. Correct, but some make medical claims, and if that——

Mr. GARDNER. A medical claim as in, you weigh 150 pounds, which clearly I do not.

Mr. JARRIN. But this could be used for medicine.

Mr. GARDNER. But aren't scales used for medicine?

Mr. JARRIN. Not all.

Mr. GARDNER. Well, why would you check your weight then?

Mr. JARRIN. For informational purposes. You want to lose weight——

Mr. GARDNER. For informational purposes, so it is like reading a description of a coloring box, this is red, this is blue, this is yellow. That has nothing to do with the color, it just is information?

Mr. JARRIN. It is information.

Mr. GARDNER. That makes no sense to me. A scale is used to check your weight.

Dr. Dagi, at what point does everything in your room then, the Bluetooth connection, the iPad, could it check your oxygen level? Is the scale a medical device subject to a tax?

Dr. DAGI. You are 72 years old. You have just come out of the hospital with congestive heart failure. If your weight goes up 6 pounds, you may be about to go back into the hospital with another cycle of congestive heart failure. That scale has to be sufficiently accurate and precise to be able to adjust your medications, and at

that point it becomes a medical device. If you put a penny in a scale at an arcade, that is not a medical device.

Mr. GARDNER. So is there clarity, though, of whether the iPad at that point that collects the information from the scale?

Dr. DAGI. It depends on whether the iPad has a built-in algorithm that does something with the information. It is not only the data, it is converting the data into usable information and how that information will be used.

Mr. GARDNER. So I am hearing from several of the panelists that it depends. It might be, it could be. To me, that is not clarity. To me, that means that you have an entire room of iPhones, iPads, BlackBerrys that communicate with each other but it just depends on whether or not something is used for its intended purpose.

Dr. Dagi, is there the clarity that we need in this field to ensure innovation?

Dr. DAGI. We do not have the necessary clarity.

Mr. GARDNER. And Mr. Jarrin, would you agree with that at that point?

Mr. JARRIN. It depends.

Mr. GARDNER. It depends? "It depends" is not clarity. If it depends, that doesn't seem to me to give you the kind of certainty and innovation and funding that we are seeking.

Mr. JARRIN. There is insufficient clarity with low-risk medical devices or low-risk devices.

Mr. GARDNER. But is low risk a scale?

Mr. JARRIN. Yes, it could be, if it is for recreational purposes.

Mr. GARDNER. Mr. Spalter, so is there sufficient clarity in this realm to know that innovation can continue unfettered?

Mr. SPALTER. Clearly not, and we have a group of experts here that are struggling with this question. Imagine what it must be like for the members that we represent, the app developers who are sitting on their laptops in their living rooms trying to dream up the next innovations. How are they dealing with this level of uncertainty? What we are asking for is not necessarily one framework or another. What we are asking for is let us create that balance, let us find the line, let us put down on paper where we actually—what we need to understand, and once we get there, I think the hockey stick that we talked about, 40,000 medical apps, will become 100,000, 200,000 medical apps. In fact, I would even say that if we had that clarity, that the smartphone that is enabled to test urinalysis that we talked about earlier today, there would already be three or five new apps that have been developed just this morning.

Mr. GARDNER. Madam, if I can just ask one follow-up? So I mean, the line clearly is in the wrong place at this point, and we have got to adjust it. Would you agree with that, Mr. Spalter?

Mr. SPALTER. I believe that we need clarity, yes.

Mr. GARDNER. Dr. Dagi?

Dr. DAGI. Yes, sir.

Mr. GARDNER. Thank you. Madam Chair, thank you for your indulgence.

Mrs. ELLMERS. Thank you. Mr. Luján, did you have additional questions or comments that you wanted to make? OK. I will finish up with my questioning.

Mr. Thompson, I have a question for you. In the wireless world, most wireless devices are replaced in a 2-year cycle, and mobile operating systems are replaced in as little as 1 year by their next version. Considering the high rate of technology advancement that is taking place, in your experiences with the FDA's regulatory processes, how long does the premarket approval process take on average for a noninvasive medical device?

Mr. THOMPSON. There is quite a range but the range could be anywhere from about 90 days at the earliest for the actual FDA review, to up closer to a year and a half would also be reasonably typical.

Mrs. ELLMERS. So basically a year and a half is going to elapse before some of these very important medical applications can be put forward.

I would just like to finish by asking all of you to respond to a couple of questions. Yes or no or unclear, I would like the response. I think one of the things that this very important subcommittee hearing has really brought to light is, one, we all care about patient safety and we want to practice appropriately. We agree that there is FDA approval and regulatory processes that need to be in place for certain levels, especially when we are looking at something as important as diagnosing a disease. Mr. Spalter, I listened to your testimony and I have personal experience with diabetes. My older brother was diagnosed 40 years ago. Where would he be today had we had some of that innovation in place.

This is one where I would like to start to get a yes, no or unclear answer. Do you all agree that it is still unclear where we are with what is a medical device, starting with Mr. Jarrin?

Mr. JARRIN. Yes.

Mr. THOMPSON. Yes.

Mr. CHODOR. Yes.

Mr. SPALTER. Yes.

Dr. DAGI. Yes.

Mr. FORD. Yes.

Mrs. ELLMERS. The other question that I have for you is this. FDA regulation and medical device tax, or gross tax are the two issues that we are really talking about today. In your opinion, if it is FDA regulated, should the medical device tax be in place? I guess I should preface that by saying, do you believe that the medical device tax is going to hamper innovation? And I would like for each of you to answer that question first.

Mr. JARRIN. Unclear.

Mr. THOMPSON. I would say it definitely hampers innovation.

Mr. CHODOR. Unclear.

Mr. SPALTER. It is still unclear.

Dr. DAGI. Definitely yes.

Mr. FORD. The tax will hamper innovation.

Mrs. ELLMERS. In your opinion then, if FDA regulation is in place, and certainly we have seen the need for FDA regulation. We need to make sure we are practicing safely and best practices are being adhered to. Do you believe if the FDA regulation is in place that a medical device tax for such a product should be in place as well?

Mr. JARRIN. Unclear.

Mr. THOMPSON. We oppose the tax.

Mr. CHODOR. Unclear.

Mr. SPALTER. Unclear.

Dr. DAGI. Separate the tax from the regulation.

Mr. FORD. Two completely different questions.

Mrs. ELLMERS. Thank you very much. I truly appreciate the testimony that all of you have given here today. This really opens up that door on this discussion that we need to have as to whether or not this medical device tax is something we need to move forward with, and of course, all important FDA regulations, so thank you very much.

This subcommittee hearing is adjourned.

[Whereupon, at 12:24 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Imagine the potential to improve Americans' wellbeing if we were to bring wireless innovation to health care. Wireless carriers invested $25.4 billion in capital expenditures from mid-2011 to mid-2012, and that investment was made in a poor fiscal environment. The mobile application business has experienced explosive growth since its inception a half decade ago—responsible for the creation of approximately 500,000 jobs and it is now a projected $25 billion industry for this year. The 321.7 million connected mobile devices in the United States as of mid-2012 exceeds the number of citizens, as many consumers now use a combination of smartphones, tablets, and laptops. And 60 percent of adults already say they track health data, seven percent using an "app" or other tool on their wireless device. That figure is only going to continue to rise as apps become more and more a part of our daily lives. Helping people take better care of themselves with their mobile devices can make them healthier while at the same time cutting costs.

The question is: how do we harness this innovation? The mobile application economy is characterized by low barriers to entry, quick time to market, inexpensive retail prices, and rapid upgrade cycles. That will not be sustainable, however, if we indiscriminately regulate and tax mobile applications, smartphones, and tablets as if they were artificial hips or pacemakers. Arbitrarily applying the definition of "medical device" and the medical device tax to the wireless world could prove disastrous and grind this innovation cycle to a halt.

We certainly want to ensure patient safety, but the approach we take must be a smart one. My hope today is that our witnesses can shed light on how the medical device definition and tax is being applied to mobile devices and applications and what the impact is. I look forward to their testimony.

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PREPARED STATEMENT OF HON. LEONARD LANCE

Thank you Mr. Chairman and thank you to the witnesses who have all come to share their experience and expertise with us today.

The mobile app market place is growing at an exponential pace. We are seeing more innovative new apps on the market every day that help American consumers with innumerable daily tasks. This is one space where we are truly seeing fast paced development and where new, tech savvy entrepreneurs can quickly make their brainstorm into a reality and bring it to the market almost immediately upon completion.

There is a significant sector of this market aimed at helping Americans live healthier lives; this is the mobile health sector. A simple search for health and fitness apps for the iPhone produces page after page of options ranging from heart rate monitors, to calorie counters, to exercise apps and so much more. These technologies, as well as more advanced equipment and programs that are being used in doctor's offices and hospitals every day are helping to improve consumers' health and well being and in my cases bring down the overall cost of providing health care in this country.

Unfortunately, the prospect of arduous regulatory processes, or worse, the prospect of being subject to a poorly thought out regressive tax loom as potentially chilling barriers for some new entrants into this market. There rightly is a role for the FDA to have a regulatory role with many of these new technologies but they must be clear about what kinds of apps and devices will be required to undergo their full regulatory review and what others would be exempt. Some of our witnesses point out that FDA is still finalizing many of its regulations that determine what is a "medical device" and what is not and that this final analysis may have a significant impact on what qualifies under Obamacare's medical device tax. Uncertainty like this is one of the largest drags on our nescient economic recovery.

This brings me to the Medical Device Tax itself. I, like many of my colleagues on both sides of the aisle, view the imposition of the 2.3% tax on the medical device industry as arbitrary and wrongheaded. Mr. Ford makes that case pretty succinctly in his testimony in my opinion. This $20 billion tax should be repealed as soon as possible. The fact that there is any question as to whether or not a mobile device like an iPhone, iPad, or blackberry may be subject to this regressive tax would be comical if it weren't such a potentially serious issue.

I have a constituent back home in New Jersey who is working with companies on the leading edge of some of this innovation. John Letko is President & CEO of U.S. Healthcare Supply located in Milford, NJ. His company provides care for roughly 150,000, most Medicare beneficiaries with diabetes. Mr. Letko is currently working with another company in development of a new glucometer that attaches to a smartphone and a corresponding app to help patients with diabetes monitor and track their glucose levels and seamlessly share that information with caregivers or family members. Fortunately for him, recent IRS guidance appears to put this new device under the so called retail exemption from the medical device tax and hopefully the same applies to the app. However, he recently wrote me a letter expressing serious concerns he has with the medical device tax's possible effect on his industry. He rightfully points out that for a company like his, the President's sequester has already resulted in a 2% cut the provider side of Medicare and recent cuts to the reimbursement for mail order diabetes supplies have created a very challenging environment. A further 2.3% tax could be very damaging to the industry.

While my colleagues and I work to finally repeal this damaging tax provision I would encourage the FDA to carefully consider how it regulates these new and innovative technologies. We must ensure safety but should not impede technological progress unnecessarily. We must find the right balance between protecting consumers and harnessing the power of America's innovators to ensure that the U.S. remains at the forefront of the boom we are seeing in the development of such technologies.

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Mr. Chairman, today's hearing provides an opportunity to examine the exciting intersection between mobile technology and healthcare. Representing Silicon Valley and serving as Co-Chair of the House Medical Technology Caucus, I see first-hand the impact that the next generation of mobile health applications and devices are having on healthcare accessibility and improvements to care.

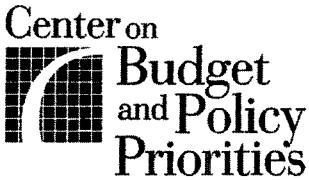
In July 2011, the FDA announced it was seeking input with respect to how the agency should approach oversight of certain mobile medical apps used on smartphones, tablets and other mobile devices. In the nearly two years since the FDA sought comment, there have been over 700 pages of comments, the vast majority of which support the FDA's draft guidance. The FDA also conducted a two-day workshop on mobile medical apps which provided feedback from a variety of stakeholders, including manufacturers, healthcare providers and app developers. Unfortunately, in a hearing intended to examine how "FDA regulations and taxes could impact innovation in mobile applications and services," we don't have the FDA here to tell their story.

Also absent from this discussion is the importance of unlicensed spectrum to hospitals and other healthcare professionals around the country. For example, in Logan, Ohio, through the power of unlicensed spectrum below 1 gigahertz, the Hocking Valley Community Hospital has a robust broadband solution that is improving the efficiency and quality of care throughout the hospital. Elsewhere in the country, unlicensed spectrum is supporting nurse call systems, mobile duress pendants, as well as fluid pump, respirator and other medical equipment alarm telemetry.

I understand the desire of innovators to have a predictable regulatory process for the apps they're developing. But mobile medical applications are an emerging and exciting new field of technology and we're still trying to get a handle on what the

landscape looks like. As technology advances, the clear lines of what's considered a medical device are becoming blurred. We have to be careful not to lock ourselves into a misguided pathway without a more complete picture of what these new technologies are capable of. The FDA's primary goal is to ensure patient safety and I believe they are working diligently on final guidance for regulation of mobile health applications.

Despite the FDA's absence from today's hearing, I look forward to hearing from our witnesses and their enthusiasm for this emerging field of innovation that could one day transform our healthcare system. I share this enthusiasm and hope to see patients and the industry flourish.



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Excise Tax on Medical Devices Should Not Be Repealed

Industry Lobbyists Distort Tax's Impact

By Paul N. Van de Water

Bills introduced in the House (H.R. 523) and Senate (S. 232) would repeal the 2.3-percent excise tax on medical devices that policymakers enacted in 2010 to help pay for health reform. The provision is sound, however, and the arguments against the tax don't withstand scrutiny.

- **The tax does not single out the medical device industry for unfair treatment.** The excise tax is one of several new levies on sectors that will gain business due to health reform. The expansion of health coverage will increase the demand for medical devices and could offset the effect of the tax.

- **The tax will not cause manufacturers to shift production overseas.** The tax applies equally to imported and domestically produced devices, and devices produced in the United States for export are tax-exempt.

- **The tax will have little effect on innovation in the medical device industry.** To the contrary, health reform may well spur medical device innovation by promoting more cost-effective ways of delivering care.

The Joint Committee on Taxation estimates that repealing the excise tax would cost $29 billion over the 2013-2022 period.[1] Repealing the tax would undercut health reform in at least two ways. Pay-as-you-go procedures would require Congress to offset the cost of repeal by increasing other taxes or reducing spending; one likely target would be the provisions of the Affordable Care Act (ACA) that expand health coverage to 27 million more Americans. Also, repealing the tax would encourage efforts to repeal other revenue-raising provisions of the ACA, which in turn would either require still more painful offsets or increase the budget deficit (if Congress failed to offset the cost).

The industry's lobbying campaign against the medical device tax is based on misinformation and exaggeration, as a number of industry executives and analysts confirm. For example, Martin Rothenberg, head of a device manufacturer in upstate New York, calls claims that the tax would cause layoffs and outsourcing "nonsense." The tax, he writes, will add little to the price of a new

[1] Joint Committee on Taxation, *Description of H.R. 436, The "Protect Medical Innovation Act of 2011,"* Publication JCX-45-12, May 29, 2012. In March 2010 the committee estimated that the excise tax would raise $20 billion over the 2013-2019 period. The more recent estimate is higher only because it covers three more years.

device that his firm is developing. "If our new device proves effective and we market it effectively, this small increase in cost will have zero effect on sales. It would surely not lead us to lay off employees or shift to overseas production."[2] Martin Boyle, founder of a Massachusetts firm that makes diagnostic equipment, insists that the device tax is "not a job killer. It would never stop a responsible manager from hiring people when it's time to grow the business."[3]

The Excise Tax on Medical Devices

Congress carefully designed the ACA so that it will not add to the budget deficit. To help pay for the expansion of health coverage to 27 million uninsured Americans, the ACA either reduces Medicare payments or increases taxes for a wide range of industries that will benefit from health reform, including hospitals, home health agencies, clinical laboratories, health insurance providers, drug companies, and manufacturers of medical devices.

The ACA imposes a 2.3-percent excise tax on the sale of any taxable medical device by the manufacturer or importer of the device starting in 2013. The tax does not apply to eyeglasses, contact lenses, hearing aids, or any other medical device that the public generally buys at retail for individual use.[4] Sales for further manufacture or for export are also tax-exempt.[5] The Internal Revenue Service (IRS) published proposed regulations in February 2012 and final regulations in December providing detailed guidance on how the tax will be applied.[6] The IRS has also issued interim guidance for determining the price of a taxable device and providing transition relief from penalties for failure to pay the tax.[7]

Lawmakers initially considered a higher tax, but the medical device industry succeeded during the health reform debate in halving the amount of revenue that a fee or tax on devices would raise. Since the excise tax was enacted, lobbyists for the industry have been pressing for its delay or repeal. Last year the House passed H.R. 436, which would have repealed the tax, and bills to repeal the tax have been introduced in both the House and Senate this year.

Medical devices encompass an extremely wide range of products, such as surgical gloves, dental instruments, wheelchairs, coronary stents, artificial knees and hips, defibrillators, cardiac pacemakers, irradiation equipment, and advanced imaging technology. The U.S. medical device industry has estimated total sales of $106 billion to $116 billion a year.[8] A few large firms account for the lion's

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[2] Martin Rothenberg, "Numbers show ACA not responsible for layoffs," *Syracuse Post-Standard*, September 25, 2012, http://blog.syracuse.com/opinion/2012/09/numbers_show_aca_not_responsib.html.

[3] Alec MacGillis, "Um, About That Medical Device Tax," *The New Republic*, September 28, 2012.

[4] The excise tax is established by section 1405 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), which effectively substituted for section 9009 of the Patient Protection and Affordable Care Act of 2010 (Public Law 111-148).

[5] The excise tax is one of several manufacturers' excise taxes included in subtitle D, chapter 32, of the Internal Revenue Code. Section 4221 of the Code provides that sales for further manufacture or export are exempt from these excises.

[6] *Federal Register*, February 7, 2012, pp. 6028-38; December 7, 2012, pp. 72924-39.

[7] Internal Revenue Service, *Notice 2012-77, Interim Guidance and Request for Comments; Medical Device Excise Tax; Manufacturers Excise Taxes; Constructive Sale Price; Deposit Penalties*, http:// www.irs.gov/pub/irs-drop/n-12-77.pdf.

[8] Christopher Flavelle, *Medical Device Industry Overstates Tax Impact*, Bloomberg Government Study, February 9, 2012.

share of this revenue. For example, Johnson and Johnson's worldwide sales of medical devices and diagnostics totaled $27 billion in 2012; the firm had total sales (on both medical devices and other products) of $67 billion, on which it earned profits of nearly $11 billion.[9] Medtronic had $16 billion in sales and profits of nearly $4 billion in its 2012 fiscal year.[10] One trade group has estimated that the ten largest medical device makers will account for 86 percent of the sales of covered medical devices and hence pay 86 percent of the receipts from the excise tax.[11]

Tax Will Not Shift Employment Offshore

Despite claims to the contrary, the excise tax creates no incentive whatever for medical device manufacturers to move production overseas. The tax applies to imported as well as domestically produced devices. Thus, sales of medical devices in the United States will be equally subject to the tax whether they are produced here or abroad, and the tax will not make imported devices any more attractive to domestic purchasers.

In addition, devices produced in the United States for export are exempt from the tax, so it will not reduce the competitiveness of U.S.-made devices in international markets. Making a tax-free sale for export is straightforward, and the administrative burden of securing an exemption is small. The device manufacturer and the U.S. exporter will register with the IRS (foreign purchasers of articles for export need not register), and the U.S. exporter must simply provide its registration number to the manufacturer and certify that the devices will be exported.[12]

A much-cited 2011 study financed by AdvaMed, an industry trade association, alleges that the tax would cause 10 percent of device manufacturing to move offshore, leading to the loss of 43,000 U.S. jobs.[13] Analysis by Bloomberg Government, however, finds that the study "is not credible." Its assumptions, Bloomberg concludes, "conflict with economic research, overstate companies' incentives to move jobs offshore, and ignore the positive effect of new demand created by the [health reform] law."[14]

AdvaMed commissioned another study in 2012, but it is not credible either. AdvaMed hired the consulting firm Battelle to assess the effect of a "hypothetical economic event" that results in a $3

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[9] *Johnson & Johnson Reports 2012 Fourth-Quarter and Full-Year Results*, January 22, 2013, http://www.investor.jnj.com/releasedetail.cfm?ReleaseID=734718.

[10] Medtronic, Inc., *2012 Annual Report*, p. 28.

[11] Staff of Massachusetts Medical Devices Journal, "Medical device tax would mostly hit the biggest firms," *MedCity News*, March 24, 2010, http://www.medcitynews.com/2010/03/medical-device-tax-would-mostly-target-the-biggest-companies/.

[12] *Federal Register*, February 7, 2012, p. 6033.

[13] Diana Furchtgott-Roth and Harold Furchtgott-Roth, *Employment Effects of the New Excise Tax on the Medical Device Industry*, Advanced Medical Technology Association, September 2011, http://www.advamed.org/NR/rdonlyres/27ADDF3E-292D-4DFC-B4ED-B01E93E6D5AD/0/090711EmploymentEffectofTaxonMedicalDeviceIndustryFINAL.pdf.

[14] Christopher Flavelle, "How Much Will the Medical Device Tax Hurt?," *BloombergBusinessweek*, March 22, 2012, http://www.businessweek.com/printer/articles/14874-how-much-will-the-medical-device-tax-hurt.

billion annual decline in the medical device industry.[15] Battelle used what economists call an input-output model to estimate that this event would cause a loss of 10,000 jobs in the medical device industry and 29,000 jobs in other sectors of the economy. But there is no reason to think that the tax will cause a $3 billion drop in the sale of devices. Moreover, input-output models are not an appropriate way to analyze how changes in a given industry affect the economy as a whole.[16]

As *The Economist* magazine states, the effect of the excise tax on the medical device industry will be "trivial compared with other shifts," such as "scandals, recalls, stingy customers, [and] anxious regulators," all of which have left the industry in a "rut."[17] For example, device-maker Stryker Corporation revealed plans last year to lay off 1,000 workers, or 5 percent of its workforce, and implement other restructuring activities. In a press release announcing the changes, Stryker cited the excise tax but also stated that the restructuring aims "to allow for continued investment in strategic areas and drive growth despite the ongoing challenging economic environment and market slowdown in elective procedures."[18] Critics of the excise tax, however, have rushed to ascribe the layoffs to the tax.[19] When the *Columbus Dispatch* investigated similar claims in Ohio, home to many small device manufacturers, it found that "industry officials could not cite an example in Ohio of a company that has cut jobs or put growth plans on hold in anticipation of the tax."[20]

In fact, health reform may, on balance, benefit the medical device industry and boost its sales. By extending health coverage to 27 million more Americans, or by nearly 10 percent, the Affordable Care Act will increase the demand for medical devices and the revenue of device manufacturers. As the industry notes, older patients, who use a disproportionate number of medical devices, already have coverage through Medicare. However, the substantial expansion of health coverage will increase the number of elective medical procedures performed on those who were previously uninsured and, in turn, the use of medical devices. Bloomberg Government finds that the effect of the tax "could be offset by demand from millions of new customers."[21]

Tax Will Have Little Effect on Innovation

The excise tax also will likely have very little effect on innovation in the medical device industry, despite claims to the contrary. The consulting firm PricewaterhouseCoopers has identified five

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[15] Battelle, *The Economic Impact of the U.S. Advanced Medical Technology Industry*, March 2012, http://www.advamed.org/NR/rdonlyres/6C514FB6-8497-475C-84DC-7872A9DDBADC/0/BattelleFinalAdvaMedEconomicImpactReportMarch2012.pdf.

[16] Paul N. Van de Water, "More Bogus Economics from the Medical Device Industry," *Off the Charts Blog*, March 30, 2012, http://www.offthechartsblog.org/more-bogus-economics-from-the-medical-device-industry/.

[17] "Left to their own devices: Medtronic and the woes of America's medical-technology industry," *The Economist*, September 10, 2011, http://www.economist.com/node/21528644.

[18] Stryker Corporation, "Stryker Announces Actions to Drive Over $100 Million in Annual Productivity Gains," November 10, 2011, http://phx.corporate-ir.net/phoenix.zhtml?c=118965&p=irol-newsArticle&ID=1629222&highlight.

[19] Han Zhong, *Medical Device Excise Tax Claims Its First Victims*, American Action Forum, November 16, 2011.

[20] Ben Southerly, "Medical-device makers fight tax," *The Columbus Dispatch*, May 15, 2012, http://www.dispatch.com/content/stories/local/2012/05/15/medical-device-makers-fight-tax.html.

[21] Flavelle, "How Much Will the Medical Device Tax Hurt?"

pillars of medical technology innovation: financial incentives, human and physical resources, a favorable regulatory climate, demanding and price-insensitive patients, and a supportive investment community.[22] Each pillar comprises more than a dozen separate factors, and the tax rate is just one of the many factors affecting financial incentives.

The rate of innovation in medical technology has slowed in recent years for reasons entirely unrelated to the excise tax. "Like Big Pharma, which introduced many 'me too' drugs," writes *The Economist,* "device companies have sustained themselves by making small improvements to existing products. Spending on R&D has so far failed to yield many truly innovative devices."

Health reform may well spur medical-device innovation by promoting more cost-effective ways of delivering care. As PricewaterhouseCoopers observes:

> Government pressure to lower healthcare costs could . . . forc[e] developed nations to turn to innovative technology to achieve better results at lower costs. In the United States, for example, the [ACA] calls for reduced annual payment updates for most Medicare services, substantial cuts to managed care plan payments, and the creation of an Independent Payment Advisory Board. These are small steps in what will be a prolonged and complex effort by Western nations to rein in healthcare costs.[23]

Tax Will Have Minimal Effect on Consumers

The effect of the excise tax on consumers' costs for health care and health insurance will be minimal and will be swamped by other factors. Spending on taxable medical devices represents less than 1 percent of total personal health expenditures, so a small increase in their price would have an almost imperceptible effect on health insurance premiums.

Device manufacturers generally do not hold enough market power to pass on the entire excise tax to consumers through higher prices. For some common medical devices (for example, heart valves and hip and knee replacement parts), buyers have several available alternatives and can negotiate for a favorable price. For other products, manufacturers may not be able to pass on the full tax to consumers because treatment of the health condition is elective or physicians can select other treatment options.[24]

Taking all of its provisions into account, health reform will modestly reduce the cost of health insurance. The Congressional Budget Office estimates that the ACA will reduce premiums for employers with more than 50 workers — which account for 70 percent of the total insurance market — by up to 3 percent by 2016. For small employers, the estimated change in premiums ranges from an increase of 1 percent to a reduction of 2 percent.[25]

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[22] PricewaterhouseCoopers (PwC), *Medical Technology Innovation Scorecard: The Race for Global Leadership,* January 2011.

[23] PwC, p. 12.

[24] Personal communication from Dr. Rena Conti, assistant professor of health policy and economics, University of Chicago.

[25] Congressional Budget Office, *An Analysis of Health Insurance Premiums Under the Patient Protection and Affordable Care Act,* November 30, 2009, http://www.cbo.gov/ftpdocs/107xx/doc10781/11-30-Premiums.pdf.

March 18, 2013

The Honorable Greg Walden
Chairman
Energy and Commerce Committee
Subcommittee on Communications and Technology
US House of Representatives

The Honorable Anna Eshoo
Ranking Member
Energy and Commerce Committee
Subcommittee on Communications and Technology
U.S. House of Representatives

Dear Chairman Walden and Ranking Member Eshoo,

Recent comments concerning the Medical Device Tax and potential harmful effects on job creation and innovation are interesting, but seem more like political speech rather than thoughtful analysis. Current technology such as smartphones and tablets, for which apps are being developed have also come under scrutiny as possibly being subject to the Tax and, therefore hindering innovation.

We are a small business with just over 50 employees. We manufacture our products right here in America. As with most such companies we are in business to make money. We are finally pulling out of the economic slowdown. We fully expect that in the next few years we will see a growth spurt due to more Americans having affordable health care. If we manage our business prudently we will welcome the increased sales and the positive effects there from. It is difficult to imagine that a responsible manager would not embrace growth even though there will be a tax imposed on it. Why would we not hire new people, buy new production equipment and increase space to have the resources to make more money? That is our job. To avoid growth to avoid a tax is not prudent management.

The same logic applies to development of new products whether they be new hardware based or app based. If the innovation would result in a saleable product it would make no sense for a responsible manager to not innovate. There are thousands and thousands of new products under development across the entire medical device industry. There seems to be no reduction in FDA applications for new products due to the ACA.

In terms of the applicability of FDA regulations to new smartphone and tablet devices we see no reason that current reasoning should not continue. The definition of a medical device is rather straightforward. The use of this definition could be easily applied to new app technology. If a device is simply used to record data and not used to actually generate the data or make a diagnosis based on the data, it would not fit the definition. If the

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device were used to make measurements and/or diagnose from those data, then it would be regulated. We have all seen the effects of insufficient regulation. China which is well known to have had severe problems with lack of oversight has suffered from many cases of serious effects from contaminated food and drugs. Right here in Massachusetts there is an ongoing situation with a firm that produced products that were not regulated by the FDA and under regulated by the state. Americans deserve to have the confidence that products that can affect their health are safe and effective. We also need reasonable and logical debate on matters that effect laws and regulations that can produce that confidence.

Sincerely,

Michael J. Boyle, President

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STUDY

ONLINE FIRST

Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection

Joel A. Wolf, BA; Jacqueline Moreau, BA; Oleg Akilov, MD; Timothy Patton, DO; Joseph C. English III, MD; Jonhan Ho, MD; Laura K. Ferris, MD, PhD

Objective: To measure the performance of smartphone applications that evaluate photographs of skin lesions and provide the user with feedback about the likelihood of malignancy.

Design: Case-control diagnostic accuracy study.

Setting: Academic dermatology department.

Participants and Materials: Digital clinical images of pigmented cutaneous lesions (60 melanoma and 128 benign control lesions) with a histologic diagnosis rendered by a board-certified dermatopathologist, obtained before biopsy from patients undergoing lesion removal as a part of routine care.

Main Outcome Measures: Sensitivity, specificity, and positive and negative predictive values of 4 smartphone applications designed to aid nonclinician users in determining whether their skin lesion is benign or malignant.

Results: Sensitivity of the 4 tested applications ranged from 6.8% to 98.1%; specificity, 30.4% to 93.7%; positive predictive value, 33.3% to 42.1%; and negative predictive value, 65.4% to 97.0%. The highest sensitivity for melanoma diagnosis was observed for an application that sends the image directly to a board-certified dermatologist for analysis; the lowest, for applications that use automated algorithms to analyze images.

Conclusions: The performance of smartphone applications in assessing melanoma risk is highly variable, and 3 of 4 smartphone applications incorrectly classified 30% or more of melanomas as unconcerning. Reliance on these applications, which are not subject to regulatory oversight, in lieu of medical consultation can delay the diagnosis of melanoma and harm users.

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As smartphones use increases, these devices are applied to functions beyond communication and entertainment and often become tools that are involved intimately in many aspects of daily life through the use of specialized applications. Several applications in the field of health care, marketed directly to the public, are readily available. Some examples include applications that are intended to aid users in learning about adverse effects of medications, to track their caloric intake and expenditure to manage weight loss, and to log their menstrual cycles to monitor fertility. Although such applications have the potential to improve patient awareness and physician-patient communication, applications that provide any type of medical advice might result in harm to the patient if that advice is incorrect or misleading.

A review of the applications available for the 2 most popular smartphone platforms reveals several that are marketed to nonclinician users to assist them in deciding whether a skin lesion is potentially a melanoma or otherwise of concern and requires medical attention or whether it is likely benign based on analysis of a digital clinical image. Such applications are available for free or for a relatively low cost compared with an in-person medical consultation. These applications are not subject to any sort of validation or regulatory oversight. Despite disclaimers that these applications are intended for educational purposes, they have the potential to harm users who may believe mistakenly that the evaluation given by such an application is a substitute for medical advice. This risk is of particular concern for economically disadvantaged and uninsured patients. Because a substantial percentage of melanomas are detected initially by patients,[1-4] the potential effect of such applications on melanoma detection patterns is particularly relevant. We therefore sought to determine the accuracy of these applications in determining the benign vs malig-

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nant nature of a series of images of pigmented skin lesions using the histologic finding as the reference standard.

METHODS

SKIN LESION IMAGES

The University of Pittsburgh institutional review board reviewed this study and determined that it was exempt from full board review provided that all images used did not contain identifiable patient features or data and images were already in existence at the start of the study. The images of skin lesions were selected from our database of images that are captured routinely before skin lesion removal to allow clinicopathologic correlation in making medical management decisions. We only used close-up images of lesions. Images that contained any identifiable features, such as facial features, tattoos, or labels with patient information, were excluded or cropped to remove the identifiable features or information. Because histologic diagnosis was used as the reference standard for subsequent analysis, we only used images for which a clear histologic diagnosis was rendered by a board-certified dermatopathologist (J.H.). Lesions with equivocal diagnoses, such as "melanoma cannot be ruled out" or "atypical melanocytic proliferation," were excluded, as were Spitz nevi, pigmented spindle cell nevus of Reed, and other uncommon or equivocal lesions. We also excluded lesions with moderate or high-grade atypia given the controversy over their management. The remaining images were stratified into 1 of the following categories: invasive melanoma, melanoma in situ, lentigo, benign nevus (including compound, junctional, and low-grade dysplastic nevi), dermatofibroma, seborrheic keratosis, and hemangioma. Because 1 application used assessments by a remote dermatologist, we cropped images to remove rulers or stickers that might reveal that our images were from a dermatologist and not a patient. This process was performed using a computer program (iPhoto; Apple Inc) and did not compromise the integrity of the images. Two investigators (J.W. and L.K.F.) then reviewed all images for image quality and omitted those that were of poor quality or resolution.

SMARTPHONE APPLICATIONS

We searched the application stores of the 2 most popular smartphone operating systems for applications that claim or suggest an ability to assist users in determining whether a skin lesion may be malignant. Our search terms included *skin, skin cancer, melanoma,* and *mole.* We reviewed the descriptions of all applications returned by these searches to determine whether they use a photograph of a skin lesion to make assessments and whether they suggest any type of diagnosis or estimate the risk of malignancy. These applications then were evaluated to determine whether they could be used with an existing image (ie, if an image could be uploaded into the application rather than requiring that the image be captured in real time within the application). Three applications were excluded because they could not use existing photographs. Applications that allowed the use of existing images were selected for further evaluation. Our search yielded a total of 4 applications that met our criteria. Because the purpose of our study was to determine the accuracy of such applications in general and not to make a direct statement about a particular application, we have chosen not to identify the applications by their commercial name but rather to number them.

Application 1 uses an automated algorithm to detect the border of the lesion, although it also allows manual input to confirm or to change the detected border. Of the applications we tested, only application 1 has this feature of user input for border detection. The application then analyzes the image and gives an assessment of "problematic," which we considered to be a positive test result; "okay," which we considered to be a negative test result; or "error" if the image could not be assessed by the application. We categorized the latter group as unevaluable.

Application 2 uses an automated algorithm to evaluate an image that has been uploaded by the user. The output given is "melanoma," which we considered to be a positive test result, or "looks good," which we considered to be a negative test result. If the image could not be analyzed, a message of "skin condition not found" was given and we considered the image to be unevaluable.

Application 3 asks the user to upload an image to the application and then to position it within a box to ensure that the correct lesion is analyzed. The output given by the application is "high risk," which we considered to be a positive test result, or "medium risk" or "low risk," both of which we considered to be a negative test result. The presence of a medium-risk category in application 3 presented some difficulty in analysis because only this application among those tested gave an intermediate output. Thus, we performed sensitivity and specificity analyses with medium-risk lesions counting as a positive test result because we do not know how a user would interpret such a result. Some lesions generated a message of "error," and these were considered unevaluable.

Application 4 can be run on a smartphone or from a website. This program differs from the others because it does not use an automated analysis algorithm to evaluate images; rather, each image is sent to a board-certified dermatologist for evaluation, and that assessment is returned to the user within 24 hours. The identity of the dermatologist is not given, and we do not know whether all the images were read by the same dermatologist or by several different dermatologists. The output given is "atypical," which we considered to be a positive test result, or "typical," which we considered to be a negative test result. For some images we submitted, we were given a response of "send another photograph" or "unable to categorize," and we considered these images to be unevaluable in our analysis.

DETERMINATION OF APPLICATION ACCURACY AND STATISTICAL ANALYSES

Each of the 4 applications was presented with each eligible pigmented skin lesion image, and we attempted evaluation. We recorded output as a test result of positive, negative, or unevaluable as described in the preceding section. We calculated the percentage of images presented to each application that were considered to be evaluable. Subsequent analysis of the overall sensitivity, specificity, positive predicative value (PPV), and negative predictive value (NPV) for each application was performed with 95% confidence intervals. These calculations were performed only for evaluable lesions because we did not have the option of submitting another image, and we did not want this limitation to bias our results. To compare application performances with each other, the relative sensitivities of each application were compared using the McNemar test with Holm-Bonferroni adjustment for multiple comparisons. To perform this calculation, only lesions that were considered evaluable by both applications being compared were included. We performed statistical analysis using commercially available software (Stata, version 12.1; StataCorp).

RESULTS

IMAGES SELECTED FOR EVALUATION

We reviewed a total of 390 images for possible inclusion in this study. We excluded 202 as being of poor image qual-

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Table 1. Histologic Diagnosis of 188 Evaluated Lesions

Lesion	No. (%)
Melanoma	60 (31.9)
Invasive	44 (23.4)
In situ	16 (8.5)
Benign lesions	128 (68.1)
Lentigo	8 (4.3)
Benign nevus	94 (50.0)
Seborrheic keratosis	20 (10.6)
Hemangioma	2 (1.1)
Dermatofibroma	4 (2.1)

Table 2. Sensitivity and Specificity of Applications Using Evaluable Images

Application No.	Evaluable Image, No. (%)	Sensitivity, % (95% CI)	Specificity, % (95% CI)
1	182 (96.8)	70.0 (56.6-80.8)	39.3 (30.7-48.6)
2	185 (98.4)	69.0 (55.3-80.1)	37.0 (28.7-46.1)
3	170 (90.4)	6.8 (2.2-17.3)	93.7 (87.0-97.2)
4	159 (84.6)	98.1 (88.8-99.9)	30.4 (22.1-40.3)

ity, containing identifiable patient information or features, or lacking sufficient clinical or histologic information. A total of 188 lesions were evaluated using the 4 applications. Of these lesions, 60 were melanoma (44 invasive and 16 in situ). The remaining 128 lesions were benign. The categorization of all lesions is given in **Table 1**.

APPLICATION SENSITIVITY, SPECIFICITY, PPV, AND NPV

Each application was presented with each of the 188 lesions in the study, and the test result was recorded as positive, negative, or unevaluable as outlined in the "Smartphone Applications" subsection of the "Methods" section. The primary end point of our study was the sensitivity to melanoma categorization because most of the lesions removed in our practice are removed owing to concern about malignancy, and thus we expected the specificity to be low.

As reported in **Table 2**, the applications considered 84.6% to 98.4% of the images evaluable. Using only those images considered evaluable for each application, we calculated the overall sensitivity and specificity with 95% confidence intervals for each application (Table 2). Sensitivities ranged from 6.8% to 98.1%. Application 3 had the lowest sensitivity when a readout of medium risk was considered to be a negative test result. When analysis was performed considering the medium-risk readout to be a positive test result, the calculated sensitivity was 54.2% (95% CI, 40.8%-67.1%). Application specificities ranged from 30.4% to 93.7%. When the medium-risk result was considered to be a positive test result, the specificity of application 3 dropped to 61.3% (95% CI, 51.5%-70.2%). When we compared the 4 applications with each other, application 4 had higher sensitivity than the other 3 ($P < .001$ vs applications 1 and 3; $P = .02$ vs application 2).

We also calculated the PPV, NPV, and 95% confidence interval for each application. The results are shown in **Table 3**. The PPVs ranged from 33.3% to 42.1%; the NPVs, from 65.4% to 97.0%.

Table 3. Predictive Values of Applications Using Evaluable Images

Application No.	PPV, % (95% CI)	NPV, % (95% CI)
1	36.2 (27.6-45.7)	72.7 (60.2-82.6)
2	33.3 (25.2-42.6)	72.3 (59.6-82.3)
3	36.4 (12.4-68.4)	65.4 (57.4-72.7)
4	42.1 (33.4-51.2)	97.0 (82.5-99.8)

Abbreviations: NPV, negative predictive value; PPV, positive predictive value.

COMMENT

More than 13 000 health care applications marketed to consumers are available in the largest online application store alone, and the mobile health application industry generated an estimated $718 million worldwide in 2011 according to a recent report.[5] Two-thirds of physicians use smartphone applications in their practice.[6] Some of these applications have been evaluated in the peer-reviewed literature, including instruments used to aid autobiographical memory in patients with Alzheimer disease,[7] to assist in the delivery of cardiac life support,[8] and to manage diabetes mellitus.[9] However, this type of evaluation is not common for applications marketed directly to consumers.

In dermatology, several applications are available that offer educational information about melanoma and skin self-examination and that aid the user in tracking the evolution of individual skin lesions. However, the applications we evaluated in our study go beyond aiding patients in cataloging and tracking lesions and additionally give an assessment of risk or probability that a lesion is benign or malignant. This finding is of particular concern because patients may substitute these readouts for standard medical consultation. Three of the 4 applications we evaluated do not involve a physician at any point in the evaluation. Even the best-performing among these 3 applications classified 18 of 60 melanomas (30%) in our study as benign.

The explosion of smartphone applications geared at health-related decision making has not gone unnoticed by the US Food and Drug Administration (FDA). In July of 2011, the FDA announced plans to regulate smartphone applications that pair with medical devices already regulated by the FDA, such as cardiac monitors and radiologic imaging devices.[10] In June 2012, Congress approved the FDA Safety and Innovation Act,[11] which allows the FDA to regulate some medical applications on smartphones. However, how this process will occur, which applications will be subject to this regulation, and which applications will be exempt remain unclear. Although clarification of these guidelines were projected before the end of 2012, at the time of publication their impact remains uncertain. In 2011, the Federal Trade Commission fined the developers of 2 applications that made unsubstantiated claims to treat acne using colored light that could

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be shone on the skin from a smartphone application. Both applications were withdrawn from the market.[12]

In our study, the application with the highest sensitivity essentially functions as a tool for store-and-forward teledermatology. Using this application, only 1 of the 53 melanomas evaluated was rated as typical (ie, benign). Although our results show that the physician-based method is superior in sensitivity to the applications that use an automated algorithm for analysis, this application was also the most expensive in terms of cost per use at $5 for each lesion evaluated. By contrast, the costs of the other applications range from free to $4.99 for evaluation of an unlimited number of lesions. In addition, although applications 1, 2, and 3 provided immediate feedback on lesions (mean duration, <1 minute), the evaluation given by application 4 was received in about 24 hours.

Our study has some intrinsic limitations. To power this pilot study adequately while restricting our inclusion criteria to lesions for which histopathologic evaluation as the reference standard for diagnosis was available, we were limited to the use of existing photographs of lesions that had been removed before the start of the study. This limitation has several implications. First, our images consisted primarily of lesions that were considered to be atypical in clinical appearance by at least 1 dermatologist. For this reason, and because of the potentially devastating consequences of missing a melanoma (compared with classifying a benign lesion as of concern), we made sensitivity our primary end point. In addition, we could not evaluate the performance of applications that require images to be captured in real time within the application because we limited our study to existing images. However, because we are not comparing applications for the purpose of recommending one over the other, our results still provide valuable information about the general threat that such applications may pose. Finally, because the lesions in our images were no longer present on the patient, we could not retake a photograph if a lesion was considered unevaluable. To compensate for this limitation, we included only evaluable lesions in our analyses.

Technologies that improve the rate of melanoma self-detection have potential to improve mortality due to melanoma and would be welcome additions to our efforts to decrease mortality through early detection. However, extreme care must be taken to avoid harming patients in the process. Despite disclaimers presented by each of these applications that they were designed for educational purposes rather than actual diagnosis and that they should not substitute for standard medical care, releasing a tool to the public requires some thought as to how it could be misused. This potential is of particular concern in times of economic hardship, when uninsured and even insured patients, deterred by the cost of copayments for medical visits, may turn to these applications as alternatives to physician evaluation. Physicians must be aware of these applications because the use of medical applications seems to be increasing over time; whether such applications may be subject to regulatory oversight, whether oversight is appropriate, and when oversight might be applied remain unclear. However, given the recent media and legislative interest in such applications, the dermatologist should be aware of those relevant to our field to aid us in protecting and educating our patients.

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Author Contributions: Dr Ferris had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Wolf and Ferris. *Acquisition of data:* Wolf, Akilov, Patton, English, Ho, and Ferris. *Analysis and interpretation of data:* Wolf, Moreau, and Ferris. *Drafting of the manuscript:* Wolf, Moreau, and Ferris. *Critical revision of the manuscript for important intellectual content:* Wolf, Moreau, Akilov, Patton, English, Ho, and Ferris. *Statistical analysis:* Moreau. *Obtained funding:* Akilov and Ferris. *Administrative, technical, and material support:* Wolf, Patton, Ho, and Ferris. *Study supervision:* English and Ferris.
Conflict of Interest Disclosures: Dr Ferris reported having served as an investigator and consultant for MELA Sciences, Inc.
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CTIA
The Wireless Association®

Expanding the Wireless Frontier

March 18, 2013

The Honorable Greg Walden
Chairman
House Subcommittee on Communications & Technology
2182 Rayburn House Office Building
Washington, D.C. 20515

Re: March 19 Hearing on Health Information Technologies: Harnessing Wireless Innovation

Dear Chairman Walden:

On behalf of CTIA-The Wireless Association® ("CTIA"), I commend you for conducting tomorrow's subcommittee hearing. Innovative mobile health ("mHealth") technologies and applications have enormous potential to improve the delivery of health care in the United States and around the world by strengthening personalized care for patients, lowering health care costs, and removing geographic and economic disparities in health care delivery. However, licensing restrictions limit the potential of mHealth technologies and applications, and additional actions by the Food and Drug Administration ("FDA") and Congress could further hinder their availability and effectiveness.

The migration of U.S. wireless networks from second-generation to third-generation and now fourth-generation capabilities has created a powerful platform on which mHealth technologies and applications can thrive. These advanced mobile networks provide faster and more-intelligent delivery of a multitude of voice, video, and data applications. While many such applications are focused on entertainment and productivity, an increasing number facilitate real-time interaction between patients and health care professionals.

For example, there are applications that turn any web-enabled phone into an interactive diabetes monitoring and management device. There are systems that link a patient's home with his or her pharmacy and prescribing physician, and even include a medication dispensing unit that can be installed in a patient's home and connect with the prescribing physician using a secure two-way connection. In addition, there are services that connect cardiac telemetry capabilities to remotely monitor thousands of patients with chronic heart conditions; and other services that dispatch home health care and hospice personnel to patients in the greatest need in real time.

mHealth applications can allow the millions of Americans living in rural or insular areas to "visit" the best doctors' offices in the nation, eliminating health care disparities based on geographic location and economic differences. These applications could radically change decisions about where and from whom to seek medical advice, especially for patients who are not physically capable of travelling long distances to obtain medical care.

One study estimated that remote monitoring of patients with chronic diseases could save $197 billion in direct costs over 25 years by reducing emergency room visits, hospital admissions, and the length of stay in hospitals. (See Robert E. Litan, "Vital Signs via Broadband: Remote Health Monitoring Transmits Savings, Enhances Lives.") The societal and economic impact of mHealth applications is thus substantial.

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To ensure that mHealth technologies and applications flourish, policymakers must be mindful of the impact of government actions. U.S. wireless carriers must have access to enough licensed spectrum to enable real-time delivery of bandwidth-intensive mHealth applications. Access to a sufficient amount of licensed spectrum has become more important as the use of applications on smartphones and tablets has led to an exponential growth in consumer demand for spectrum. This is why it remains critically important for the subcommittee to pursue policies aimed at bringing additional spectrum for licensed, commercial mobile use to market as expeditiously as possible.

In addition, wireless carriers must be able to manage traffic on their networks so that patients can establish secure connections with their doctors and other health care providers. If carriers cannot manage their networks, connections could be hacked, exposing sensitive health information, which would discourage patients from utilizing potentially life-saving applications. Patients would also lose confidence in diagnostic applications that were slow or repeatedly subject to interruptions.

Further, restrictions on the delivery of health care across state lines inhibit the effectiveness of mHealth solutions. As mentioned above, mHealth applications can obliterate the disparity of health care options between urban and rural areas. However, if health care delivery has to stop at state lines, patients in certain states will not have access to the same level of care as patients in other states, even though technology enables them to do so.

Finally, several actions by the FDA and Congress could have a significantly negative impact on the success of mHealth applications and the use of mobile technology to improve health care delivery. If the FDA classifies mHealth applications, as well as the smartphones and tablets on which they operate, as medical devices, the FDA could subject such applications and devices to a time-consuming approval process, which would provide an enormous disincentive to innovation in this sector and compromise the availability of life-saving technologies.

And the excise tax on medical devices (a category in which the FDA may seek to include mHealth applications and mobile devices) enacted as part of the Affordable Care Act threatens to raise the cost of wireless health products and services, and to discourage research and innovation intended to enable more effective, lower cost treatments. It should be repealed.

Thank you again for exploring how wireless can help to improve health care in America. CTIA's members are truly excited about the potential for mHealth solutions to revolutionize health care delivery and we look forward to working with you to ensure that government actions facilitate the development and deployment of life-saving technologies and applications.

Sincerely,

Steve Largent
President and CEO

Ideomed
648 Monroe Ave NW
Grand Rapids, MI 49503

Tuesday, March 19th 2013

The Honorable Fred Upton
Chairman
House Energy and Commerce Committeee
2125 Rayburn House Office Building
Washington, DC 20515

Chairman Upton,

Thank you very much for holding this important hearing. My name is Keith Brophy and I am the CEO of a health focused software development company based in Michigan. My company, Ideomed, is changing the game in health care tracking. Our apps help people with asthma, heart conditions, and diabetes with more on the way. We work to transform the usual pitfalls such as medication adherence into new opportunities for patient engagement – and lasting behavior change. Our applications do not dispense medical advice but they do provide motivation, inspiration and self-tracking capabilities.

Mobile applications have enormous value in the healthcare space, especially from the consumer perspective. During the development process of our application, we undertook rigorous clinical trials to understand what consumers needed from a patient engagement application. We are using the experience gained in this effort to inform our product development of existing and new products.

Ideomed has 25 employees with offices in Grand Rapids, and Ann Arbor Michigan, and employs some of the nation's best and brightest technology, product development, and human engagement experts. Our solution has received the State of Michigan's Accelerate Michigan award for most innovative IT company, the Michigan Comcast award for Business Innovation, and a national Edison Silver Medal award for on-line tool innovation. The accomplishment we are most proud of, however, is that our solution has made a positive impact on the lives of those who use it as measured by clinical trial outcomes and by glowing user feedback.

Unfortunately, the FDA's failure to put out a final rule governing mobile applications and health IT hampers innovation and increases uncertainty. The slow pace of the FDA does not match today's pace of innovation; there is pent-up desire by both developers and health care providers to address today's medical problems using

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mobile devices and mobile applications. However, emerging businesses in this space need seed capital from venture capitalists and venture capitalists need regulatory certainty.

The traditional FDA process is lengthy and often very costly. This is a process we respect and recognize as merited for certain kinds of applications and clinical use. However, we believe it will be critical for any FDA mobile health rule to be "right sized" and not capture every application as the same by default simply because it has the word "medical" or "health" in the description. We've been able to scale up our operation from an app that helps people with asthma to apps that help people with heart condition tracking and diabetes tracking. However, if each one of our current and future platforms required a new extensive FDA approval process, we would be unable to respond to the needs of our consumers in a timely fashion, slowing our growth as a company and our consumers ability to manage their own health.

At Ideomed, we understand the value the FDA provides and believe that products with clinical applications need oversight. We agree that mobile applications with clear clinical applications should need to follow the FDA process. However, burdensome rules for very useful apps that improve patient engagement may drive emerging business entities to step back from the market rather than deal with a lengthy approval process. The FDA has a tremendous opportunity to allow safe and well thought innovation to be embraced and flourish in the healthcare space.

Again, I want to thank you and the committee for undertaking this hearing, and I hope that it produces the kind of results we are working for: a happier, healthier nation that is engaged in stewarding health in innovative ways.

Sincerely,

Keith Brophy

Keith Brophy
Chief Executive Officer
Ideomed

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