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

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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.

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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

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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.
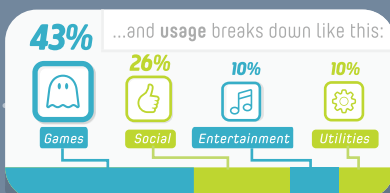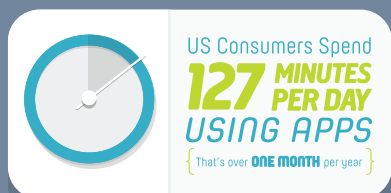
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Thank you again for the opportunity to testify this morning, and I look forward to your

questions and the continued opportunity to work together to help promote innovation and
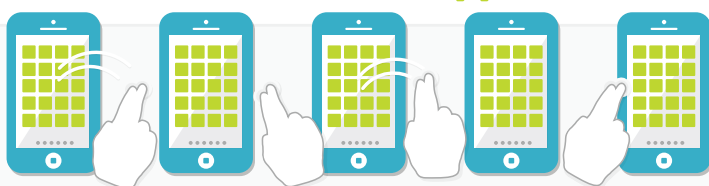
opportunity in the mobile broadband ecosystem.

ALL ABOUT APPS

In 2007, the Mobile App Industry was nonexistent, **but now...**

US Consumers Spend
127 MINUTES PER DAY USING APPS
That's over ONE MONTH per year

43% ...and **usage** breaks down like this:

26%	**10%**	**10%**
Social	Entertainment	Utilities

Games

The average user has more than **100 apps** on their device.

This **adoption + growth** of app usage has been **EXPONENTIAL**.

Apple launched the App Store in **2008**.

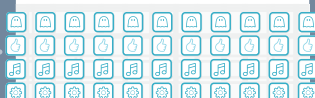It took **9 months** for **1 BILLION APPS** to be downloaded.

By the end of **2013** we will be downloading **2 BILLION** iOS + Android Apps **....PER WEEK!**

2008   2009   2010   2011   2012   2013   2014

Now, some people will even **wait in line** to download apps

One week after launch, nearly **1 MILLION** people were queued up to download Mailbox.

More than **26,000** apps are submitted to the Apple store per week.

That's about **1.3 MILLION** in a year

Today's app economy has created more than

500,000 JOBS

In **2013**, mobile apps will generate **$25 BILLION** IN REVENUE

By **2016**, the app economy is expected to reach **$46 BILLION**

...the future is BRIGHT.

MOBILE FUTURE