Statement of
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U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health

Hearing on "Examining Federal Regulation of Mobile Medical Apps and Other Health Software"

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Summary

Mobile technology continues to be the largest platform in history. Innovation continues to personalize healthcare as health apps are more available than ever via sophisticated smartphones and tablets that rely on powerful, ubiquitous 3G and 4G mobile broadband networks.

After two years the FDA delivered on its promise: a deregulatory and practical roadmap for the mobile health industry. This is significant for solo developers, garage entrepreneurs and established medical device manufacturers such as Qualcomm's wholly-owned medical device subsidiary Qualcomm Life. FDA has raised the bar and demonstrated how it can work with industry, be progressive, help speed innovation and ensure public safety.

But more is yet to come as broader issues linger which require the same light-touch, flexible approach FDA has now demonstrated it is capable of adopting. The final FDASIA report due at year's end by FDA, ONC, and FCC should contain a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications.

Qualcomm offers the following recommendations for consideration:

1. As recommended by the FDASIA external working group report, FDA should utilize current program mechanisms that could enable innovation, such as:
   a. assess exemption from good manufacturing practices for lower-risk Health IT;
   b. expedite guidance on Health IT software and related matters, particularly those on its fiscal year (FY) 2014 Proposed Guidance Development "B List" including "Medical Device Decision Support Software", "Medical Device Accessories", and "General Wellness Products";
   c. continue to improve internal coordination on Health IT software and its regulatory treatment; and
   d. continue to utilize external facing resources to proactively educate the public about how policies and regulation impact Health IT and mobile medical apps.
2. FDA, ONC and FCC should address policy and regulatory deficiencies, ambiguities and duplication in the final FDASIA report.
3. 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.
4. Interoperability is a critical concern for reliable data exchange and secure health communications to and from mobile devices. The FDA should collaborate closely with the ONC in supporting the Direct Messaging Exchange standard and the DirectTrust Security and Trust Framework.
5. Privacy, Data Use Rights, and Identity Management issues have unique concerns in relation to mobile health devices. Close collaboration between the FDA, ONC, and FTC are essential to the establishment of consistent standards and requirements for industry, healthcare providers and the public.

Qualcomm underscores the importance for Agencies to utilize existing program mechanisms to enable innovation immediately; while they explore how to improve and modify existing frameworks, or if needed, develop recommendations for Congress to consider a new risk-based framework. What the public and industry don't need is a situation where innovation suffers as a result of regulatory confusion in the health IT software space, which is why existing program mechanisms are vital policy tools that can be employed promptly. The end goal should be for a regulatory framework that allows new technology to flourish, promotes innovation, protects patient safety and avoids regulatory duplication.

Good morning, Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee. Earlier this year the House Energy & Commerce Committee, Subcommittee on Communications and Technology held a series of hearings during the third week of March on health information technologies and innovation, including mobile medical apps. I was honored to have been invited to participate in the first of those hearings, and I am honored to be here again today.

At the March hearing, my testimony centered around four core themes:

1) Mobile technology is the largest platform in history; it is at the center of our lives and touches every aspect of society;
2) The pervasiveness and costs of chronic disease in America, where almost one out of every two adults in the U.S. has at least one chronic illness[1];
3) Innovations are personalizing healthcare unlike ever before, such as mobile health apps that are available to hundreds of millions of people via sophisticated smartphones, tablets and devices that rely on powerful and ubiquitous 3G and 4G mobile broadband networks;
4) And a call for clarity from the Food and Drug Administration to finalize and release final guidance on mobile medical applications.

Over the past eight months, much has happened: mobile technology is as popular as ever with a recent TIME Invention Poll reporting that 71% of global consumers feel the mobile phone

[1] *See Chronic Diseases and Health Promotion*, Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) http://www.cdc.gov/chronicdisease/overview/index.htm.

is the most useful invention[2]; the Centers for Disease Control continue to affirm that as a nation, 75% of our health care dollars go towards the treatment of chronic diseases[3]; according to mobihealthnews RESEARCH, unique health apps for smartphone users in the U.S. continue to enjoy unprecedented growth accounting for over 33,000[4]; the FDASIA working group of external stakeholders and experts delivered strategy and recommendations to FDA, ONC and FCC, on the regulation of health IT and mobile medical apps; and after two years the Food and Drug Administration delivered on its promise to issue final guidance on mobile medical applications.

Overall, the final mobile medical apps guidance document is deregulatory and practical for the mobile health industry. In some respects it's quite an expansive document that seeks to liberalize the nimble and innovative mobile health apps industry, while ensuring patient safety. FDA makes the bold statement that "the majority of mobile apps on the market" are either not regulated outright or fall under "enforcement discretion." This is significant for solo developers, garage entrepreneurs and established medical device manufacturers such as Qualcomm's wholly-owned medical device subsidiary Qualcomm Life. FDA has raised the bar by demonstrating that it can work with industry, be progressive, help speed innovation and ensure public safety.

The issuance of this guidance did not come about without its share of controversy as many sides weighed in on whether FDA should even have the authority to regulate health IT software at all, let alone mobile medical apps. The hearings this Committee held earlier this year

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[2] *See The TIME Invention Poll*, TIME http://techland.time.com/2013/11/14/the-time-invention-poll/.
[3] *See Chronic Diseases and Health Promotion*, Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) http://www.cdc.gov/chronicdisease/.
[4] *See Consumer Health Apps By The Numbers*, mobihealthnews RESEARCH (2013).

illuminated the arguments for and against finalizing guidance and certainly played a role to expedite the delivery of the final guidance. But another development may have also played a role: the convening of the FDASIA external working group and its findings and recommendations.

In July of 2012 the Food and Drug Administration Safety and Innovation Act ("FDASIA") was signed into law, under which Section 618, titled "Health Information Technology" called for the Secretary of Health and Human Services, acting through the Commissioner of the FDA, and in consultation with the National Coordinator for Health Information Technology (ONC) and the Chairman of the Federal Communications Commission (FCC), to post within 18 months "a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication." Section 618 of the Act allowed the Secretary to convene a working group of external stakeholders to provide input for a final report to be developed by FDA, ONC and FCC.

In total, thirty-two expert stakeholders (including Qualcomm) served as members of the FDASIA external working group who represented patient advocates, healthcare providers, start-ups, health plans, venture capital investors, information technology vendors and ex-officio federal officials. The recommendations by the external working group were delivered to the three agencies on September 4, 2013, and included the unequivocal statement that: "FDA should expedite guidance on HIT software, mobile medical apps and related matters."

Three weeks later on September 25, 2013, the FDA issued final guidance on mobile medical apps. The final guidance was a marked improvement over the original draft guidance issued on July 21, 2011. Final guidance included two new appendices that help clarify which apps are not medical devices and those apps that will not be regulated under the Agency's "enforcement discretion," (i.e., apps that FDA will choose not to regulate even though they may meet the definition of a medical device but pose such a low-risk to the public it makes little sense to impose regulation). By doing so, FDA expressed that it will not actively enforce any requirements it typically would obligate under the law. To strengthen this point, FDA provides several pages of examples of mobile apps that fit in this category, including:

- Medication reminders are currently regulated as Class I medical devices, that are exempt from 510(K) and good manufacturing practices. FDA will no longer enforce any requirement for manufacturers of these types of medication reminders. It means manufacturers and specification developers developing medication reminders will not have to register with FDA, list those devices with FDA or conform to general controls as required of manufacturers by FDA, regardless of platform (whether mobile or other). This is an important development going forward as a number of wireless health companies, some of which are Qualcomm Life partners, have brought medication reminders to market including WellDoc, Vitality, Vocel, MedMinder, and CleverCap, to name a few.
- Mobile medical apps that allow a user to collect (electronically or manually entered) blood pressure data and share these data through e-mail, track, trend or upload them to a PHR or EHR. Such an app is not regulated through enforcement discretion.

- Mobile medical apps intended for medical uses that utilize a mobile device's built in camera or connected camera for documenting and transmitting pictures of medical conditions to supplement verbal descriptions in consultations with healthcare providers or between providers – not regulated under enforcement discretion.
- Mobile medical apps that provide patients with simple tools to organize and track health information without providing recommendations to alter or change a prescribed treatment or therapy on specific conditions or chronic disease (e.g., obesity, anorexia, arthritis, diabetes, heart disease) to log, track, or trend events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their health care provider as part of a disease-management plan – not regulated under enforcement discretion.
- Mobile medical apps that serve as a checklist of symptoms that provide possible medical conditions and offer advice on when to consult a healthcare provider – not regulated under enforcement discretion.
- Mobile health apps intended to enable patients to interact with PHR systems or EHR systems – not regulated under enforcement discretion.
- Medical calculators (i.e., BMI, total body water/urea volume of distribution, mean arterial pressure, Glasgow Coma Scale score, Apgar score, NIH stroke scale, and delivery date estimators), some of which were listed in the original draft guidance as regulated mobile medical apps – not regulated under enforcement discretion.

Indeed there are dozens of references throughout the final guidance that bring much needed clarity on what it is, what is not, and what will not be regulated.

FDA should be commended for what this guidance has provided, as well as for what the Agency did as a result of its release. FDA has created a new public facing webpage on mobile medical apps with informational links for the public and developers; on a public call hosted by FDA and timed with the release of the guidance, Dr. Jeffrey Shuren the FDA's Center Director of the Center for Devices and Radiological Health, alluded to the creation of a "special team under CDRH senior management" that would be tasked with answering public inquiries submitted to a newly created FDA mobile medical apps e-mail address for questions (mobilemedicalapps@fda.hhs.gov); and lastly, the FDA posted a list of regulated mobile medical apps that serve as examples of devices which FDA has cleared or approved since 1997.

These pronouncements and actions by FDA, taken in part or as a whole, are good for the industry, great for developers and excellent for the people who stand to utilize these novel devices to learn, track and improve upon their health and wellbeing. Through the release of this helpful document, FDA has demonstrated its ability to ensure predictability, consistency and transparency in a radically changing technological age. However, it's important to note that more is yet to come as issues linger which require the same light-touch, flexible approach that FDA has demonstrated it is capable of adopting.

Qualcomm offers the following recommendations for consideration:

1. As recommended by the FDASIA external working group report, FDA should utilize current program mechanisms that could enable innovation, such as:
   a. assess exemption from good manufacturing practices for lower-risk Health IT[5];
   b. expedite guidance on Health IT software and related matters, particularly those on its fiscal year (FY) 2014 Proposed Guidance Development "B List" including "Medical Device Decision Support Software", "Medical Device Accessories", and "General Wellness Products" [6];
   c. continue to improve internal coordination on Health IT software and its regulatory treatment; and
   d. continue to utilize external facing resources to proactively educate the public about how policies and regulation impact Health IT and mobile medical apps.
2. FDA, ONC and FCC should address policy and regulatory deficiencies, ambiguities and duplication in the final FDASIA report due at year's end.
3. 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.
4. Interoperability is a critical concern for reliable data exchange and secure health communications to and from mobile devices. The FDA should collaborate closely with the

[5] "HIT" as defined according to the FDASIA External Working Group in the September 4, 2013, final "Committee Report," (*Defining Characteristics of What Should be Included as HIT/ "Eight Key Dimension of HIT"*).
[6] *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm.

ONC in supporting the Direct Messaging Exchange standard and the DirectTrust Security and Trust Framework.[7]

5. Privacy, Data Use Rights, and Identity Management issues have unique concerns in relation to mobile health devices. Close collaboration between the FDA, ONC, and FTC are essential to the establishment of consistent standards and requirements for industry, healthcare providers and the public.

The final FDASIA report due at year's end by FDA, ONC, and FCC should contain a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications. "A risk-based regulatory framework" can be interpreted to mean an existing regulatory framework – or – a new one to be created. Qualcomm's recommendation would be for FDA, ONC and FCC to consider both tracks: utilize existing program mechanisms that could enable innovation immediately; while they explore how to improve and modify existing frameworks, or if needed, develop recommendations for Congress on a new risk-based framework. It is essential that these agencies recognize the growing importance of managing risk at a systems level and that any comprehensive regulatory scheme should take into account existing solutions when contemplating future innovations. The end goal should be for a regulatory framework that allows new technology to flourish, promotes innovation, protects patient safety and avoids regulatory duplication.

[7] *See ONC Partners with Two Health Information Exchange Governance*, Office of the National Coordinator for Health Information Technology (ONC), Health IT Buzz Blog (April 2013) http://www.healthit.gov/buzz-blog/health-information-exchange-2/onc-partners-health-information-exchange-governance-entities/.

What the public and the industry don't need is a situation where innovation suffers as a result of regulatory confusion in the health IT software space, which is why FDA's existing program mechanisms are vital policy tools that can be employed immediately. Any new framework regardless of how well intentioned it may be, will take time, intense legislative action, rulemaking, subsequent implementation, a modicum of uncertainty and potentially millions in taxpayer dollars to establish. Wasting time through uncertainty only harms innovation and that's something we should all try to avoid.

About Qualcomm

Qualcomm Incorporated is the number one global supplier of wireless chips, and the leading inventor of wireless technologies. To date, Qualcomm's chip shipments surpass 11 billion. 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, 2net™ Mobile, 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, Wi-Fi, and ANT+ local area radio protocols. 2net Mobile is a software module that enables mobile computing devices such as mobile phones and tablets to serve as gateways to the cloud-based 2net Platform. The 2net™ Platform reliably captures and delivers medical device data to integrated portals or databases. In April 2013, QCL acquired HealthyCircles™, a care coordination platform that is an enterprise software-as-a-service (SaaS) solution designed to connect care teams and deliver transitional care, telehealth and exception-based care management solutions. As a care coordination and management platform company, HealthyCircles™ provides Enterprise clients with private-label branded web, mobile and multi-lingual solutions and services that address hospital readmission reduction, care transitions, home health monitoring and management, accountable care organizations (ACO) and patient-centered medical homes (PCMH).

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 88 projects in various stages of development in 34 countries (over 30 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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