Statement of
Robert Jarrin
Senior Director, Government Affairs
Qualcomm Incorporated

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Subcommittee on Health
Subcommittee on Communications & Technology

Hearing on "21st Century Technology for 21st Century Cures"

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Summary

Mobile technology continues to be the largest platform in history. With a global population of approximately 7.1 billion people, there are now over 7 billion mobile connections — 4.4 billion of which are unique. In the U.S. alone, there are 355 million mobile connections for a population of just over 317 million. The Centers for Disease Control (CDC) recently reported that the percentage of U.S. households that do not have a landline phone and rely only on a mobile phone has risen to 41 percent.

Qualcomm, an American company is the world's largest supplier of chips for wireless devices and the world's largest licensor of mobile technology. Sophisticated mobile computing devices have helped underpin consumer health IT technologies, software and mobile medical and wellness apps. Remote patient monitoring is rapidly proliferating. Interoperability and data integration are starting to take hold.

Qualcomm's subsidiary Qualcomm Life and its partners produce some of the most novel 21st century mobile medical solutions that are commercially available: mobile ECG recorders, hospital grade wireless telemetry sensors, mobile blood glucose monitors for diabetics, medical software systems that deliver live patient data to a doctor's smartphone or tablet, wireless medical sensors for use with inhalers, software to make radiological imaging viewers available for mobile devices, wireless blood pressure cuff monitors, implantable pulmonary sensors that communicate wirelessly with bedside monitors, Wi-Fi enabled medical grade weight scales, and medical device data systems.

Investments in the mobile health space for the first half of this year show that approximately 143 companies have successfully raised $2.3B in 2014 YTD, which eclipses the 2013 total of around $2B. Those investments include some by the Qualcomm Life Fund which was formed in 2011 and has consistently ranked as one of the most prolific investors in the wireless health space.

Challenges to adoption persist. Lack of reimbursement payment coverage is a major barrier to telehealth and remote patient monitoring technologies. Current Medicare telehealth reimbursement provisions in the Social Security Act are outdated inhibitors to the proliferation of mobile health. They are limiting patient access to new technologies, effectively discouraging providers from utilizing advanced information communications in their practices.

Another challenge has been the lack of references to remote patient monitoring technologies and patient generated health data (PGHD) as criteria in the Centers for Medicare and Medicaid Services EHR incentive payment program, popularly referred to as the "Meaningful Use" rules.

Meaningful use has focused on Certified EHRs, EHR modules, and EHR systems, but has yet to fully encourage the involvement of patients and families in their care. The ability to upload PGHD into certified EHRs should be included in future stages of meaningful use as criteria to incentivize eligible providers to embrace the use of remote monitoring technologies.

Another important component of any 21st Century technology for 21st Century cures is spectrum, the life blood of our wireless networks. Spectrum is a finite natural resource which is rapidly being constrained. Qualcomm commends this Committee and Congress for its work to make available additional mobile broadband spectrum.

The speed of innovation should never come at the expense of patient safety. As innovative and essential products race to market, quality assurance processes and methodologies, including verification and validation found in rigorous quality and design controls should be implemented. Health IT software products and mobile medical apps should naturally be supported by data collection mechanisms to foster a true patient safety and quality learning environment.

Good morning, Chairman Walden and Chairman Pitts, Ranking Members Eshoo and Pallone, and Members of the Subcommittees. On behalf of Qualcomm, an American company that is the world's largest supplier of chips for wireless devices and the world's largest licensor of mobile technology, it is an honor to be here before you today – thank you for inviting me to testify.

Mobile technology, Qualcomm's specialty, has become the largest communications platform in the history of the world. With a global population of approximately 7.1 billion people, there are now over 7 billion mobile connections — 4.4 billion of which are unique.[1] In the United States alone, there are 355 million mobile connections for a population of just over 317 million.[2] A Pew Research report states that the national adoption rate for smartphones is 55 percent,[3] and the Centers for Disease Control (CDC) recently reported that 41 percent of U.S. households do not have a landline phone and rely exclusively on a mobile phone. Meanwhile, the CDC also found that of consumers who only use a mobile phone, just over 63 percent describe their health status as excellent or very good. Qualcomm believes it is crucial, indeed essential, that this enormous mobile technology platform be used to improve healthcare, and we are working on this in many ways.

It's easy to overlook how quickly mobile technology and smart devices have proliferated. For example, the Android operating system, so common today, was officially launched in 2007. Apple's iPhone and iPad were introduced in 2007 and 2010, respectively.[4] One would not know

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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; GSMA Intelligence, Apr. 2014.
[2] See https://gsmaintelligence.com/session/log-in/?return_url=%2Fmetrics%2F3%2F0%2Fdata%2F%3Freport%3D53c409e13c017.
[3] *See* http://www.pewinternet.org/2014/04/03/usage-and-adoption/.
[4] *See* "iPhone introduced June 29 2007"

that considering how consumers rely on these devices and the technologies they incorporate for many things, including healthcare. Thus, it is not at all surprising that U.S. users of 4G LTE services already consume considerably more data than users of 3G technologies.[5] Wireless data usage has been doubling annually over the past several years, and if this trend continues for the next ten years, the level of usage will be more than 1000 times today's level. Given this extraordinary growth trend, Qualcomm has set a corporate goal to meet what we call the "1000x Challenge" — to support this growth by expanding the wireless capacity of today's mobile broadband networks 1000 fold. 3G and 4G technologies have literally helped to transform the way we transact in commerce, conduct public safety, learn, play sports, and most notably, deliver and personalize healthcare.

Qualcomm cannot make this happen by itself. One of our core values at Qualcomm is to work with partners—a wide variety of companies throughout the many facets of the ever-expanding wireless eco-system. In fact I am pleased to be joined at the witness table today by one of our technology partners, Amazon.com. Their leading edge Kindle Fire HDX Tablets, recently released Fire Smartphone, and innovative Fire TV media player all take full advantage of Qualcomm's innovative Snapdragon chipsets.

Let me turn to Qualcomm's health-related initiatives. In 2011 Qualcomm launched Qualcomm Life, Inc., a wholly owned subsidiary, with a goal to improve lives and advance the capabilities of wireless medical devices. Qualcomm Life is focused on medical device

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https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&es_th=1&ie=UTF-8#q=iphone%20introduced&safe=off; *See* "iPad introduced April 3, 2010" https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&es_th=1&ie=UTF-8#q=ipad+introduced&safe=off.

[5] *See* Sue Marek, "Study: U.S. LTE subscribers use about 1.6 GB of data per month," FierceWireless (June 23, 2014) *available at* http://www.fiercewireless.com/story/study-us-lte-subscribers-use-about-16-gb-data-month/2014-06-23 ("U.S. subscribers … are among the heaviest users of mobile data [and] LTE subscribers use dramatically more data than 3G subscribers.").

connectivity and data management, empowering medical device manufacturers to deliver wireless medical data quickly and easily to those who need it. Mobile computing platforms are ideal for improving healthcare.

Qualcomm Life's 2net™ Platform, is a unique, cloud-based solution that enables the wireless transfer, storage and display of medical device data. The platform is designed to be interoperable with different medical devices and applications, providing end-to-end wireless connectivity. The 2net Hub, one of many gateways used to access the 2net Platform's data center, houses a short-range radio that provides security, interoperability and seamless data transfer, while serving as the information highway for machine-to-machine (M2M) connectivity for medical devices into and out of the home.

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 solution enables a mobile phone or tablet to collect and visualize data from medical devices and biometric sensors and securely transmit that information via the mobile phone or tablet's wireless wide area network (WWAN) cellular connection or Wi-Fi to the 2net Platform's data center. As mobile broadband-enabled smartphones, tablets, and laptops are becoming an extension of the person they belong to, products such as 2net Mobile are but one of the many applications that are available to the end user. We are rapidly approaching a day when everyone and everything in our world will be connected through seamless, ubiquitous wireless technologies.

There is no better example of how mobile technologies can transform a sector than by looking at the way patient engagement in healthcare also has changed throughout the past eight years. On August 16, 2006, my mother was diagnosed with Stage III-C late term ovarian cancer.

At the time, she was 65 and a widow with limited English proficiency attempting to navigate the U.S. medical system.

Early in my mom's odyssey, a number of frustrating challenges with her healthcare emerged. It quickly became clear that her doctors, clinics, and hospitals were not collaboratively sharing her healthcare information in any way, shape, or form. I foolishly thought that every healthcare encounter she had would be digitally documented in some kind of a shared healthcare data service that pooled her information and made it available for anyone on her care team. I assumed her tests, images, medications, and clinical interventions were freely available to her, the doctors or whomever else she chose. This was not the case.

I was particularly struck by the lack in continuity of care. When she left a doctor's office, hospital or clinic, there was no mechanism to remotely monitor her basic physiological parameters. The inability to remotely monitor her care was particularly dangerous in light of countless doses of chemotherapy, protein inhibitors, and toxic serums, with various side effects ranging from chronic high blood pressure to edema. There are over 117 million adults in the U.S., (not including children) suffering from at least one chronic illness in this same situation. [6]

In the eight years since my mom's initial diagnosis, sophisticated mobile computing devices have helped enable consumer health IT technologies, software and mobile medical and wellness apps. Remote patient monitoring is now rapidly proliferating through the use of medical devices and health IT software platforms that are beginning to drive systemic change within healthcare institutions and health networks. Today, solutions such as Qualcomm's Life's HealthyCircles™ and 2net ™ platforms facilitate the seamless and secure data capture, case

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[6] *See* http://www.cdc.gov/chronicdisease/overview/index.htm.

management, and patient-centered care coordination by and between any stakeholder across a patient's care team, including healthcare professionals, patients, and their families. These platforms are ideally suited to enable scalable and cost-effective approaches for healthcare professionals to succeed with the latest CMS innovations such as Transitional Care Management (TCM) and the proposed Chronic Care Management (CCM) programs. Interoperability and data integration are starting to take hold for data exchange between platforms and electronic health records, clinical practice systems, hospital and lab records, and claims and medication history made more easily available for whoever needs it via mobile computing platforms.

In fact, Qualcomm Life and its partners produce some of the most novel 21st century mobile medical solutions that are commercially available, such as mobile ECG recorders for broad analytics, advanced hospital grade wireless telemetry sensors, mobile blood glucose monitors for diabetics, medical software systems that deliver live patient data to a doctor's smartphone or tablet, wireless medical sensors for use with inhalers, software to make radiological imaging viewers available for mobile devices, wireless blood pressure cuff monitors, implantable pulmonary sensors that communicate wirelessly with bedside monitors, Wi-Fi enabled medical grade weight scales, and medical device data systems that transmit, store, convert and display medical device data. These are not far-fetched scientific prophecies, but a short inventory of the types of medical technologies that exist and are readily available today.

What the future holds is even more exciting. People are beginning to engage more directly and effectively with providers. Diagnostic medical devices and sensors are being packed with wireless functionality and ever-increasing computing power to seamlessly track a patient's health state.

With this vision for the future in mind, the X PRIZE Foundation and Qualcomm developed a competition, the Qualcomm Tricorder X PRIZE, to spur radical innovation in personal healthcare technology. Qualcomm's Tricorder X PRIZE is a $10 million global competition to stimulate innovation and integration of precision diagnostic technologies, to ultimately help consumers make their own reliable health diagnoses virtually anywhere, at anytime. Qualcomm's Tricorder X PRIZE seeks the development of a portable, wireless device that monitors and diagnoses one's health conditions to allow unprecedented access to personal health metrics. The competition is set to conclude in January 2016, when we hope that the winning solution will be a wireless medical device that can check for anemia, urinary tract infection, type 2 diabetes, atrial fibrillation, stroke, obstructive sleep apnea, tuberculosis, COPD, pneumonia, ear infection, leukocytosis, hepatitis A, and other conditions and vital signs.

In the same vein, investments in the mobile health space are rapidly accelerating. Data for the first half of this year show that approximately 143 companies have successfully raised $2.3B in 2014 YTD, which already eclipses the 2013 total of around $2B. The funding is helping to seed six general categories of healthcare, including payer administration, digital medical devices, healthcare consumer engagement, population health management, personalized medicine, analytics and big data.[7] Qualcomm began making strategic investments in early-stage high-technology ventures in the wireless health space in 2007. In 2011, the Qualcomm Life Fund was formed with the mission 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 areas of specific interest to the fund range from personal wellness to disease management in areas such as: body worn or implantable biosensors or devices for vertically focused applications such as

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[7] *See* http://rockhealth.com/2014/06/2014-midyear-digital-health-funding-update/.

chronic disease care, medication adherence, and fitness or wellness; integrated system providers that do remote diagnosis, monitoring or specialize in independent living; mobile software health IT applications; and health informatics/analytics.

Challenges to mobile health adoption do persist. In comments provided to this Committee, the American Telemedicine Association (ATA) cited the lack of payment coverage as a major barrier to the proliferation of telehealth and remote patient monitoring technologies.[8] For over a decade, ATA and its vast membership of industry leaders have argued that current Medicare telehealth provisions in the Social Security Act 1834(m) are overly restrictive and exclude the majority of technological innovations due to outdated and narrow definitions.[9] A 2012 report by a public-private task force on mHealth consisting of federal officials, academia, industry and other stakeholders, named outdated reimbursement regulations and policies as inhibitors to the proliferation of mobile health technologies. More recently, the Telecommunications Industry Association (TIA) sent a multi-stakeholder letter to the Secretary of Health and Human Services stating that the arduous reimbursement restrictions on telehealth services are limiting patient access to new technologies, effectively discouraging providers from utilizing advanced information communications technologies and solutions in their practices.[10] In fact, over the course of this Committee's 21st Century Cures hearings and roundtables, several witnesses and panelists have echoed the sentiment that the biggest obstacle to health IT

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[8] *See* http://www.americantelemed.org/docs/default-source/policy/american-telemedicine-assn-for-e-c-health.pdf?sfvrsn=4.
[9] *See* 42 CFR § 410.78.
[10] *See* http://www.tiaonline.org/sites/default/files/pages/Multi-Assn%20Letter%20-%201834%28m%29%20%26%20MSSP%20ACOs%20060914.pdf .

innovation is the issue of reimbursement and the need to improve upon those outdated coverage regulations.[11]

Another challenge has been the lack of references to remote patient monitoring technologies and patient generated health data (PGHD) as criteria in the Centers for Medicare and Medicaid Services EHR incentive payment program, popularly referred to as the "Meaningful Use" rules. To date, meaningful use has focused on Certified EHRs, EHR modules, and EHR systems, but has yet to fully encourage the involvement of patients and families in their care. Remote patient monitoring technologies such as telemedicine, telehealth and mobile health are increasingly playing a vital role capturing PGHD. The ability to upload PGHD into certified EHRs should be included in future stages of meaningful use as criteria to incentivize eligible providers to embrace the use of remote monitoring technologies. Doing so would promote those capabilities to patients and families, particularly the most chronically ill who can be monitored in their homes and outside of healthcare institutions.

Another important component of any 21st Century technology for 21st Century cures is spectrum, which is the life blood of our wireless networks. Mobile health solutions are part and parcel of the enormous surge in wireless data usage, which is causing the spectrum crunch we are all now facing. Qualcomm commends this Committee and Congress for the work it is doing to unleash additional mobile broadband spectrum, which will be needed to support mobile medical applications and the growing number of new uses and users over the coming years.

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[11] *See* 21st Century Cures: The President's Council of Advisors on Science and Technology (PCAST) Report on Drug Innovation, May 20, 2014, http://energycommerce.house.gov/hearing/21st-century-cures-president%E2%80%99s-council-advisors-science-and-technology-pcast-report-drug; 21st Century Cures Roundtable: Digital Health Care, June 24, 2014, http://energycommerce.house.gov/event/21st-century-cures-roundtable-digital-health-care.

In closing, the speed of innovation should never come at the expense of patient safety. As innovative and essential products race to market, quality assurance processes and methodologies, including verification and validation found in rigorous quality and design controls should be implemented. Health IT software products and mobile medical apps should naturally be supported by data collection mechanisms to foster a true patient safety and quality learning environment.

Nearly eight years after my mother's initial diagnosis, I'm thankful to her healthcare team that she's continuing to live an enjoyable life. I'm also grateful for the advancements in 21st century medical technologies which are helping society as a whole. Qualcomm is playing a significant role mobilizing healthcare to improve lives and help advance digital medicine.

Thank you, I look forward to 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 15 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 100 projects in various stages of development in 35 countries (many of which 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.

Global Employee Health Services, GEHS, is a department at Qualcomm with a mission to support the health of our employees and our business. Our vision is a healthy global community of Qualcomm employees engaged in engineering their health and healthcare for all. GEHS achieves its mission by providing a variety of health services to Qualcomm employees. Some examples include: clinical services from a premier onsite health center in San Diego, workplace health promotion programs that include health education activities and biometric health screening, employee activity challenges incorporating mobile technology, Global Health

Observances Celebrations like World Health Day and World Diabetes Day, and vaccination campaigns.

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