

**Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554
and the
FOOD AND DRUG ADMINISTRATION
Silver Spring, MD 20993**

In the Matter of

Converged Communications and Health Care
Devices Impact on Regulation; Public
Meeting; Request for Comment

FCC Docket No. ET 10-120

FDA Docket No. FDA-2010-N-0291

COMMENTS OF QUALCOMM INCORPORATED

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SUMMARY

Qualcomm applauds the Federal Communications Commission (“FCC”) and the Food and Drug Administration (“FDA”) for following up on the National Broadband Plan’s recommendation to seek public input on how to streamline the regulatory process for bringing the next generation of innovative wireless health care products and services to market in a timely, safe, and cost-effective manner. *See* FCC NBP Recommendation 10.3.

For more than two decades, Qualcomm’s innovations have fueled the successful development of wireless networks and countless mobile devices – including those used today by health care providers to serve their patients’ medical needs. In fact, Qualcomm CDMA Technologies (“QCT”) is the world’s largest provider of wireless chipset technology that is integrated into hundreds of millions of cellular phones and mobile broadband devices – from smartphones to wireless PC cards and USB dongles to Mi-Fi devices (which connect multiple Wi-Fi devices to a 3G mobile broadband connection) to mobile broadband-embedded laptops, netbooks, and pocketable computing devices. In addition, Qualcomm’s mobile broadband initiatives, namely the Snapdragon-, Gobi-, Kayak-, and mirasol-based platforms and devices, which are described herein, are enabling the next generation of wireless smartphones, smartbooks, tablets, and laptops that will support health care delivery across the United States and throughout the world.

The proliferation of personal mobile devices and associated licensed wireless networks presents an unprecedented opportunity to leverage America’s pervasive communications platform to completely transform the health care delivery system and improve the lives of all patients. By broadly licensing its technology innovations and providing equipment vendors with complete chipset and software solutions, Qualcomm is playing a key role in this transformation

by enabling both new and established companies to introduce wireless infrastructure, mobile devices, and associated health care applications to market more quickly and at lower cost. In this regard, Qualcomm-enabled devices will support remote monitoring of vital signs, secure transmission of patient data, video consultations, near-real-time analysis of diagnostic test results, and, in critical situations, the automatic alerting of emergency responders where patient medical devices sense a life-threatening event, such as cardiac arrest. Against this background, Qualcomm strongly supports the agencies' joint commitment to working together to facilitate the development and deployment of tomorrow's wireless medical devices and systems that will better serve patients.

As Qualcomm explains herein, wireless health care solutions that operate in licensed spectrum will best support the next generation of wireless medical systems, devices, and applications that require highly reliable and secure communications and virtually ubiquitous coverage. Medical communications via purely unlicensed devices, which, by definition, have no right to the continued use of any given frequency and must accept any and all interference from all other RF devices, *see* 47 C.F.R. § 15.5 Part 15 General Conditions of Operation, are, on the other hand, less reliable and secure and are not able to provide the same wide-area coverage supported by commercial wireless providers that operate in licensed spectrum. Many wireless health care personal devices will rely upon both unlicensed spectrum (for short range links) and licensed spectrum for wide area communications. The FCC and the FDA must keep in mind the characteristics of wireless connectivity supported by duly licensed commercial wireless service providers as well as the limitations of the exclusively unlicensed wireless regime as both agencies consider the reliability, security, and coverage needs of wireless medical communications.

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Qualcomm is pleased to provide these comments to the Federal Communications Commission (“FCC”) and the Food and Drug Administration (“FDA”) for consideration at their upcoming joint public meeting to examine regulatory issues associated with advanced wireless health care devices.¹ Qualcomm strongly supports the agencies’ decision to hold a public meeting to address the means of promoting investment and innovation in mobile health care technology by streamlining government processes, based upon the recommendations in the National Broadband Plan.² Indeed, FCC/FDA interaction with medical professionals, patients, wireless medical device manufacturers, and wireless service providers is an essential step

¹ See FCC Public Notice DA 10-1071, “FCC and FDA to Hold Public Meeting on Regulatory Issues Arising From Health Care Devices that Incorporate Radio Technology; Comments Sought,” FCC Docket No. ET 10-120, FDA Docket No. FDA-2010-N-0291 (June 15, 2010) (asking interested parties to file comments 30 days prior to the agencies’ July 26 and 27, 2010, public meeting) (hereinafter, the “Public Notice”).

² See FCC National Broadband Plan: Connecting America (rel. Mar. 16, 2010) (“FCC NBP”) at 207 (Recommendation 10.3: FCC and FDA should clarify regulations and approval processes for converged communications and health care devices).

towards ensuring that next generation medical innovations are brought to market in a timely and safe manner.³ As explained in these comments, Qualcomm-enabled mobile broadband connectivity will help to realize the full potential of health care information technology (“Health IT”) and allow “eCare” to improve population health by expanding access to affordable care and by delivering care more effectively and efficiently.⁴

Both agencies serve key roles in this endeavor. The FCC is charged with regulating communications by radio, television, wire, satellite and cable. It oversees the wireless communications services, including cellular, personal communications services and other commercial and private radio services. The FDA is tasked with, among other things, ensuring the safety and efficacy of medical devices by regulating manufacturers and the technology that is integrated into their products. The FCC/FDA Joint Meeting is timely as the agencies’ regulations, many of which are decades old, have not adequately kept pace with the rate of technological advancements, particularly in the area of wireless innovation. In this regard, both the FCC and the FDA have acknowledged the need to update and clarify regulations for converged communications and healthcare devices that incorporate aspects of health information technology.⁵ Qualcomm submits these comments pursuant to that collective goal.

³ See FCC News Release, “FCC/FDA Joint Meeting Scheduled to Streamline Review Process For Life-Saving Wireless Medical Technology” (June 15, 2010) (comments of Chairman Genachowski).

⁴ See FCC National Broadband Plan: Connecting America (rel. Mar. 16, 2010) (“FCC NBP”) at 200 (defining “eCare” as “[t]he electronic exchange of information—data, images and video—to aid in the practice of medicine and advanced analytics. Encompasses technologies that enable video consultation, remote monitoring and image transmission (“store-and-forward”) over fixed or mobile networks”).

⁵ See Genevieve Douglas, FDA Discusses Oversight, Regulation of HIT at ONC Workgroup Hearing on Patient Safety, BNA Health IT Law & Industry Report (Feb. 26, 2010) available at <http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-832S8W?OpenDocument&PrintVersion=Yes> (FDA CDRH Director identifying potential three

BACKGROUND

A. Qualcomm Innovations Have Fueled The Development Of Wireless Networks And Devices Underlying Today's Wireless Medical Applications

For more than two decades, Qualcomm's innovations have served an integral role in the development and evolution of wireless networks and countless mobile devices. Thus, it is not at all surprising that Qualcomm technology also underlies many of today's wireless medical devices and applications.

Qualcomm is a world leader in developing innovative wireless communications technologies and enabling products and services based on those technologies. Qualcomm pioneered code division multiple access ("CDMA") technology, which is utilized in the 3G CDMA family of wireless technologies. These technologies include CDMA2000 and HSPA/WCDMA interfaces used in today's 3G wireless networks and devices to enable tens of millions of Americans to enjoy advanced, high speed, and ubiquitous mobile broadband services. Qualcomm also is deeply involved in the development and launching of the Long Term Evolution ("LTE") technology, which many carriers in the US and around the world currently are deploying.

Since its inception in 1985, Qualcomm has invested more than \$13 billion in R & D. In fiscal 2009 alone, Qualcomm spent \$2.4 billion, or approximately 23% of its revenues, on R & D. These enormous expenditures enabled Qualcomm to invent many of the wireless technologies that are fueling the mobile broadband boom. Qualcomm holds or has applied for

approaches for addressing HIT safety concerns: (1) require HIT device manufacturers to register their devices, submit medical device reports to the FDA, and correct identified safety issues; (2) require manufacturers to comply with the terms in (1) and follow FDA's rules to assure the quality and consistency of devices; or (3) apply the FDA's traditional regulatory framework for medical devices to Health IT software and systems, which includes risk-based premarket review). *See also* FCC NBP at 224.

approximately 12,600 US patents (3,900 issued and 8,700 pending) and 59,200 foreign patents (20,700 issued and 38,500 pending). Every division and subsidiary of Qualcomm has multiple R & D teams working on projects with the expectation that their original work will lead to patentable inventions. Such work occurs in many offices and labs around the US and the world.

1. **Qualcomm Is Playing A Key Role In The Mobile Revolution**

Qualcomm broadly licenses its technology to over 180 handset and infrastructure manufacturers around the world that make wireless network equipment, handheld and other consumer devices, and develop applications based on the CDMA2000, HSPA, and LTE air interfaces. Qualcomm CDMA Technologies (“QCT”), the world’s largest provider of wireless chipset technology, has led the diversification of mobile broadband into new types of wireless devices including those used everyday by medical professionals, patients, and their loved ones. These devices include wireless monitoring devices, smartphones, mobile broadband PC cards and USB dongles, Mi-Fi devices (which can connect five Wi-Fi devices to a 3G mobile broadband connection), mobile broadband-embedded laptops and netbooks, and a wide variety of handheld computing devices equipped with mobile broadband connectivity.

QCT’s chipsets provide a high degree of integration and support all the major frequency bands, the full gamut of wide area licensed cellular technologies, Assisted GPS, as well as unlicensed Bluetooth and Wi-Fi technologies, and multiple operating systems, including Android, Windows Mobile, and Symbian. QCT’s chips also support Qualcomm’s BREW⁶ Mobile Platform (“Brew MP”), a mobile operating system that delivers high-end features across all 3G technologies and virtually all market tiers of mobile devices, including the emerging low-cost smartphone category. By enabling low-cost smartphones and related data devices, Brew

⁶ BREW stands for Binary Runtime Environment for Wireless.

MP will give wireless service providers and device manufacturers – including medical device makers and application developers – the ability to differentiate services and monetize innovative wireless medical systems for the mass consumer market.

In addition, Qualcomm Internet Services offers software platforms that bring any application to any device on any network in any location. These software platforms began with BREW MP, which enabled the downloading of applications onto wireless phones, *i.e.*, the first application store. More recently, Qualcomm Internet Services began offering Plaza Mobile Internet, a platform which allows mobile devices to access widgets associated with the features and interactivity of Web 2.0 applications, and Plaza Retail, which provides support for multiple application stores across multiple software platforms and gives wireless subscribers easy access to applications, including health and well-being apps, on a broad collection of wireless devices.

2. **QCT Mobile Broadband Technology Initiatives Will Support A Growing Number Of Wireless Medical Communications Devices**

QCT continually develops new chipsets incorporating more functionality and lower power to drive mobile broadband into an increasing variety of devices at all price points. QCT is in the midst of three important initiatives that are intended to expand the scope and use of mobile broadband devices by creating new classes of mobile devices, which will be used by medical professionals, patients, and other health care stakeholders.

QCT's first mobile broadband initiative is a platform by the name of Snapdragon. Snapdragon, which is a single chip solution with integrated wireless modem, application processor, multimedia, GPS and other features, enables a new generation of mobile computing devices with embedded broadband connectivity. These new wireless computing devices, known as smartbooks, are smaller, thinner, and much less expensive than traditional notebook computers and have a longer battery life that lasts for many hours longer than a typical laptop,

which must be recharged every few hours. These new smartbooks combine the simplicity and connectivity of smartphones with the power and usability of laptops. At present, 20 major manufacturers are developing more than 60 Snapdragon-based mobile broadband-enabled smartphones and smartbooks, which will support wireless medical services and related applications.

Qualcomm's second QCT mobile broadband initiative, which is called Gobi, consists of a global mobile broadband and GPS-embedded solution for notebook computers and other wireless devices. Gobi-enabled notebooks can operate on mobile broadband networks throughout the United States and around the world. The original Gobi solution included a Qualcomm chipset, associated software and API, GPS functionality, and a reference design for a data module supporting both the EV-DO Revision A and HSPA mobile broadband air interfaces. Gobi2000, the second generation embedded Gobi module that Qualcomm announced last year, provides many enhancements, including support for additional frequency bands, increased data speeds, enhanced GPS functionality, and additional operating systems, such as Windows 7 and Linux. In addition, IREX Technologies touch-screen e-Reader, the IREX DR800SG, uses a Gobi module and its embedded 3G multi-mode capability to enable the wireless downloading of books, newspapers, and magazines around the world.

Kayak is QCT's third mobile initiative and offers a new category of low-cost, low power devices that use mobile broadband networks for wireless internet access and support e-mail, social networking, e-commerce, distance learning as well as telehealth applications. Kayak-based devices thus offer a low-cost PC alternative and use wireless broadband technology to fill the niche between mobile broadband-enabled smartphones and desktop computers, which typically access the Internet via wireline or cable connections that are often unavailable in rural

areas. There is no question that Snapdragon-, Gobi-, and Kayak-based modules will power wireless devices that enable communications between physicians and other medical professionals and their patients.

Finally, Qualcomm MEMS Technologies, Inc. (“QMT”), has developed a product that spans each of the foregoing classes of mobile broadband devices, a dramatically lower power consumption visual display with greatly enhanced quality in a wide range of ambient light conditions, including direct sunlight. QMT’s mirasol display is the world’s first direct-view, Microelectromechanical Systems or MEMS-based, mobile device display. Depending on the nature of the usage, it uses one-tenth to one-hundredth of the power of a traditional mobile display, which allows roughly 40% additional time between charges as compared to a traditional display. Mobile devices equipped with mirasol displays will allow medical professionals to work a 12-hour shift without having to recharge the devices.

B. Qualcomm Is Partnering With The Medical Community To Develop Next Generation Wireless Health Care Services and Products.

Wireless healthcare is a field of great emphasis for Qualcomm, as demonstrated via the following examples of the company’s close interactions with the medical community.

CardioNet. Qualcomm provides services to CardioNet, one of the world’s leading suppliers of Mobile Cardiac Outpatient Telemetry™, which uses 3G connectivity to provide ambulatory cardiac monitoring service with real-time beat-to-beat analysis, automatic arrhythmia detection, and wireless electrocardiography (“ECG”) transmission.⁷ The CardioNet system is helping clinicians prevent disability, morbidity, and mortality with rapid diagnosis and treatment of patients with cardiovascular disease.

⁷ See CardioNet, “Medical Professionals: CardioNet Comprehensive,” available at <http://www.cardionet.com/>.

Triage Wireless, a medical device company in which Qualcomm has invested, has developed an innovative solution for the wireless monitoring of a patient's vital signs, and the company is developing a product to continuously measure blood pressure and other vital signs using a "wireless band-aid," comprised of an arm-worn transceiver that sends data to a monitor via short range, unlicensed technology and then from the monitor to a hospital via a cellular module.

MedApps. The MedApps Mobile Health Monitoring System connects health care providers to patients and their families using cellular technology to remotely collect, store, and report timely health information anywhere patients may be.⁸ A key component of the MedApps System is the MA106 CDMA HealthPAL, a lightweight 3G mobile device that automatically collects readings from glucose meters, blood pressure monitors, scales and pulse oximeters and then wirelessly transmits their data into the MedApps System. Readings from the FDA-cleared device are accessed through the MedApps web-based care-provider portal, HealthCOM, which provides clinicians with the ability to monitor and manage medical information collected through the MedApps System. Readings also can be stored in an online personal health record.

Myca Health offers a 3G-powered, fully integrated, customizable web-based application that streamlines the engagement between health care providers and patients. The Myca Health system combines an electronic medical record, a comprehensive administrative system with scheduling and diagnostic tools that allows physicians to interface with patients and other medical professionals through multiple channels, such as email, instant messaging, and video.⁹

⁸ See "The MedApps Remote Health Monitoring Solution begins with HealthPAL," available at <http://www.medapps.com/HealthPAL.html#>

⁹ See Myca Health Inc., "What is MycaHub™?" available at <http://www.myca.com/mycahub-technology/what-it-is>.

Epocrates is a developer of comprehensive drug guides for handheld 3G based Palm, Windows Mobile, iPhone, and BlackBerry devices and other smartphones.¹⁰ Users are able to download via multiple platforms the free *Epocrates* application that includes a drug guide, formulary information, drug interaction checker and medical news.

Jitterbug offers highly user-friendly 3G CDMA wireless cell phone services that are targeted to accommodate the needs of elderly and disabled persons with unique and intuitive, life-enhancing cell phones. *Jitterbug*'s phones, which operate nationwide via the Verizon Wireless network, have larger keypads that are easier to read and operate along with a patented ear cushion for comfort and adaptability.¹¹ *Jitterbug* offers a variety of targeted services, including the “*Jitterbug LiveNurse™*”, which provides users with 24/7 access to live, registered nurses that address health-related questions.¹²

AirStrip Technologies offers a suite of products for remote healthcare surveillance supported by Apple's 3G UMTS iPhone. *AirStrip*'s signature product is *AirStrip OB*, which is now installed in nearly 200 U.S. hospitals with several thousand physician users, delivers vital patient waveform data such as fetal heartbeat and maternal contraction patterns in virtual real-time directly from the hospital labor and delivery unit to a physician's mobile device.¹³ In this

¹⁰ See *Epocrates*, “*Epocrates Products*,” available at <http://www.epocrates.com/>.

¹¹ See Verizon Wireless, “*Jitterbug's Easy-To-Use Services Are Now Available On The Verizon Wireless Network*” (Released August 8, 2009) available at <http://news.vzw.com/news/2009/08/pr2009-08-26d.html>

¹² See *Jitterbug* website, “*Services for Health and Wellness – Jitterbug LiveNurse*” available at <http://www.jitterbug.com/ServicesStore/health-and-wellness.aspx>. *Jitterbug* recently announced that it will launch a Personal Emergency Response Services (M-PERS) this fall using technology that it acquired from *MobiWatch*. See Brian Dolan, *Jitterbug: 12K Live Nurse customers*, *MobiHealthNews* (June 9, 2010) available at <http://mobihealthnews.com/7883/jitterbug-12k-live-nurse-customers/>.

¹³ See *Airstrip*, “*AIRSTRIP OB™*,” available at <http://www.airstriptechnology.com/TheAirStripOBSERVERSuitetrad/AirStripOBtrade/tabid/61/Default.aspx>

way, the system allows physicians to monitor multiple patients outside the labor and delivery unit.

The *Vocel Pill Phone* is a patented mobile medication reminder software that is available for download on many 3G wireless phones.¹⁴ The Pill Phone application incorporates an electronic version of the best selling guide, *The Pill Book*, and helps ensure that patients take the appropriate medication at the right time. To track patient pill-taking, the application provides visual/audible prompts, displays an image of the appropriate medication (along with potential side effects), and provides confirmation to patients and attending physicians.

Qualcomm is also directly involved in several innovative wireless health care initiatives. Through its Wireless Reach program, an initiative designed to promote the socially beneficial uses of mobile broadband technology in the U.S. and around the world, Qualcomm is working with the US Army Trauma Training Center to implement 3G mobile technology in a busy trauma setting.¹⁵ The project uses an InTouch Health RP-7 Robot for trauma care in a battlefield hospital.¹⁶ With a laptop equipped with special controls and an EV-DO Rev. A wireless broadband connection, physicians use the robot's two-way audiovisual capabilities to check vitals, zoom in on the patient, and provide advice to attending doctors, nurses and clinicians.

[lt.aspx](#). See also Testimony of William Cameron Powell, AirStrip President, before U.S. House Committee on Veterans' Affairs, Health Subcommittee Hearing (June 24, 2010).

¹⁴ See *The Pill Phone: Mobile medication reminder and guide*, available at <https://www.pillphone.com/PillLogin.htm>.

¹⁵ See Qualcomm Press Release, "United States: Trauma Surgeons Using Robot to Reach Patients in Need," available at http://www.qualcomm.com/citizenship/wireless_reach/projects/health_care.html.

¹⁶ The InTouch Health RP-7® Robot allows a physician to connect remotely to stethoscopes, otoscopes, and ultrasounds and other Class II medical devices via a 3G mobile broadband connection. The InTouch Remote Presence Robotic Systems are the first and only FDA-cleared remote presence medical devices. See InTouch Health®, "Explore Remote Presence," available at http://www.intouchhealth.com/products_rp7robot.html.

Enabling surgeons to instantly connect to the field ICU through high-speed wireless technology can help lower mortality rates by speeding up the delivery of trauma care during the “golden hour,” that is, the critical 60 minutes after an injury.

In addition, Qualcomm has formed a joint venture with the American Medical Alert Corporation and Hughes Telematics, Inc., called Lifecomm, LLC.¹⁷ Lifecomm will provide mobile Personal Emergency Response Service (“PERS”) focused on seniors and their caregivers in the United States in 2011. Whereas most PERS systems in use today allow patients to call for help within a single location, such as a home or assisted living facility, the new mobile PERS solution will provide patients with one-touch access to an emergency assistance call center via a wearable pendant wherever they may be. Inside the patient device, a cellular modem will enable wireless voice and data communications, and an embedded GPS combined with other sensors will enable location-based tracking and monitoring of the person wearing the device. The PERS solution also offers patients and caregivers a personalized web portal that provides information on patient activity and location.

Qualcomm also has joined with the Gary and Mary West Foundation and Scripps Health to create the West Wireless Health Institute, which is one of the world’s first medical research organizations dedicated to advancing health and well-being through wireless technology. The Institute has teamed with Corventis to conduct its first clinical research of the benefits of wireless health – a multi-center, randomized trial to validate remote wireless monitoring technology by proactively managing heart failure patients in order to lower hospital

¹⁷ See Hughes Telematics, Qualcomm and American Medical Alert Corporation Announce Joint Venture to Create Lifecomm, New company to offer mobile Personal Emergency Response products and services (May 12, 2010) *available at* <http://www.qualcomm.com/news/releases/2010/05/12/hughes-telematics-qualcomm-and-american-medical-alert-corporation-announce->.

readmissions. Such clinical research is vitally important to improving patient care and quantifying the substantial cost savings from wireless health services.

As demonstrated above, Qualcomm and its communications industry partners are at the forefront of helping to address the concerns of chronic diseases, aging, and our aging workforce by providing robust broadband technologies and fast data networks. And, as detailed in the responses below to the questions for comment in the Public Notice, it is clear that mobile health care will require reliable, secure, and ubiquitous communications networks supported by commercial mobile service providers using licensed spectrum.

RESPONSE TO QUESTIONS FOR COMMENT IN THE PUBLIC NOTICE

I. Wireless Health Care Devices And Applications That Carry Time-Critical And Life-Critical Patient Data Are Best Supported By Licensed Spectrum.

Several of the Areas for Comment in the Public Notice seek input on the reliability and security of using wireless spectrum for medical device applications.¹⁸ Qualcomm submits that licensed wireless communications supported by commercial cellular networks operated and maintained by commercial carriers should be used for wireless health care devices and applications that communicate time-critical and life-critical medical information. Commercial carriers design their networks to be highly resilient so they continue to operate reliably during emergencies and periods of high demand. Indeed, carriers invest billions of dollars each year to maintain and improve this resiliency and reliability.¹⁹ Public and patient needs demand that life-

¹⁸ See, e.g., Public Notice Questions for Comment: A & D.

¹⁹ Thus, it is not at all surprising that public safety agencies, which previously relied on narrowband land mobile radio technology, now acknowledge the need for ubiquitous wireless broadband service and are turning to cellular technology. See Public Safety Spectrum Trust Website, available at <http://www.psst.org/index.jsp>, for information on the Public Safety Spectrum Trust, which is advocating creation of a nationwide wireless broadband network based on cellular technology.

critical “medical- grade” applications take advantage of the exceedingly high quality of service that commercial service providers offer via licensed spectrum.

In contrast, medical device connectivity supported exclusively by unlicensed spectrum is, by its nature, much less reliable because unlicensed devices are required to accept interference from all other uses of the RF spectrum, including licensed as well as all other unlicensed operations.²⁰ Unlicensed operations are best suited for local area connectivity in a home or office suite, but they cannot offer reliable wide-area connectivity supported by licensed commercial operators. Indeed, many mobile health care devices and application will rely make use of both unlicensed spectrum (for short range links) and licensed spectrum for wide area communications. While unlicensed technologies play a useful role in supporting short range applications and offloading traffic from the wide area mobile broadband networks operating in licensed bands, however, unlicensed systems do become overwhelmed where there are many users in a single area, such as a conference hall.

3G wireless technologies, as well as fourth-generation LTE technology, are highly reliable and secure. The fact that more than 20% of U.S. households now rely on mobile cellular technology as their sole source of telephone service – something that was unthinkable a few years ago – shows the high degree of reliability and security that public cellular networks have achieved. So many Americans conduct financial transactions and communicate sensitive personal and business information via their mobile devices, further demonstrating the high level of security that these systems support. And, because of the ubiquitous nature of commercial

²⁰ *See, e.g.*, 47 C.F.R. § 15.5(b) (“Operation of an intentional, unintentional, or incidental radiator is subject to the conditions that no harmful interference is caused and that interference must be accepted that may be caused by the operation of an authorized radio station, by another intentional or unintentional radiator, by industrial, scientific and medical (ISM) equipment, or by an incidental radiator.”).

cellular networks that operate on licensed spectrum, they are uniquely suited to support a whole host of applications, including the monitoring of vital signs and tracking of patients wherever they may be.²¹

II. Wireless Medical Device Trends Indicate That An Increasing Number Of Doctors And Patients Will Rely On Wireless Connectivity To Support Medical Monitoring, Diagnostic, Therapeutic, and Emergency Communications Needs.

Item C in Section III of the FCC/FDA Public Notice seeks information on trends in medical devices using licensed spectrum and unlicensed operation, and medical devices and applications that use commercial networks with consideration of various wireless networking scenarios and use cases.²² Qualcomm believes that wireless medical technology will necessarily play a major role in the health care ecosystem by improving health care delivery and patient care while lowering the cost, and by allowing medical professionals to provide better care to more patients.

As explained in the background section above, Qualcomm spends billions of dollars annually to develop innovative technologies that extend into every aspect of wireless, including wireless healthcare technologies. Along with its many partners, Qualcomm is working hard to bring about an unprecedented convergence of science, engineering and technology to enable dramatic improvements in the quality and delivery of healthcare. Qualcomm's 3G mobile broadband supports connectivity for chronic disease management, remote monitoring of medical diagnoses, as well as general health and wellness.

Medical devices, health sensors and their applications are increasingly relying on wireless broadband functionality and interoperability to transmit raw data, diagnostic health information,

²¹ See n.17. The Lifecomm mobile PERS device would not be possible without commercial wireless networks that operate via licensed spectrum.

²² See Public Notice, Section III Questions for Comment.

critical aspects of care, emergency services and personalized information. These services are at the forefront of a revolution in the provision and delivery of care in America – a revolution that will collapse space, time, and distance to more effectively monitor patients and improve care while keeping down costs. More and more devices will utilize mobile broadband technologies to seamlessly present important medical information to healthcare professionals, clinicians, patients and their loved ones, in a timely, low-cost, and secure manner.

Remote patient monitoring and eCare technologies utilize medical devices and sensors to remotely collect and send data – such as blood glucose levels or heart electrocardiography (“ECG”) data – to a monitoring station for interpretation.²³ These services will be used to augment the work of visiting nurses, clinicians and doctors. A telehealth electroencephalography (“EEG”) device monitors the electrical activity of a patient’s brain and then transmits that data to a specialist – either in real-time or via store-and-forward technology.²⁴ Qualcomm expects that the remote collection and analysis of such critical test data will become routine.

In addition to the underserved patients in rural America that will benefit greatly from wireless medical technology, the aging baby boomer demographic – which is placing increasing demands on the nation’s health care infrastructure – will benefit from future wireless medical innovations. In the U.S., the population of those 65 and older will more than double by 2050, rising from 39 million in 2009 to 89 million.²⁵ An aging population creates a demand for health

²³ See American Telemedicine Association, “Telemedicine Defined,” *available at* <http://www.americantelemed.org/i4a/pages/index.cfm?pageid=3333>. (telemedicine includes remote analysis of patient test results, scans, and x-rays, remote patient consultations and patient monitoring, medical education, patient access to medical and health information).

²⁴ *Id.*

²⁵ See U.S. Census Bureau, “Census Bureau Reports World’s Older Population Projected to Triple by 2050” (rel. June 23, 2009), *available at* http://www.census.gov/Press-Release/www/releases/archives/international_population/013882.html. Worldwide, the 65-and-

services. At the same time, our nation is facing a shortage of healthcare providers from nurses to primary care providers. Moreover, many nurses and physicians are among the baby boomers that are set to retire in the next three to five years.²⁶ The federal government predicts that by 2020, nurse and physician retirements will contribute to a shortage of approximately 24,000 doctors and nearly 1 million nurses.²⁷ The healthcare labor shortage coupled by an increasingly older population will exponentially increase healthcare disparities in urban, suburban and rural America all the same. These logistical burdens – be it 5 miles or 250 miles away – will impede access to health care by the elderly, infirm, and chronically ill.

Not surprisingly, remote patient monitoring and diagnosis via video consultations supported by mobile wireless technologies are the means by which the growing number of patients can be served by a limited number of medical professionals. Moreover, maximized cost savings would be realized through the accelerated use of remote monitoring telemedicine, supported specifically by widespread deployment of wireless broadband.²⁸ Such medical technologies enabled by widespread ubiquitous high-speed networks help diagnose health problems sooner, thus reducing or avoiding costly hospitalizations and improving overall quality of life and care.

older population is projected to triple by 2050, from 516 million in 2009 to 1.53 billion in 2050, according to the US Census Bureau. *Id.*

²⁶ See Benjamin Isgur, “Healing the Health Care Staffing Shortage,” Trustee, ABI/INFORM, Health Forum Inc. at 18 (Feb. 2008).

²⁷ See Health Resources and Services Administration, “Exhibit A-5. Baseline FTE RN Supply and Demand, 2020,” *available at* <http://bhpr.hrsa.gov/healthworkforce/reports/behindrnprojections/6.htm>; see PriceWaterhouseCoopers “Healthcare Practice: Workforce,” *available at* <http://www.pwc.com/us/en/healthcare/workforce.jhtml>.

²⁸ See Robert Litan, Vital Signs via Broadband: Remote Health Monitoring Transmits Savings, Enhances Lives, at 3 (Oct. 24, 2008) *available at* <http://www.betterhealthcaretogether.org/www/docs/broadband.pdf>.

While telehealth and remote patient monitoring are not substitutes for direct patient care, they will enhance patient care through serving as part of a broader solution for advancing healthcare in America. These technologies offer healthcare professionals, providers, caregivers and loved ones real-time information and critical data to monitor patients with far more frequency and accuracy without the need to make an aged senior citizen or ill patient leave the comfort of their homes.²⁹

Mobile broadband enabled telehealth technologies, such as vital signs monitors, mobile PERS devices, Internet-enabled medication reminders, compliance sensors, remote trending analysis services, gas alerts, mobile accelerometers, will help health care professionals to better monitor patients in reliable, secure, and non-disruptive ways. In this way, healthcare professionals can focus on the health and well being of their patients and maximize their own valuable human resources in much more cost-effective and efficient ways.

A recent New England Healthcare Institute study determined that a 60% reduction in hospital readmissions were realized using remote patient monitoring compared to traditional care.³⁰ The study also found a 50% reduction in hospital admissions using remote patient monitoring compared to disease management programs without remote monitoring. In addition,

²⁹ In fact, the American Association of Retired Persons (“AARP”) has been advocating to reform the long-term care provisions to include home and community-based services. *See* American Association of Retired Persons, “Little-Known Provisions in Health Care Reform Bills Would Offer Help With Long-Term Care; Americans could enroll in a new federal plan and receive cash benefits to help them age in place,” (rel. Nov. 10, 2009) *available at* http://bulletin.aarp.org/yourhealth/policy/articles/little_known_provisions_in_health_care_reform_bills_offer_help_with_long_term_care.2.html .

³⁰ *See* New England Healthcare Institute, Remote Physiological Monitoring: Research Update (Jan. 21, 2009) *available at* http://www.nehi.net/publications/36/remote_physiological_monitoring_research_update (estimating an annual national cost savings of \$6.4 billion dollars based on the reduction in hospital readmissions). *See also* Testimony of Kerry McDermott, Expert Advisor, FCC, before U.S. House Committee on Veterans’ Affairs, Health Subcommittee Hearing (June 24, 2010).

this study found remote patient monitoring has the potential to prevent between 460,000 and 627,000 heart failure related hospital admissions each year.

In sum, America is moving quickly beyond traditional methods of delivering health care. eCare solutions enabled by secure, reliable and robust mobile broadband networks are already supplementing traditional healthcare delivery, and they will continue to play an increasing role in providing care to the ill and the aged. Qualcomm has a long track record of wireless innovation and investment in mobile technologies and is ready to work with the FCC, the FDA and other wireless health care stakeholders to improve healthcare delivery through mobile broadband connectivity.

CONCLUSION

It is clear that we are well beyond the decision of whether wireless health care technologies should be implemented and that we now need to determine the best way to timely and safely enable such technologies. Qualcomm applauds the FCC and the FDA for working together to make this happen.

Respectfully submitted,

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