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

Hearing on "Health Information Technologies: Harnessing Wireless Innovation"

March 19, 2013

Summary

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

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

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

On July 21, 2011, the FDA issued a Draft Guidance on Mobile Medical Applications (MMA).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

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

Qualcomm offers the following recommendations for consideration:

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 FDA should promptly finalize the MMA draft guidance document.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

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

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

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

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

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

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

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

[4] *See Id.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Qualcomm offers the following recommendations for consideration:

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

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

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

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

About Qualcomm

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

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

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

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

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

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

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

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Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20554

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications

Docket No. FDA-2011-D-0530

COMMENTS OF QUALCOMM INCORPORATED

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INTRODUCTION

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

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

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

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

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

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

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

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

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

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

5 Id.

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

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

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

M-HEALTH AND HEALTHCARE DELIVERY IN AMERICA

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

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

[7] Id.

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

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

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

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

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

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

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

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

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

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

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

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

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

Mobile Broadband And America's Shrinking Healthcare Workforce

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

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

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

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

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

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

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

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16 Id.

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

18 Id.

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

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

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

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

ABOUT QUALCOMM

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

[20] Id.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

RECOMMENDATIONS AND COMMENTS

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

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

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

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

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

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

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

II. FDA Should Provide Clarity On "Intended Use"

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

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

[24] Id, at Page 7.

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

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

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

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[25] Id. footnote 4, Page 7.

[26] Id. at Pages 10-11.

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

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

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

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

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

28 Id. at Pages 5, 24.

29 Id. at Page 24.

30 Id. at Page 5.

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

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

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

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

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

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

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

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

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

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

[33] Id. at Page 12.

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

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

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

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

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[34] Id.

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

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

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

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

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[36] Id.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3) A framework for software in an mHealth system.

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

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

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

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CONCLUSION

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

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

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

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

Respectfully submitted,

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