August 10, 2013

The mHealth Conundrum: Smartphones & Mobile Medical Apps – How Much FDA Medical Device Regulation is Required?

Vincent J Roth, Esq

THE mHEALTH CONUNDRUM: SMARTPHONES & MOBILE MEDICAL APPS – HOW MUCH FDA MEDICAL DEVICE REGULATION IS REQUIRED?

Vincent J. Roth†

ABSTRACT

Smartphones and tablets have provided a plethora of new business opportunities for a number of industries including healthcare. Technology, however, appears to have outpaced the regulatory environment, which has spawned criticism over the current guidance of the Food and Drug Administration ("FDA") with regard to software and what level of regulation is required for mobile medical applications. Commentators have remarked that the FDA's guidance in this area is complex and unclear.

This article explores the current FDA regulatory scheme for mobile medical applications and adapters for mobile devices designed to provide mobile healthcare, or "mHealth." Attention is given to further guidance anticipated as a result of the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA").

Smartphone applications are so much more readily available than traditional medical devices that a new and unaddressed issue of consumer access to medical tools has emerged. This has put the power of self-treatment back in the hands of citizens through a phenomena referred to here as "marketplace interposition," which creates new safety implications. There is clearly a need for regulation that balances the interests in safety and oversight with invention and advancement.

This discussion provides recommendations on how to improve the FDA regulatory environment. This includes proposals to streamline the regulatory requirements such as defining the regulation better and implementing preliminary review assessment and accelerated approval processes. It also covers the concepts to target so that regulatory efforts can acknowledge and address marketplace interposition. While regulation of medical devices is necessary to ensure safety, the inevitable increase in mHealth and consumer access requires a more defined, targeted and streamlined regulatory scheme for mobile devices in order to keep pace with this quickly evolving technology.

† General Counsel, StatRad, LLC. LL.M. in Intellectual Property, University of San Diego (2013). LL.M. in Business & Corporate Law, University of San Diego (2003). J.D./M.B.A., Temple University (1999). M.A., University of Pennsylvania (1995). B.B.A., Temple University (1990). I thank Professor Ted Sichelman, professor at the University of San Diego School of Law, Thomas A. Smith, professor at the University of San Diego School of Law, Anil Bhalani, Principal RA Consultant at Extomed, LLC, and Miro Copic, CEO of BottomLine Marketing and professor at the San Diego State University School of Business Administration, for their valuable suggestions and comments.

TABLE OF CONTENTS

Topic Page

I. INTRODUCTION

Mobility in today's society is not only a fact of life, but a booming opportunity for business. Mobile devices, particularly smartphones, have provided a plethora of new business opportunities for a number of industries including healthcare. The increasing availability of mobile devices and high speed data has generated a demand for convenience from healthcare providers and consumers.[1] This increased demand has garnered the attention of device and software developers wishing to capitalize on the growing mobile health market.[2] Increased activity in "the use of mobile telecommunications in healthcare," or "mHealth"[3] has drawn the attention of regulators, which has spawned considerable debate over FDA medical device regulation for mHealth products.

This article examines the developing mHealth industry and related medical device regulation. Particular attention is given to the emerging but unclear stance of the Food and Drug Administration ("FDA") with regard to the current medical device regulatory regime as it applies to smartphones, software applications and adapters. The current regulatory regime consists of several overlapping analyses. A threshold question is whether a smartphone, application or adapter is a medical device.[4] Determining whether a product is a medical device is key because if it is not, then no medical device regulation applies.

With regard to FDA regulation, if the object at issue is a medical device, various layers of analysis are required. The first inquiry is in which one of three FDA classifications does the

---

[1] Tatiana Melnik, *There's an App for That! The FDA Offers a Framework for Regulation Mobile Health*, 13 No. 5 J. HEALTH CARE COMPLIANCE 45 (Sept.-Oct. 2011).
[2] Patricia Mechael and Sarah Struble, *Healthcare by Numbers: Using Mobile Phones to Save Lives*, UCA News (Mar. 21, 2013) http://www.ucanews.com/news/healthcare-by-numbers-using-mobile-phones-to-save-lives/67799 (last visited Mar. 31, 2013).
[3] Deborah Runkle, Note, *THE MHEALTH REVOLUTION*, 9 No. 4 ABA SCITECH LAW 24, 24 (2013).
[4] Vernessa T. Pollard and Chandra Branham, *FDA Medical Device Requirements: A Legal Framework for Regulation Health Information Technology, Software, and Mobile Apps*, THOMSON REUTERS/ASPATORE. 2011 WL 5833341, 2 (Nov. 2011).

object belong.[5] Classification typically indicates what level of controls the FDA requires of the medical device, but often there are exceptions to the FDA's rules such that control requirements do not necessarily align with the classification scheme.[6] Thus another examination is what FDA control measures are pertinent. Adding to this mix is the fact that every device these days involves some software, and in the case of an application, it may be purely software, which then triggers another inquiry – which of three levels of FDA concern are presented with the particular software. If the application is for a mobile device there is one more layer of scrutiny, and that is the FDA's recent guidance on mobile medical applications. These multiple and overlapping layers present burdensome complexity.

Another characteristic of medical device regulation is that the FDA tends to provide broad guidance.[7] Commentators indicate the regulatory terrain presents uncertainty to mobile medical application developers.[8] In the case of software, and mobile medical applications in particular, the guidance is "proposed" and not "final,"[9] further giving rise to doubt. The FDA could presumably provide some clarity by declaring certain guidance as final. Furthermore, the FDA has stated that it will exercise discretion when regulating mobile medical applications, yet it fails to explain when it will exercise that discretion.[10] Is discretion based on criteria or is it arbitrary? In areas where the FDA has indicated it would exercise discretion, the FDA could better define the characteristics and circumstances that warrant discretion so that developers can better understand when compliance is required.

---

[5] *Id*. at 3.
[6] Telephone Interview with Anil Bhalani, Principal RA Consultant, Extomed, LLC (June 28, 2013).
[7] *Id*.
[8] *See generally*, Bradley Merrill Thompson et al., *A Call for Clarity: Open Questions on the Scope of FDA Regulation of mHealth*, mHealth Regulatory Coalition (2010) (hereinafter "*A Call for Clarity*"), available at http://mhealthregulatorycoalition.org/wp-content/uploads/2010/12/mrcwhitefinal122210.pdf (last visited July 28, 2013).
[9] Interview with Linda Moore, Director of Operations and Regulatory Affairs, StatRad, LLC, in Poway, Cal. (Aug. 5, 2013).
[10] Scott D. Danzis & Christopher Pruitt, Note, *Rethinking the FDA's Regulation of Mobile Medical Apps*, 9 No. 4 ABA SCITECH LAW 26, 27 (2013).

Complicating the inquiry is the fact that mobile medical applications are so widely prevalent and readily available that consumers have far greater access to them than consumers have with traditional medical devices. Commentators, Congress and the FDA have yet to address the unprecedented access consumers have to applications that can assist with the delivery of healthcare. Consumers are availing themselves of healthcare tools that perform functions akin to medical devices previously reserved to medical practitioners – tools that consumers now use on themselves and others to address medical issues. Is this the return of the right to self-treatment? Does consumer access instigate the unauthorized practice of medicine? To what extent does society want consumers to provide healthcare to themselves or others?

Related to consumer access is the concept of the actual use of an article. At present, the FDA looks at how a manufacturer intends its product to be used.[11] It is questionable whether the FDA principle of "intended use" still makes sense when applied to a product that is deployed for an intended purposes of the manufacturer as demonstrated in its product claims, but that is utilized in a way that is potentially unintended or not expected by the manufacturer. Intended use with medical devices is similar to the concept of label claims with drugs and biologics. That environment, however, limits the availability of pharmaceuticals through prescriptions and pharmacies.[12] Furthermore, in the drug and biologic markets there is serious ongoing public discussion regarding concern over promotion of off-label use. Such discussion is lesser so with medical devices.

The current regulatory landscape for medical devices with its focus on intended use, rather than actual use, however, seems to allow a loophole for mobile devices because there is no gatekeeping through prescriptions or pharmacies for mobile medical applications. Moreover,

[11] Pollard and Branham, *supra* note 4, at 3.
[12] George Lasezkay, Professor of Law, Pharmaceutical Law & Policy Class Lecture at the University of San Diego School of Law (Jan. 24, 2013) (on file with author).

public discussion does not demonstrate concern over off-label use with mHealth products that is prevalent in the pharmaceutical industry. Does medical device regulation turn a blind eye to actual use? Current FDA regulation focuses on the device itself, but more attention also needs to be given to the effects of consumer access and actual use, otherwise the system cannot be properly improved.

The presence of consumer access, self-treatment, the unauthorized practice of medicine and actual use along with the absence of these concepts in regulatory discourse have coalesced into a phenomena referred to here as "marketplace interposition." Marketplace interposition is where commerce, in this case technological advancement, encourages society to tacitly permit self-treatment and the unauthorized practice of medicine through consumer access and actual use. This article will recommend a more targeted focus on the concepts and principles that underlie the purpose of the regulation, which is consumer safety. Consumer access, self-treatment, the unauthorized practice of medicine, and actual use all bear on patient safety. These cannot be ignored if practical discussions are to be had regarding the appropriate level of regulation. Safety cannot be ensured by looking at just the device. Targeting the right concepts will yield better solutions.

In light of the various overlapping inquiries required when evaluating a product under medical device regulation, this article will recommend streamlining the regulations for simplicity and consistency. Further along the lines of streamlining, the regulatory environment could be improved not just with the regulations but with increased efficiency internally at the FDA. The current backlog in review and approval of medical devices needs to be reduced. The system could also benefit from a preliminary review process. Such a process could allow developers to receive a perspective from the FDA regarding a particular product early and cost effectively before a product is even developed. A preliminary review process would better enable

manufacturers to determine whether their products need to comply with regulations and if so, what level of regulation. This would likely increase compliance.

Another possible measure to streamline FDA regulation is accelerated approval. Being that mobile technology changes rapidly, this article will also recommend an accelerated approval process for mobile medical applications to move regulatory review along quicker. The FDA is already familiar with accelerated approval in the drug industry. Congress also recognizes the need to improve the regulatory landscape as well as speed up the review and approval process. With this in mind, Congress recently charged the FDA under the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA") to implement measures that will promote innovation while maintaining safety.[13] Thus further regulation is expected with regard to medical devices. Whether such new measures improve mHealth regulation or add to the burden remains to be seen.

Part II of this article reviews the entrance of smartphones into mHealth. Part III studies the current FDA medical device regulation. Part IV examines various forms of smartphone mHealth products. Part V provides recommendations on how to improve the regulation of mHealth products. While regulation of medical devices is necessary to ensure safety, the inevitable increase in mHealth and consumer access requires a more defined, targeted and streamlined regulatory scheme for mobile devices in order to keep pace with this quickly evolving technology.

II. THE ADVENT OF SMARTPHONES AND MOBILE HEALTH

While mobile telephones are now commonplace in today's society, mobile telephones capable of viewing websites and data through various cellular networks, so called "smartphones," only began to emerge in 1997 when Stockhold Smartphone released the Sony

[13] S. 3187 (112th): Food and Drug Administration Safety and Innovation Act. 112th Congress, 2011–2013, Section 618(a).

Ericsson GS88.[14] Then Research In Motion came along with BlackBerry devices in 1999, which gained wide popularity shortly after the turn of the century.[15] Soon thereafter, Apple, Inc. entered the mobile phone business when it launched the first iPhone on June 29, 2007.[16] That same month, Apple announced third parties could develop applications to run on the iPhone.[17] This opened the door for the mobile applications market.[18] It has been flourishing ever since. As of January 2013, there were over 775,000 iPhone applications,[19] about the same for Android phones (estimated to have reached 1 million by June 2013),[20] and about 100,000 applications for BlackBerries.[21]

In addition to the ubiquity of mobile applications is the pervasiveness of mobile phones. As of December 2012, 87% of adults in the United States ("US") own a mobile phone and 45% of US adults own a smartphone.[22] Moreover, as of January 2013, 31% of US adults have a tablet.[23] The rest of the world reveals a similar profile. The International Telecommunications Union of the United Nations reported that when the global population reached 7 billion people at the end of 2011, there were approximately 6 billion mobile phone subscriptions worldwide.[24]

---

[14] History, Stockholm Smartphone, http:// www.stockholmsmartphone.org/history/ (last visited Mar. 30, 2013).
[15] The History of the Blackberry, BBGeeks (Apr. 15, 2008), http://mobilemoo.com/blackberry/blackberry-guides/the-history-of-the-blackberry/ (last visiting Mar. 30, 2013).
[16] iPhone 2G History, iPhone History, http://www.iphonehistory.com/iphone-2g/ (last visited Mar. 30, 2013).
[17] Press Release, Apple Inc., iPhone to Support Third-Party Web 2.0 Applications (Jun. 11, 2007), http://www.apple.com/pr/library/2007/06/11iPhone-to-Support-Third-Party-Web-2-0-Applications.html (last visited Mar. 31, 2013).
[18] Alex Krouse, Note, *iPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 731, 734 (2012).
[19] Sam Costello, *How Many Apps Are in the iPhone App Store*, About.com (2013) http://ipod.about.com/od/iphonesoftwareterms/qt/apps-in-app-store.htm (last visited Mar. 31, 2013).
[20] Dan Rowinski, *Google Play Will Beat Apple App Store to 1,000,000 Apps*, READWRITE MOBILE (Jan. 8, 2013) http://readwrite.com/2013/01/08/google-play-to-hit-1-million-apps-before-apple-app-store (last visited Mar. 31, 2013).
[21] Mark Jones, *BlackBerry App World Re-Branded Ahead of BB10 Launch*, RETHINK WIRELESS (Jan 22, 2013) http://www.rethink-wireless.com/2013/01/22/blackberry-app-world-re-branded-ahead-bb10-launch.htm (last visited Mar. 31, 2013).
[22] Joanna Brenner, *Pew Internet: Mobile*, PEW INTERNET (Jan. 31, 2013) http://pewinternet.org/Commentary/2012/February/Pew-Internet-Mobile.aspx (last visited Mar. 31, 2013).
[23] *Id.*
[24] Mechael, *supra* note 2.

Mobile applications have noticeably migrated into the healthcare industry.[25] 81% US adults use the Internet and of these, 72% reported to have searched online for health information in 2012, which is approximately 59% of all US adults.[26] Furthermore, 31% of mobile phone owners are reported to use their phones for health or medical information.[27] Manhattan Research determined that 64% of physicians used smartphones by the end of 2011 and it is estimated that as of 2013, 81% of physicians use smartphones.[28] With the pervasiveness of mobile devices, it is no wonder the mobile health industry is booming.

The proliferation of mobile phones has caught the attention of global health experts, developers, innovators and entrepreneurs.[29] Collectively they form a movement called "mobile health," or "mHealth," to capitalize on the potential mobile devices have to deliver healthcare.[30] Mobile health applications are integral to mHealth because they facilitate the provision of healthcare over standard and common hand held machines.[31] Their advent has led to interesting phenomena. Healthcare providers have been using various software packages for many years to assist in their medical determinations, but mobile devices can now make actual diagnoses.[32] MHealth also offers solutions for the direct consumer.[33] The increasing availability to consumers creates the dilemma that many may use these applications for self-diagnosis and treatment.[34] In fact, 35% of US adults report having tried at some time to determine online what

[25] Krouse, *supra* note 18, at 738.
[26] Susannah Fox & Maeve Duggan, *Health Online 2013 Report*, PEW INTERNET 6 (Jan. 15, 2013) http://pewinternet.org/~/media//Files/Reports/PIP_HealthOnline.pdf (last visited Mar. 31, 2013).
[27] Brenner, *supra* note 22.
[28] MobiHealthNews, WIRELESS HEALTH: STATE OF THE INDUSTRY 2009 YEAR END REPORT 1, 2 (Dec. 16, 2009) available at http://mobihealthnews.com/wp-content/Reports/2009StateoftheIndustry.pdf (last visited Mar. 31, 2013).
[29] Mechael, *supra* note 2.
[30] *Id.*
[31] Krouse, *supra* note 18, at 738.
[32] *Id.*
[33] *Id.*
[34] *Id.*

medical condition they or someone else was experiencing.[35] 38% of these folk reported they believed it was something they could remedy without professional medical attention.[36]

Access to mHealth may be a pioneering way to provide healthcare in developing countries, but in highly regulated countries like the United States,[37] this raises the concern of where the line crosses into practicing medicine and where regulation of the mHealth tool is appropriate. CTIA, an international association for the wireless telecommunications industry, and Harris Interactive, a global custom marketing research firm,[38] conducted a recent survey that revealed 78% of US citizens are interested in mobile health solutions.[39] While about 40% of the respondents indicated that mHealth was an appealing supplement to the healthcare they receive from their providers, 23% indicated they believe mHealth could altogether replace visiting a healthcare provider.[40] If mHealth supplants professional medical attention, the need for regulation is obvious.[41] Patient safety is at risk. Thus it is essential that a device work properly and be used property to reduce the incidence of injury. What level of regulation is appropriate has yet to be determined.

Healthcare providers also find mHealth appealing because of the cost, time and effort savings the mHealth industry is creating.[42] Glen Stream, the president of the American Academy of Family Physicians, acknowledges and endorses the "explosion" of mobile medical apps.[43] He purports to be an "iPhone guy" utilizing 20 or so medical or health apps stating, "People want to

---

[35] Fox, *supra* note 26, at 2.
[36] *Id*.
[37] Krouse, *supra* note 18, at 738.
[38] *CTIA and Harris Interactive Release New National Study; Reveals How Teens Are Shaping & Reshaping Their Wireless World*, PRWEB (Sept. 12, 2008) available at http://www.prweb.com/releases/CTIA-teen-cell-phone/92008/prweb1322754.htm (last visited Aug. 9, 2013).
[39] MobiHealthNews, *supra* note 28, at 2.
[40] *Id*. at 3.
[41] Krouse, *supra* note 18, at 738.
[42] *Id*. at 739.
[43] Laura Ruane, *Smartphone apps now playing doctor*, USA Today (Aug. 8, 2012) available at http://usatoday30.usatoday.com/tech/news/story/2012-08-05/smartphones-health/56764686/1 (last visited July 14, 2013).

be empowered to take care of their health."[44] Nonetheless, he contends that mobile devices and mobile medical apps "certainly are not going to replace the need for a collaborative relationship with a family physician."[45]

A recent report revealed the United States spent 17.6% of its Gross Domestic Product in 2010 on healthcare, which is one and a half times as much as any other country and almost twice that of the average in a report from the Organization for Economic Co-operation and Development.[46] The increase in spending on healthcare is also remarkable. The United States spent $256 billion on healthcare in 1980.[47] By 1990 the dollars spent reached $714 billion.[48] By 2010 this number almost reached $2.6 trillion.[49]

There is considerable opportunity for savings. In 2009, Verizon Wireless estimated mobile broadband solutions saved nearly $6.9 billion in healthcare costs through improved productivity.[50] Further increased productivity is expected to save $27.2 billion by 2016.[51] Another survey polled healthcare providers, patients, payers and technology enablers whereby 75% of respondents indicated they believe that mHealth could cut healthcare expenses by as much as 40%.[52]

With such potential savings, it is understandable why there is so much attention on mHealth. The regulatory environment, as will be seen, is not designed well to propel this impetus. Too much bureaucracy impedes innovation. MHealth momentum necessitates revision to the system. While regulation of medical devices is necessary to ensure safety, the inevitable

---

[44] *Id.*
[45] *Id.*
[46] Jason Kane, *Health Costs: How the U.S. Compares With Other Countries*, PBS NEWSHOUR (Oct. 22, 2012) http://www.pbs.org/newshour/rundown/2012/10/health-costs-how-the-us-compares-with-other-countries.html (last visited Mar. 31, 2013).
[47] U.S. Health Care Costs, KAISEREDU.ORG, http://www.kaiseredu.org/Issue-Modules/US-Health-Care-Costs/Background-Brief.aspx# (last visited Mar. 31, 2013).
[48] *Id.*
[49] *Id.*
[50] MobiHealthNews, *supra* note 28, at 5.
[51] *Id.*
[52] *Id.*

increase in mHealth and consumer access requires a more defined, targeted and streamlined regulatory scheme for mobile devices in order to keep pace with this quickly evolving technology.

III. FDA REGULATION OF MEDICAL DEVICES

In order to understand why mHealth requires a more defined, targeted and streamlined regulatory scheme, it is necessary to review the FDA regulatory requirements as they pertain to medical devices. MHealth products are often comprised of software and sometimes include sensors or attachments for a mobile device, and thus invite additional layers of scrutiny beyond the standard medical device requirements. As successive layers are discussed, it becomes apparent that this is a complex environment fraught with generalities and exceptions wherein even a diligent manufacturer can end up unintentionally out of compliance.

To fall within the purview of the FDA, a product must first meet the definition of a medical device, whereby it is then subject to regulation before and after it is marketed.[53] Section 201(h) of the federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals."[54] If the product in question is not a medical device, then no regulation applies. If it is a medical device, then one must evaluate several layers of regulation.

[53] Krouse, *supra* note 18, at 745.
[54] 21 U.S.C. § 321(h) (2010); *see also* Is The Product a Medical Device?, U.S. Food & Drug Admin., available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm (last visited Apr. 1, 2013).

A. INTENDED USE

A significant threshold inquiry is whether the product in question is intended to diagnose or treat a disease or condition.[55] "Intended use" is a critical element in determining FDA regulation.[56] If an article, like software, is *intended* to be used for medical purposes the FDA considers it a medical device.[57] However, an article is not considered a medical device if it is intended for general health or wellness.[58] Applications for diet and exercise information are examples of products that are regarded as being for general health and wellness purposes.[59] Thus a threshold question is whether the mHealth product is intended for general health or wellness or intended to diagnose or treat a disease or condition.[60] The former is not a medical device. The latter is. There is a gray area in that at some point along the spectrum general health and wellness bleeds into diagnosis and treatment. For example, an overweight person might use mHealth products to assist with an exercise regime and manage diet, which might otherwise be considered health and wellness, but at what point does managing weight become treatment of obesity? Is that what the manufacturer of such a health and wellness application intended?

Related to the concept of "intended use" is "indication of use." The indication of use designates the parameter for which the medical device is approved.[61] A company presents this in its submission for approval to the FDA.[62] When the FDA approves the medical device, the FDA makes public the indication of use.[63] Take for example cough medicine. The indication of use is "coughing, sore throat…etc."[64] These are the *indications* for which the product is approved to

[55] Danzis, *supra* note 10, at 28.
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] Krouse, *supra* note 18, at 760.
[60] Pollard and Branham, *supra* note 4, at 3.
[61] Interview with Linda Moore, *Supra*, note 9.
[62] Correspondence with Anil Bhalani, Principal RA Consultant, Extomed, LLC (Aug. 3-7, 2013).
[63] *Id.*
[64] *Id.*

treat as reflected in the submission documents and subsequent FDA approval.[65] The *intended* use is "to treat an infection."[66]

The FDA derives "intent" from the product promotional claims.[67] Promotional claims revealing intended use may be found on a product label, in advertising materials, or they may even be oral or written statements made by the product manufacturer or its representatives.[68] Thus manufacturers generate the intended use for their products based on how they promote the product to the public through what they say and write. If the intent is health, the appliance is not a medical device.[69] If the intent is medical, then the appliance is a medical device. But what is the difference between health purposes and medical purposes? As will be seen later, although intended use is still a primary focus of FDA regulation, technology may have already evolved to a point where a different paradigm may be warranted. At present, the principle of intended use drives much of the subsequent regulatory inquiry. If the intended use indicates a medical purpose, and thus a medical device, this leads to evaluation of what class of injury might arise from that use.

B. CLASSIFICATION

Since 1976, the FDA's paradigm has categorized medical devices in three distinct classes based on the potential health risks to the public – Class I, Class II, and Class III.[70] Medical devices are assigned a classification based on the level of control needed in order to provide the

---

[65] *Id.*
[66] *Id.*
[67] Danzis, *supra* note 10, at 27.
[68] FDA, Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications, issued July 21, 2011 (hereinafter "FDA Draft Guidance for Medical Apps"), 7-8, available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf (last visited July 28, 2013).
[69] Danzis, *supra* note 10, at 27.
[70] *Id.*

FDA reasonable assurance of the product's safety and effectiveness.[71] If a device represents a very low risk of injury, it is considered Class I and does not require any premarket approval.[72] While most Class I devices are exempt from premarket notification requirements and regulations for good manufacturing practices,[73] there are some general controls that companies must conduct such as registering the company with the FDA, listing the device, paying an annual registration fee and tracking device activity.[74] Bandages, examination gloves and hand-held surgical instruments are examples of Class I devices.[75]

Devices that present an intermediate level of risk of injury to people are considered Class II.[76] The FDA's perspective is that for Class II devices "general controls alone are insufficient to assure safety and effectiveness."[77] In addition to general controls, Class II devices also require special controls such as specified content on labels, adherence to performance standards and surveillance of the product in the marketplace.[78] Some medical devices are also subject to a "Premarket Notification" under Section 510(k) of the FDCA.[79] Most Class I and some Class II devices are exempt from the 510(k) Premarket Notification requirement.[80] The premarket notification is sometimes colloquially referred to simply as "510(k)" (spoken as "five-ten-kay").

If a Class II device is subject to the 510(k) requirement, the manufacturer must file a premarket notification with the FDA to demonstrate that the device is "substantially similar" to

[71] Medical Devices, Regulatory Controls, Introduction, U.S. Food & Drug Admin., available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (last visited Aug. 3, 2013).
[72] Danzis, *supra* note 10, at 27.
[73] General and Special Controls, U.S. Food & Drug Admin., available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (last visited Aug. 3, 2013).
[74] Krouse, *supra* note 18, at 746-47; *see also* General and Special Controls, U.S. Food & Drug Admin., *supra* note 73.
[75] *Id*. at 746.
[76] Danzis, *supra* note 10, at 27.
[77] General and Special Controls, U.S. Food & Drug Admin., *supra* note 73.
[78] *Id*.
[79] Danzis, *supra* note 10, at 27.
[80] Premarket Notification 510(k) – 21 CFR Part 807 Subpart E, U.S. Food & Drug Admin., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm#510k (last visited Apr. 20, 2013).

another Class II device already on the market.[81] Establishing substantial similarity provides the FDA reasonable assurance that the device is safe and effective.[82] The FDA reviews the submission to determine whether the proposed medical device is substantially similar to another already marketed device.[83] An appliance that is already legally on the market is called a "predicate device."[84] If the FDA agrees, it provides a letter of substantial equivalence to the manufacturer authorizing the commercial distribution of the product.[85] Powered wheelchairs, infusion pumps and surgical drapes are examples of Class II devices.[86]

High risk devices are Class III.[87] These are devices that either sustain human life or present an unreasonable risk of injury to humans.[88] Because of the risks involved, the FDA does not believe that general or special controls are sufficient to assure safety and effectiveness.[89] The FDA requires general controls and premarket approval ("PMA") for Class III devices.[90] While some Class III devices may be able to receive approval through the 510(k) process, if there is no predicate device against which substantial equivalence may be shown, clinical data must be submitted to support the claims of the device.[91] In such case, a manufacturer is generally required to perform complex, extensive and expensive clinical trials[92] to produce scientific data

[81] Danzis, *supra* note 10, at 27.
[82] 510(k) Clearances Overview, U.S. Food & Drug Admin., available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm (last visited Apr. 7, 2013).
[83] Premarket Notification 510(k) – 21 CFR Part 807 Subpart E, U.S. Food & Drug Admin., *supra* note 80.
[84] Medical Devices, How to Find a Predicate Device, Introduction, U.S. Food & Drug Admin., available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm (last visited Aug. 3, 2013).
[85] Premarket Notification 510(k) – 21 CFR Part 807 Subpart E, U.S. Food & Drug Admin., *supra* note 80.
[86] Krouse, *supra* note 18, at 747.
[87] *Id.*
[88] General and Special Controls, U.S. Food & Drug Admin., *supra* note 73.
[89] *Id.*
[90] *Id.*
[91] Premarket Approval (PMA) – 21 CFR Part 814, U.S. Food & Drug Admin., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm#510k (last visited Apr. 20, 2013).
[92] Danzis, *supra* note 10, at 27.

that demonstrates the device is safe and effective for its proposed use.[93] The company then submits the results in a PMA application for the FDA to consider before the company may commercialize the product.[94] Pacemakers, artificial heart valves and breast implants are examples of Class III devices.[95]

C. QUALITY SYSTEM REGULATION

Regardless of classification, every medical device manufacturer is required to comply with the FDA's Quality System Regulation ("QSR").[96] The QSR specifies the special controls and performance standards required.[97] The FDA quality systems for regulated products are also called current good manufacturing practices (CGMP).[98] The purpose of the QSR is to maintain a certain level of quality and consistency in the manufacturing process so that products meet their specifications[99] in order to assure the safety and effectiveness of finished products.[100]

The QSR describes what is required, but it does not describe how to go about meeting those requirements. This is another example of where medical device regulation is unclear. It is left to the medical device company to interpret how much of the QSR is applicable to its operations and it determines for itself what the company thinks it needs to do in order to meet the

---

[93] General and Special Controls, U.S. Food & Drug Admin., *supra* note 73.
[94] Danzis, *supra* note 10, at 27.
[95] General and Special Controls, U.S. Food & Drug Admin., *supra* note 73.
[96] Interview with Linda Moore, *Supra*, note 9; Title 21, Food and Drugs, of the Code of Federal Regulations, Part 820, Quality System Regulation, codified at 21 CFR 820 available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1 (last visited Aug. 10, 2013).
[97] Correspondence with Anil Bhalani, *supra* note 62.
[98] Medical Devices, Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, U.S. Food & Drug Admin., available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/ (last visited Aug. 10, 2013).
[99] *Id*.
[100] Introduction to Regulation of Medical Devices, STANFORD BIODESIGN, slide 3 (2006) available at http://www.stanford.edu/group/biodesign/regulatory/materials/quality_slides.pdf (last visited Aug. 10, 2013).

QSR.[101] In complying or attempting to comply with the QSR, a company needs to implement quality systems according to certain performance standards.

D. PERFORMANCE STANDARDS

As mentioned, to satisfy special controls, manufacturers are required to adhere to certain performance standards.[102] Of the levels of regulatory compliance, next to the QSR performance standards is probably one with the least direction. First, the FDA guidelines are not mandatory, but a company must have standards in place sufficient to demonstrate safety and effectiveness.[103] Performance standards give the FDA indication regarding the quality and consistency of the manufactured item. A company may develop its own standards that it believes sufficiently evidences that the manufacturing process produces a safe and effective product.[104]

Many companies deploy the standards established by the International Standards Organization ("ISO"). ISO standards are documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.[105] The FDA, however, does not mandate ISO standards.[106] Nonetheless, the FDA has come to recognize as acceptable some ISO standards and some standards from other organization such as the International Electrotechnical Commission ("IEC"), the Association for the Advancement of Medical Instrumentation ("AAMI"), Underwriters Laboratories ("UL"), and the Canadian Standards Association

[101] Correspondence with Anil Bhalani, *supra* note 62.
[102] *Id*.
[103] *Id*.
[104] *Id*.
[105] ISO, Standards, What is a standard?, ISO, available at http://www.iso.org/iso/home/standards.htm (last visited Aug. 3, 2013).
[106] Correspondence with Anil Bhalani, *supra* note 62.

("CSA").[107] As resources for manufacturers, the FDA posts on its web site a number of standards that the FDA recognizes.[108]

While no particular standard is required, it behooves a developer to implement a recognized standard because the FDA accepts the recognized standards as the "state of the art."[109] Otherwise, the company will have to justify the criteria it used before the FDA and hope that the FDA accepts the internally crafted standards.[110] Other countries have similar standards requirements and have similarly adopted certain standards as adequate to demonstrate safety and effectiveness.[111] Performance standards are required regardless of whether the product is a physical article or purely software.

E. SOFTWARE

Software presents a challenge to the FDA. Although software is not explicitly found in the statute,[112] the FDA considers software a device if it is intended to diagnose or treat disease or conditions.[113] The FDA spoke to software products in a draft policy document in 1989 in which it expressed its perception that computer products are intended to involve competent human intervention before any impact on human health occurs because a medical provider can use clinical judgment to evaluate and interpret the computer system's output, and thus the computer program poses less risk to patients.[114] The FDA, however, withdrew this draft policy, later stating that it could not adopt a single software or computer policy to address every kind of software or computer driven medical device.[115]

---

[107] *Id*.
[108] Recognized Consensus Standards, U.S. Food & Drug Admin., available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?id=27652 (last visited Aug. 3, 2013).
[109] Correspondence with Anil Bhalani, *supra* note 62.
[110] *Id*.
[111] *Id*.
[112] *See* 21 U.S.C. § 321(h) (2010).
[113] Danzis, *supra* note 10, at 27.
[114] *Id*.; the document was entitled "FDA Policy for the Regulation of Computer Products 11/13/89 (Draft)."
[115] *Id*.

In 2005, the FDA posted guidelines for software contained in medical devices, entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (hereinafter "Software Device Guidance") which the FDA later updated in 2011.[116] According to the FDA, the types of software being regulated are "software components, parts, or accessories, or are composed solely of software."[117] Thus even software alone may be a "software device."[118] Furthermore, the FDA indicates the guidance pertains to "software devices regardless of the means by which the software is delivered to the end user."[119] Thus, this also applies to mobile medical applications.[120]

Like the three-class classification system for risk of injury in medical devices, the FDA also recommends three categories of concern over software from a risk standpoint: major, moderate and minor.[121] A major level of concern is one where failure or a latent flaw in the software "could directly result in death or serious injury to the patient or operator."[122] A moderate concern is when minor injury to the patient or operator could occur.[123] A minor concern is one in which software failure is unlikely to cause injury.[124] This "level of concern" inquiry seems redundant. The classification inquiry already evaluated whether there was a low, moderate or high risk of injury to the public in determining whether the medical device in question belongs in Class I, II or III. Why the duplicate effort? Nonetheless, if the medical device contains or consists of software, this additional layer of inquiry is required.

---

[116] Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, U.S. Food & Drug Admin., issued May 11, 2005, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm (last visited July 28, 2013).
[117] *Id*.
[118] *Id*.
[119] *Id*.
[120] Krouse, *supra* note 18, at 749.
[121] Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, *supra* note 116.
[122] *Id*.
[123] *Id*.
[124] *Id*.

Moreover, this "level of concern" method is an inexact way of regulating software, because the same piece of software may pose different levels of risk if used in different ways.[125] For example, a person using a scale for wellness purposes may not experience harm if the scale displays an incorrect weight.[126] Nevertheless, that same person may experience a moderate or high risk if the person is required to notify his/her doctor when s/he exceeds a certain weight and fails to do so because the scale displayed an incorrectly low weight.[127]

There remains no formally declared "final" policy.[128] The Software Device Guidance is still only in "proposed" form.[129] Despite this proposed state, the industry follows this as formal regulation and the FDA treats it as such.[130] Even with just proposed guidance, the FDA has classified a number of software products as Class I and Class II medical devices.[131] Laboratory information systems ("LIS"), for example, are categorized as Class I.[132] Picture archiving and communications systems ("PACS") are ranked as Class II.[133]

As of February 15, 2011, there is now at least a final rule on what is called Medical Device Data System ("MDDS")[134] software. MDDS software is now classified as Class I, which is a product that transfers, stores, converts, or displays medical device data without providing analysis, alarms, or active patient monitoring.[135] The FDA issued this final rule on its own volition to downgrade MDDS software from its previous classification of Class III, which otherwise would generally require premarket approval, down to Class I, which typically requires

---

[125] Thompson, *A Call for Clarity*, *supra* note 8 at 13.
[126] *Id*. at 38.
[127] *Id*.
[128] Interview with Linda Moore, *Supra*, note 9.
[129] *Id*.
[130] *Id*.
[131] Danzis, *supra* note 10, at 27.
[132] *Id*.
[133] *Id*.
[134] Medical Device Data Systems, Codified at 21 CFR Part 880 ("MDDS Final Rule"), Federal Register, 76 FR 8637-01, pp. 8637-38, Feb. 15, 2011, available at http://www.gpo.gov/fdsys/pkg/FR-2011-02-15/html/2011-3321.htm (last visited Aug. 3, 2013).
[135] Danzis, *supra* note 10, at 27.

only general controls.[136] The MDDS software classification is a narrow category, covering only those functions that fit within its definition.[137]

F. ACCESSORIES

Many software programs and some mobile applications are considered "accessories" to medical devices under the FDA's "accessory rule" and are generally subject to the same regulation as the parent device.[138] An accessory is an article that is targeted at and sold directly to consumers for use with a parent device.[139]

There is also the concept of a "component" under FDA regulation.[140] An accessory can be differentiated from a component in that consumers purchase accessories, whereas manufacturers purchase components.[141] Further, the same program is characterized as either an accessory or a component based on the purchaser.[142] The critical distinction is that the manufacturer of the program does not bears the regulatory burden for components it makes, but the manufacturer must bear the FDA requirements for accessories it makes.[143] That is, for a component manufacturer, components are generally exempt from FDA regulation because the regulatory burden is borne by the manufacturer that incorporates the component into another product, which ultimately gets sold to consumers.[144] An accessory manufacturer, however, must meet FDA regulation because the accessory gets sold directly to consumers.[145]

This discussion is dealing with accessories, not components. Whether the item at issue is a software program like a mobile medical app or an adapter that attaches to a smartphone, these

[136] *See* MDDS Final Rule, *supra* note 134.
[137] Danzis, *supra* note 10, at 27.
[138] *Id*.
[139] Bradley Merril Thompson, *FDA Regulation of Mobile Health* 3 (2010), available at http://mobihealthnews.com/wp-content/pdf/FDA_Regulation_of_Mobile_Health.pdf (last visited July 27, 2013).
[140] *Id*.
[141] *Id*.
[142] *Id*.
[143] *Id*.
[144] *Id*.
[145] *Id*.

products are sold separately from the smartphone. Consumers purchase programs, apps and adapters directly and then install them in or attach them to their smartphones. Thus the accessory rule is pertinent here.

The FDA has historically regulated accessories with the same scrutiny as the parent device based on the presumption that if the accessory failed, then the parent device might fail.[146] The risk of a software failure as an accessory, however, does not necessarily mean the function of the parent device is affected. For example, an application that simply downloads data from a blood pressure cuff to chart values may not affect the parent device at all.[147] Charting and analysis, however, might exceed the Class I threshold under the MDDS rule, which does not allow for analysis, and thus such an application would otherwise have to satisfy the same Class II scrutiny as the blood pressure cuff.[148] Fortunately, the FDA appears to recognize that the accessory rule may not fit all circumstances, just as the proposed software guidance is not one-size-fits-all. In a Federal Register notice on August 12, 2011 that announced a public meeting regarding the FDA's draft guidance, the FDA stated, "[a]n accessory that does not change the intended use of the connected device, but aids in the use of the connected medical device could be regulated as class I."[149] Thus, it seems the FDA is considering a lower regulatory standard for such accessories.

Regardless, none of these methodologies provide an exact way of determining how software will be regulated.[150] Thus, developers still face uncertainty as to whether their software is a medical device, and, if so, what level of regulation is required.[151] This has serious implications for mobile medical application developers because, for example, the fees for

[146] Danzis, *supra* note 10, at 28.
[147] *Id*.
[148] *Id*.
[149] 76 Fed. Reg. 50,231, 50,233 (Aug. 12, 2011) available at http://www.gpo.gov/fdsys/pkg/FR-2011-08-12/html/2011-20574.htm (last visited Apr. 6, 2013).
[150] Telephone interview with Anonymous, CEO of U.S. medical device company (Aug. 7, 2013).
[151] Krouse, *supra* note 18, at 752.

premarket notification in 2012 were $4,717, but the cost for submitting a medical device for premarket approval can exceed $1,000,000, plus user fees of $256,384 in 2012.[152] Not only is the regulation of software unclear, but the regulation of mobile health applications does not fare much better.

G. MOBILE MEDICAL APPLICATIONS

The FDA acknowledged that mobile devices are integral to modern life.[153] It further recognizes that not all software or mobile applications pose the same degree of risk to public health and safety, and thus some may require regulation as medical devices while other require less regulatory oversight.[154] On July 21, 2011, the FDA issued a draft guidance document entitled "Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications" (hereinafter "Draft Medical App Guidance") in which it proposed regulation of mobile medical applications.[155]

In the Draft Medical App Guidance, the FDA set forth proposed framework for regulating certain software applications that perform or enable critical diagnostic or treatment activities.[156] The FDA specifies in the draft guidance that this "narrowly-tailored approach" that only covers the mobile medical apps it describes.[157] The draft guidance lays out a number of concepts to help determine which mobile applications the FDA intends to regulate.[158] It also describes which persons or entities will be treated as "manufacturers" for purposes of these regulations.[159]

---

[152] Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System, 73 Fed. Reg. at 7502 (Feb. 8, 2008) (codified at 21 C.F.R. pt. 880).
[153] Vernessa T. Pollard and Joseph W. Cormier, *FDA Issues Draft Guidance Regarding Mobile Medical "Apps"*, 16 No. 7 CYBERSPACE LAWYER. 18 (Aug. 2011).
[154] *Id*.
[155] *See, generally*, FDA Draft Guidance for Medical Apps, *supra* note 68.
[156] Pollard and Cormier, *supra* note 153 at 18.
[157] FDA Draft Guidance for Medical Apps *supra* note 68, at 12.
[158] Pollard and Cormier, *supra* note 153 at 18.
[159] *Id*.

First, the Draft Medical App Guidance pertains to a "mobile platform," which is any off-the-shelf commercial handheld platform, whether or not it has wireless connectivity capabilities."[160] Examples of mobile platforms are personal digital assistants, tablets, and smartphones.[161] Another important concept is a "mobile application," which is a software application that can either run on a mobile platform or it could be a web-based software application that is customized to run on a mobile platform but is actually executed on a server somewhere else.[162]

Moreover, the Draft Medical App Guidance indicated the FDA would regulate only a subset of applications.[163] It concerns those that (1) meet the definition of a medical device *and* either (a) are used as an accessory to a regulated medical device *or* (b) transform a mobile platform into a regulated medical device.[164] The FDA calls these "mobile medical apps."[165]

First, a mobile medical app must meet the threshold question of whether it is a medical device.[166] Then one of two conditions need to be satisfied. If the mobile medical app is a medical device and also satisfied as an accessory to another regulated medical device, then the Draft Medical App Guidance applies. The other condition when the Draft Medical App Guidance applies is where the mobile medical app is a medical device and transforms a mobile platform, like a smartphone or tablet, into a regulated medical device.

According to the language of the Draft Medical App Guidance a mobile medical app can transform a smartphone into a medical device. The FDA is already familiar with standard electronic appliances, including smartphones.[167] As with many other electronic machines, the

---

[160] *Id*.
[161] *Id*.
[162] *Id*.
[163] *Id*.
[164] Danzis, *supra* note 10, at 27.
[165] *Id*.
[166] Pollard and Branham, *supra* note 4, at 2.
[167] Telephone Interview with Anil Bhalani, *supra* note 6.

FDA considers a smartphone off-the-shelf hardware.[168] Off-the-shelf hardware and software can be incorporated into a medical device system which then brings all of the parts into the medical device review. Thus it is important to understand the impact of installing a mobile medical app.

The Draft Medical App Guidance includes in "Appendix A" three inexhaustive lists of examples of mobile medical apps.[169] These lists are mobile medical apps that (1) control or extend a medical device, such as remotely accessing vital sign readings of patients at home, (2) transform a mobile platform into a traditionally regulated medical device through attachments or sensors, such as turning a smartphone into an electronic stethoscope, and (3) allow a user to enter patient-specific data and generate patient-specific outcomes using algorithmic methods or processes.[170] According to the draft guidance, this last type includes applications that perform calculations resulting in an index or score, calculate dosage for a specific medication or radiation treatment, or provide recommendations to aid a clinician with a diagnosis.[171] These apps are intended for clinicians and may automate certain tasks or calculations such as a Glasgow Coma Scale, pain index, Apgar score, or National Institute of Heath stroke scale.[172]

The proposed framework is intended to apply to a "mobile medical application manufacturer," which is "anyone who initiates specifications, designs, labels, or creates a software system or application, whether in whole or from multiple software components."[173] A manufacturer could be an entity or a person who creates, designs, develops, labels or modifies a software system to perform as a mobile medical app.[174] This does not apply to those who just

[168] Interview with Linda Moore, *Supra*, note 9.
[169] Pollard and Cormier, *supra* note 153 at 18.
[170] Danzis, *supra* note 10, at 28, *see generally*, FDA Draft Guidance for Medical Apps, *supra* note 68, at 18-20.
[171] FDA Draft Guidance for Medical Apps *supra* note 68, at 19.
[172] *Id*. at 19-20.
[173] *Id*.
[174] *Id*.

distribute a mobile medical app, like retailers and distributors who do not conduct any manufacturing activities.[175]

The FDA proposes four broad categories of mobile medical apps in the Draft Medical App Guidance that it intends to scrutinize under its usual medical device schema: (1) applications that display, store or transmit patient-specific medical device data in its original format, (2) applications that control the intended use, function, modes or energy sources of a connected medical device, (3) applications that transform a mobile platform into a traditional regulated medical device, and (4) applications that create alarms, recommendations, or new information by analyzing or interpreting medical device data.[176]

These four categories have such long names that for purposes of this discussion they will be given shorter names for ease of references. Category 1, applications that display, store or transmit patient-specific medical device data in its original format, will be called "original format apps." Category 2, applications that control the intended use, function, modes or energy sources of a connected medical device, will be called "control apps." Category 3, applications that transform or make a mobile platform a regulated medical device will be called "transforming apps." Category 4, applications that create alarms, recommendations, or new information by analyzing or interpreting medical device data, will be called "creating apps."

Original Format Apps purportedly satisfy the definition of MDDS, according to the FDA, and therefore are regulated under the FDA's device classification scheme as Class I.[177] As noted earlier, Class I entails general controls for medical devices, which requires manufactures to

[175] *Id*.
[176] *Id*. at 13-15.
[177] Pollard and Cormier, *supra* note 153 at 18.

register their companies, list their products, conform quality systems and provide the FDA with adverse event reporting.[178]

A Control Apps is considered an accessory to the device to which it connects or extends, i.e., the "parent" device.[179] These apps are required to meet the regulation applicable to the parent device.[180] For example, if the parent device is a Class II medical device, the Control App manufacturer must meet these same Class II requirements.[181]

Transforming Apps are required to meet the controls that would apply to the resulting medical device if it were manufactured independent of the mobile platform.[182] For example, a Transforming App that transforms a mobile platform into an electronic stethoscope would be required to meet the requirements for electronic stethoscopes, which, in this example, are regulated as Class II devices.[183]

Creating Apps are also considered an accessory to the medical device from which it draws its data and creates a new activity or information, and thus are regulated according to that device's classification.[184] One could also imagine that if a Creating App created something new or had a new property or function that the parent device or another predicate device does not have, the Creating App might fall into a higher classification, such as Class III, and require more stringent regulation than the parent device. The FDA specifies in the Draft Medical App Guidance that this is intended only to cover these categories.[185]This begs the question of how other apps that do not fall into these four categories are to be regulated.

---

[178] *Id*.
[179] *Id*.
[180] *Id*.
[181] *Id*.
[182] *Id*.
[183] *Id*.
[184] *Id*.
[185] FDA Draft Guidance for Medical Apps *supra* note 68, at 12.

Another aspect of this "narrowly-tailored approach" proposed under the draft guidance is that the FDA indicated it "intends to exercise enforcement discretion" with regard to mobile applications that satisfy the definition of a medical device but do not rise to the level of a mobile medical app.[186] What enforcement discretion means is the FDA will purportedly exercise discretion and thereby decline to pursue enforcement action against a mobile medical app manufacturer for violating the FDCA and its regulations.[187] The FDA indicates mobile applications that "automate common medical knowledge available in medical literature" to allow individuals to self-manage a disease or condition should receive discretion.[188] Other mobile apps that are supposed to receive discretion are those that log, track, or store personal data, but are not essential to patient diagnosis, treatment, or safety.[189]

The scope of the Draft Medical App Guidance is limited. The FDA explicitly states the guidance does not cover certain areas. The guidance does not delve into applications that analyze, process or interpret medical data from multiple medical devices.[190] The FDA explained that it will issue separate guidance for this.[191] The draft guidance also fails to address wireless safety, classification or premarket submission requirements, quality system requirements and software that implements quality systems.[192] Again, the FDA purports it will address these areas with future guidance.[193]

The Draft Medical App Guidance has received considerable criticism.[194] While the mobile app industry was generally pleased to hear that the FDA would exercise enforcement discretion toward some apps, the draft guidance fails to delineate where the threshold of

[186] Melnik, *supra*, note 1 at 45.
[187] FDA Draft Guidance for Medical Apps, *supra* note 68, fn. 1.
[188] *Id*. at fn. 13.
[189] Pollard and Cormier, *supra* note 153 at 18.
[190] *Id*.
[191] *Id*.
[192] *Id*.
[193] *Id*.
[194] Danzis, *supra* note 10, at 28.

enforcement discretion occurs.[195] In fact, the draft guidance has generated more questions than answers.[196] For example, while the draft guidance suggests most mobile medical apps will fall under Class I, which are typically exempt from premarket review, or Class II, which typically requires 510k approval for commercial distribution, there still lies the possibility that a product will fall in Class III, which will require the more stringent PMA process.[197] There is no indication when additional, alternate or final guidance will be provided. Thus these unknowns persist.

It seemed Congress provided some motivation for the FDA when it passed the Food and Drug Administration Safety and Innovation Act on January 3, 2012 ("FDASIA").[198] Section 618 of the FDASIA, entitled "Health information technology," instructs the FDA to confer with the National Coordinator for Health Information Technology and the Federal Communications Commission and prepare and post on its website "a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical apps, that promotes innovation, protects patient safety, and avoids regulatory duplication."[199] This report was due in July, 2013[200] (the "FDASIA Report"). Perhaps the marketplace will soon have greater clarity. As of the date of this article, however, the FDA has not yet published the congressionally mandated report.[201] Despite the legislated deadline, it could actually be months or even years before the FDA

[195] *Id*.
[196] *Id*. at 29.
[197] Pollard and Cormier, *supra* note 153 at 18.
[198] S. 3187 (112th): Food and Drug Administration Safety and Innovation Act. 112th Congress, 2011–2013.
[199] *Id*. Section 618(a).
[200] *Id*. stating that the report is due "Not later than 18 months after the date of enactment of this Act," which is July 3, 2013.
[201] Reports and Plans Mandated by FDASIA, U.S. Food & Drug Admin., http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm (last visited July 14, 2013) showing four reports mandated by the FDASIA, but not the specific report referenced here that is mandated by Section 618 of the FDASIA.

actually responds or takes action.[202] Until the FDASIA Report is posted, interested parties must glean insight from the draft guidance documents and related discussions.

What is apparent is that one must examine several complex layers: 1) the initial question of whether the product at issue is a medical device, 2) the product classification, 3) then the control measures, 4) quality systems, 5) applicable performance standards, 6) the software requirements and 7) the mobile medical app guidance. As demonstrated in this discussion, some of these layers are overlapping and somewhat duplicative. Others are ill-defined and leave much to the medical device company to figure out. While regulation of medical devices is necessary to ensure safety, the inevitable increase in mHealth and consumer access requires a more defined, targeted and streamlined regulatory scheme for mobile devices in order to keep pace with this quickly evolving technology.

It may be helpful to examine the categories of mobile medical apps that the FDA proposes to regulate against four different types of mHealth products for smartphones that will further be defined below – information apps, diagnostic apps, control apps and adapters. Before delving into product types, two tangential regulations will be touched on briefly.

H. HIPAA PRIVACY AND SECURITY

While the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") is not core to this discussion on FDA regulation, the use of mobile devices for healthcare raise serious HIPAA issues regarding privacy and security, and thus it will be touched upon here so that it is not completely ignored. HIPAA as it relates to mHealth could warrant its own separate paper.

HIPAA was passed by Congress in 1996 to, among other things, require protection and confidential handling of protected health information.[203] "Protected health information," or

[202] Interview with Linda Moore, *Supra*, note 9.
[203] *What is HIPAA?*, California Department of Health Care Services, CA.gov, available at http://www.dhcs.ca.gov/formsandpubs/laws/hipaa/Pages/1.00%20WhatisHIPAA.aspx (last visited July 27, 2013).

"PHI," is defined as individually identifiable health information that is transmitted or maintained in electronic media or in any other form or media, with certain exclusions.[204] The entry of mobile devices into healthcare has wrought new issues of privacy and security with regard to patient information.[205] HIPAA requires healthcare providers to implement and maintain certain privacy and security measures with regard to PHI.[206] Mobile communications are not secure because communication between the users goes through a third party's system, the telecommunication data carrier.[207] Moreover, professional communications may be audited by the U.S. Department of Health and Human Services.[208]

The issue is that communications between a patient and physician are protected under HIPAA.[209] When a healthcare provider receives data from a patient it becomes PHI under HIPAA and the provider is then required to secure the information pursuant to HIPAA requirements.[210] Security measures such as authentication and encryption are needed in order to safeguard PHI.[211] Typical commercial mobile communication lacks security protocols unless they are specifically put in place.[212] Nonetheless, electronic measures do not eliminate liability and responsibility. A survey conducted by the Ponemon Institute[213] revealed that 96% of healthcare organizations reported securities breaches, often as a result of a lost mobile device.[214]

---

[204] 45 CFR part 160, Subpart A, §160.103 definitions.
[205] Jim Sheldon-Dean & Vidya Phalke, PhD, *Healthcare Going the Mobile Way!*, METRICSTREAM, INC. (webinar Feb. 19, 2013) (remarks of Jim Sheldon-Dean, Founder and Director of Compliance Services, Lewis Creek Systems, LLC), *available at* http://info.metricstream.com/healthcare-mobile-security.html?utm_source=Campaigns&utm_medium=Email&utm_campaign=Feb19_CO_healthcare_mobile-security_Webinar&Cid=70150000000lzn4&Channel=CO (last visited July 27, 2013)
[206] Health Insurance Portability and Accountability Act, P.L.104-191.
[207] *Id*.
[208] *Id*.
[209] Runkle, *supra* note 3 at 31.
[210] *Id*. at 30.
[211] *Id*.
[212] Sheldon-Dean, *supra*, note 205.
[213] Ponemon Institute is an organization that conducts independent research on privacy, data protection and information security policies. *See* www.ponemon.org (last visited July 27, 2013).
[214] Runkle, *supra* note 3 at 31.

Fines are imposed on HIPAA violations with penalties increasing under new HIPAA rules that went into effect March 26, 2013.[215]

There are other implication as well, but HIPAA requires a separate discussion to do it justice. It is simply raised here to note the convergence of these two federal schemes, HIPAA and FDA regulation, with mHealth.[216]

I. TAXATION OF SMARTPHONES AS MEDICAL DEVICES

While taxation is also not core to this discussion on FDA regulation, the FDA's scheme is implicated, and thus it will be touched upon here so that it is also not ignored. This taxation subject could also warrant its own separate paper.

The Patient Protection and Affordability Care Act, or more colloquially "Obamacare," was signed into law by President Obama on March 23, 2010.[217] After a bustle of controversy and challenge, the Supreme Court upheld Obamacare with a 5-4 vote on June 28, 2012.[218] Obamacare is partially subsidized through a new 2.3% excise tax imposed on medical devices.[219] The question has been posed whether mobile applications will be viewed as medical devices whereby the FDA would have the ability to tax smartphones and tablets.[220]

This conjecture was set in motion on March 1, 2013 when Congress sent a letter to the FDA asking for clarification on how the FDA intends to regulate mobile medical apps.[221] The

---

[215] Sheldon-Dean, *supra*, note 205.
[216] *See generally*, Runkle, *supra* note 3.
[217] *See* PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. §§ 18001-18121 (2011)).
[218] *See* Nat'l Fed'n of Indep. Bus. v. Sebelius (*NFIB*), 132 S. Ct. 2566 (2012).
[219] Kira Davis, *Obamacare Tax on Your Smartphone?*, INDEPENDENT JOURNAL REVIEW (Mar. 16, 2013) http://www.ijreview.com/2013/03/41150-obamacare-tax-on-your-smartphone/ (last visited Apr. 1, 2013).
[220] *Id*.
[221] Letter from Fred Upton et. al., Committee on Energy and Commerce, to Margaret Hamburg, MD, Commissioner of the FDA, dated March 1, 2013, available at http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/letters/030113FDAsmartphones.pdf (last visited Apr. 1, 2013).

letter asks, among other things, whether the FDA has "discussed, prepared, or analyzed the effect of the medical device tax on smartphones (as well as tablets or similar devices)…."[222]

The issue surfaced because the Internal Revenue Service ("IRS") decided to base its medical device taxing authority on what the FDA considers a medical device.[223] A "taxable medical device" is "a device that is listed as a device with the [FDA] under section 510(j) of the [FDCA], and 21 CFR part 807, unless the device falls within an exemption from the tax, such as the retail exemption."[224] This tax applies to medical devices sold after December 31, 2012.[225]

If the FDA determines that a device should have been listed with the FDA as a medical device, then the device is deemed to be listed when the FDA notifies the manufacturer or importer in writing that the device is required to be listed.[226] This deference the IRS extends here to the FDA has the effect of transforming the FDA into a government tax agent.[227] While the FDA indicated a smartphone or tablet would not automatically be taxed as a medical device simply because it is capable of running a medical application, the FDA stated it needs to make a determination,[228] and thus speculation ensued.

The tax situation is troublesome because the excise tax is imposed regardless of whether the manufacturer makes a profit.[229] Further, most device companies are relatively small, typically with 50 or fewer employees.[230] To accommodate this tax, companies may need to cut

---

[222] *Id*. at 2.
[223] Katie McAuliffe, *Don't Allow Medical Device Taxation on Smartphones, Tablets and Apps*, THE HILL (Mar. 7, 2013) http://thehill.com/blogs/congress-blog/healthcare/286923-dont-allow-medical-device-taxation-on-smartphones-tablets-and-apps (last visited Apr. 1, 2013).
[224] *See* IRS Medical Device Excise Tax: Frequently Asked Questions, available at http://www.irs.gov/uac/Medical-Device-Excise-Tax:-Frequently-Asked-Questions (last visited Apr. 1, 2013).
[225] *Id*.
[226] McAuliffe, *supra* note 223.
[227] *Id*.
[228] *Id*.
[229] *Id*.
[230] *Id*.

costs or pass the cost on to consumers.[231] This begs the question of whether a healthcare savings is actually achieved.

The logical conclusion is smartphones should not be taxed as medical devices. The FDA is familiar with smartphones. Smartphones are standard devices now, like computer monitors and keyboards.[232] These "off the shelf" items should not be taxed as medical devices even if incorporated as part of a system. Furthermore, when a device or software package is a medical device, it supposedly may only be sold to a physician or to a consumer with a prescription from his or her physician.[233] No one needs a prescription to buy a smartphone or a tablet. Thus, a standard mobile device ought not to be a medical device for purposes of the Obamacare tax. If a mobile medical app transforms a standard mobile device into a medical device, it probably should be just the app that is subject to the tax, not the off-the-shelf device.

This discussion reveals the federal landscape is complex. Unmistakably government has its attention on mHealth. Through the FDASIA Congress has demanded further attention. Although the FDA has not yet provided the FDASIA Report, further guidance is likely forthcoming from the FDA and it is hoped here that it will lead to a more nimble system. While regulation of medical devices is necessary to ensure safety, the inevitable increase in mHealth and consumer access requires a more defined, targeted and streamlined regulatory scheme for mobile devices in order to keep pace with this quickly evolving technology.

IV. SMARTPHONE MHEALTH PRODUCTS

The four categories of mobile medical apps that the Draft Medical App Guidance discusses are merely a subset of mobile medical apps.[234] This leaves out a variety of mHealth

[231] *Id*.
[232] Telephone Interview with Anil Bhalani, *supra* note 6.
[233] *Id*.
[234] Pollard and Cormier, *supra* note 153 at 18.

products.[235] If one is to have a better understanding of when medical device regulation is required for a smartphone or tablet, it is necessary to be more inclusive in discussing mHealth products that are designed to work with standard handheld apparatus. There are a number of mHealth products available and in development. Those designed for mobile devices can be described in four types.

First, there are applications that allow users to find, view and read medical information.[236] This first type of product essentially mimics what end users can already do with personal computers by looking up information on the Internet or running a software application.[237] This will be called an "information app" for purpose of this discussion.

Then there are applications that perform a diagnostic function. This second type of product performs a calculation or analysis and computes a result or determination.[238] This is typically conducted by a user inputting certain data into the application and then the process and diagnosis is rendered without the mental step of human intervention.[239] This will be called a "diagnostic app" for this discussion.

The third type of product is an application that allows the smartphone to control an unattached medical device. For purpose of this discuss this will be called a "control app."

The fourth category is an attachment, sensor or other device that attaches to or adapts one's smartphone to perform certain medical function through the use of the attached accessory, essentially converting it into a medical device whereby the attachment enables the smartphone to execute medical functions. As noted, the FDA categorizes these as "accessories" under the "accessory rule." To differentiate between an accessory in the sense of a physical article with the principle of "accessory" under the FDA's accessory rule, which includes physical articles and

[235] *Id*.
[236] Krouse, *supra* note 18, at 741.
[237] *Id*.
[238] *Id*. at 743.
[239] *Id*.

software, for purposes of this discussion this type of product will be called an "adapter" to designate a physical item that attaches to the smartphone.

A. INFORMATION APPS

Information apps may have escaped FDA regulation. While the ability to find, view and read medical information from one's mobile phone may be a recent phenomenon, people have been using personal computers this way for years. Popular web sites like WebMD, HealthCentral and WrongDiagnosis.com provide a variety of medical information and tools for managing health.[240] None of these sites is regulated by the FDA. Information apps provide the same access. Information apps do not appear to fall within the FDA's definition of a mobile medical app because they do not connect to a medical device, transform a smartphone or tablet into a traditionally regulated medical device, or generate patient-specific data. An information app is a product that is likely not a medical device. These are more akin to general health and wellness. So perhaps information apps should be free from regulation.

B. DIAGNOSTIC APPS

What is meant by diagnostic apps here is an application that performs a calculation or function and computes a result or determination without human intervention, aside from entering the data, of course. Diagnostic apps appear to fall within the FDA's definition of a mobile medical app according to the draft guidance because these applications allow a user to enter patient-specific data, apply an algorithm or formulae, and then output patient-specific results.[241] Thus the FDA presumably intends to regulate diagnostic apps under its medical device regime of Classes I-III.[242] As noted earlier, the FDA has determined some software is either Class II or

[240] NetTop20.com, *Medical Information Sites: The Pick of the Best Medical Information Sites on the Net Today*, available at http://medical.nettop20.com/ (last visited Apr. 4, 2013).
[241] Danzis, *supra* note 10, at 27.
[242] *Id*. at 29.

Class III. This may seem reasonable; however, diagnostic apps have varying capabilities and thus represent varying levels of risk to consumers.[243]

It would make better sense that diagnostic apps that pose little health risk to consumers ought to be regulated differently than diagnostic apps that pose a greater risk to consumer health. Different diagnostic apps perform various types of analyses, and thus this type of product can be broken down into three further categories: clinical analysis, disease management analysis, and health data analysis.[244]

1. CLINICAL ANALYSIS – DIAGNOSTIC APP

Some commentators contend that basic clinical analysis programs simply automate well-understood, nonproprietary clinical algorithms and thus present a relatively low risk to consumers because physicians not only understand how to use the information that such programs generate, but that physicians are also familiar with the algorithms and calculations utilized in these applications whereby a physician would be able to recognize incorrect results and arrive at his/her own mentally derived diagnosis.[245] This allows for "competent human intervention," which the FDA prefers per its draft software policy.[246]

In such event, the FDA perceives that competent human intervention provides sufficient safeguard against the diagnostic application leading to medical error.[247] Thus it appears there is relatively low risk with such diagnostic apps. This presupposes a doctor or other healthcare professional. If the operator is a lay person with no medical training or medical education, the "competent human intervention" may be deficient.

[243] *Id*.
[244] *Id*.
[245] *Id*.
[246] *Id*. at 27, noting that in 2005, the FDA withdrew the 1989 draft policy without comment.
[247] *Id*. at 29.

Software applications that deploy simple, automated, well-understood, nonproprietary clinical algorithms have been present on the Internet for years without regulation.[248] In fact, the FDA had an oncology drug-dosing calculator on its own website.[249] Other federal government websites offer similar medical calculators. The National Heart, Lung, and Blood Institute, which is part of the U.S. Department of Health and Human Services' (DHHS) offers a "10 Year Heart Attack Risk Calculator."[250] The National Institute of Diabetes and Digestive and Kidney Diseases offers a glomerular filtration rate calculator for children and one for adults.[251] The U.S. Department of Veterans Affairs offers a calculator for cirrhosis and end stage liver disease as well as other similar clinician tools.[252] Being available on the Internet, these are open to the general public, and thus physicians and lay people can access and utilize these.

The mere portability of having this functionality on one's smartphone likely does not warrant any new regulation. That being said, the mere fact that lay people do have access begs the question of whether a different requirement should be imposed on lay people because they lack medical training.

2. DISEASE MANAGEMENT – DIAGNOSTIC APP

A disease management program also seems to be a low-risk category. Such apps manipulate patient-specific data to help patients manage a disease according to well-understood guidelines in conjunction with advice from a healthcare provider.[253] An example of a disease management diagnostic app is one that helps heart disease patients create a diet based on published nutritional guidelines.[254] Commentators think that such apps should receive FDA enforcement discretion because they are intended to operate in tandem with oversight from a

[248] *Id*.
[249] *Id*.
[250] Available at http://www.nhlbi.nih.gov/educational/hearttruth/lower-risk/tools.htm#risk (last visited Apr. 6, 2013).
[251] Available at http://nkdep.nih.gov/lab-evaluation/gfr-calculators.shtml (last visited Apr. 6, 2013).
[252] Available at http://www.hepatitis.va.gov/provider/tools/ (last visited Apr. 6, 2013).
[253] Danzis, *supra* note 10, at 29.
[254] *Id*.

healthcare provider and are not meant to encourage a patient to self-treat or self-diagnose.[255] Disease management diagnostic apps may pose a low risk to a patient under medical care. They can meaningfully improve public health. Perhaps they should be subject to lower scrutiny.

Nonetheless, this does not account for those who do not seek or receive medical attention. If a doctor is involved, risk of injury to a patient is likely low. To regulate based on the assumption that a healthcare provider is overseeing a patient misses the incidents where a lay person uses the disease management app without physician supervision. Should a different regulation apply based on the user? Regardless, it is unclear whether enforcement discretion applies and whether a disease management app will be regarded as a Class I or Class II medical device.

3. HEALTH DATA ANALYSIS – DIAGNOSTIC APP

Another diagnostic app is a program that downloads medical device data and utilizes the data for basic disease management.[256] Health data analysis diagnostic apps might perform charting, trending, or basic disease-management analysis of medical device data obtained from a medical device, such as a blood pressure cuff or glucose monitor.[257] As noted earlier, MDDS software transfers, stores, converts, or displays medical device data without providing analysis, alarms, or active patient monitoring and such software falls in Class I due to its low risk.[258]

Although the MDDS rule is a narrow category,[259] one commentator suggests it stands to reason that charting, trending and basic data analysis ought to be construed as within the scope of the MDDS rule particularly because the data, even when provided to consumers, is intended to operate in conjunction with medical attention,[260] and therefore should be entitled to FDA

[255] *Id*.
[256] *Id*.
[257] *Id*.
[258] Danzis, *supra* note 10, at 27.
[259] *Id*.
[260] *Id*. at 29.

regulatory discretion. Such discretion, however, does not provide clarity to the developer. How is one to know whether the FDA will determine the app in question must be regulated, and if so, at what level of scrutiny?

The same question regarding the user is present here as well. If the product receives enforcement discretion, i.e., is exempted from medical device requirements because a patient is being oversee by a doctor, does this same product then require different regulation when used by a consumer that is without a physician? This question cannot be answered by just examining the device and the manufacturer's intended use of it.

C. CONTROL APPS

A control app allows the smartphone to control a separate medical device, whether physically or wirelessly. As noted earlier, some software programs fall under the FDA's "accessory rule." Mobile applications that control a medical device are considered "accessories" and are generally subject to the same regulation as the parent device.[261] The aspect of control unequivocally implicates the FDA's concern that if the accessory failed, the parent device might fail. If, for example, a control app freezes it may not be able to signal the parent device to turn on, turn off, or adjust its function at a given interval, and thus the FDA's fear is realized. The FDA's draft guidance for mobile medical apps further indicates a control app is subject to regulation because a control app will "connect to or extend a medical device."[262] Pursuant to the accessory rule, a control app is subject to the same regulation as the parent device.

D. ADAPTERS

There are many products that attach to or adapt a smartphone to perform a medical function. These products contain software, but they also consist of a physical apparatus, such as an attachment or sensor that detects external stimuli for the mobile device to process. The

[261] *Id*.
[262] *Id*. at 28.

Schosche myTrek and the Polar WearLink+ allow one to track and upload one's vital signs to his/her iPhone or Android phone.[263] The iHealth BP3 and the Withings BPM are two blood pressure monitoring adapters that allow one to monitor, track and store blood pressure readings.[264] Sanofi's IBGStar blood glucose meter tracks one's glucose, carbohydrate intake and the dosage of insulin to be taken.[265] AliveCor Heart Monitor is a mobile phone case lined with electrodes that converts an iPhone into an electrocardiogram ("ECG") device to detect irregular heart rhythms that can analyze, store and transmit ECG readings.[266] The following table illustrates adapters:

Examples of Smartphone Adapters			
			
iHealth BP3 blood pressure cuff	iBG*STAR blood glucose meter	MIT's Netra refractive eye test	AliveCor Heart Monitor ECG iPhone case

Adapters allow smartphones to give eye exams, take ultrasound and replace stethoscopes.[267] Many more adapters are in development. A research team at the University of California Los Angeles is working on a mobile phone based E. coli sensor that is a lightweight attachment to a mobile phone's camera for detecting E. coli in water and other fluids.[268] CellScope, a San Francisco-based company, is developing an otoscope that also attaches to a

[263] Daniel P., *Smartphones and tablets as medical devices*, PHONEARENA.COM (Sept. 3, 2011) http://www.phonearena.com/news/Smartphones-and-tablets-as-medical-devices_id21791 (last visited July 14, 2013)
[264] *Id*.
[265] *Id*.
[266] Ruane, *supra* note 43.
[267] Daniel P., *supra* note 263.
[268] Ruane, *supra* note 43.

mobile phone's camera to enable parents to take a picture of their child's eardrum and then email the picture to a healthcare provider to check for ear infection.[269]

These and other consumer-oriented devices are part of an established and growing trend that is revolutionizing healthcare.[270] What is not revolutionary is the regulatory requirement. Because adapters are embodied in physical articles, and do not exist solely as software, they are undeniably devices. The only escape from FDA regulation is if an adapter can be characterized as a product for general health or wellness, whereby it would then not fit the definition of a "medical device."[271] An alternative approach is that many adapters may be able to satisfy the lower regulatory requirements of Class II or by doing a 510k notification if, for example, a blood pressure cuff adapter is substantially similar to a standard, pre-existing blood pressure cuff.[272] However, some adapters will inevitably have to satisfy the higher level Class III requirements by doing a PMA notification if the adapter is so innovative that there is no predicate device against which to assess and demonstrate substantial similarity. In fact, some adapters have indeed undergone clinical trials to receive FDA approval.[273] AliveCor's Heart Monitor, for example, has been the subject of several clinical trials.[274]

These and other similar advancements show there is a critical mass building in mHealth. Regulation could use an upgrade so that it does not become a bottleneck to innovation, or worse, miss the mark on consumer safety. As can be seen in these examples, some mHealth products are perceived as needing less regulation or a lower level of scrutiny, but they assume a patient is being treated by a healthcare professional. This same product may pose a higher level of risk of harm to a consumer using the product on his or her own without a medical professional. How,

---

[269] *Id*.
[270] *Smartphone Medicine*, REPERTOIRE (May 2012) available at http://www.repertoiremag.com/Article.asp?Id=3980 (last visited Apr. 7, 2013)
[271] Danzis, *supra* note 10, at 27.
[272] *Id*. at 28.
[273] Ruane, *supra* note 43.
[274] *Id*.

then, should the product be regulated? Does the same product require two different regulatory requirements based on whether healthcare practitioner is involved? This would complicate matters further. While regulation of medical devices is necessary to ensure safety, the inevitable increase in mHealth and consumer access requires a more defined, targeted and streamlined regulatory scheme for mobile devices in order to keep pace with this quickly evolving technology.

V. IMPROVING MHEALTH REGLUATION

It is unclear when mobile medical apps are subject to the FDA's 501(k) and PMA regimes.[275] Further, these medical device regulations were created during a time when technologies were developing at a slower pace and were less accessible to consumers.[276] It appears outdated to apply these schemes to mHealth technologies that are evolving at a rapid pace and are highly accessible to and often designed for consumers.[277] By 2015, it is estimated that 500 million people worldwide will use mobile medical apps on their smartphones.[278] Regulation needs to improve.

A. SAFETY AND COMPLIANCE

The purpose of the FDA is to protect the public health "by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."[279] Ensuring safety is a careful balance of how much regulation is necessary.[280] People generally want to be free of regulation.[281]

---

[275] *See generally*, Thompson, *A Call for Clarity*, *supra* note 8.
[276] Krouse, *supra* note 18, at 763.
[277] *Id*.
[278] Egle Mikalajunaite, *500m People Will Be Using Healthcare Mobile Applications in 2015*, RESEARCH2GUIDANCE (Nov. 10, 2010), http://www.research2guidance.com/500m-people-will-be-using-healthcare-mobile-applications-in-2015 (last visited Apr. 7, 2013).
[279] About FDA, What We Do, U.S. Food & Drug Admin., available at http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited Aug. 3, 2013).
[280] Correspondence with Anil Bhalani, *supra* note 62.
[281] *Id*.

However, when people or loved ones are injured, they want the government to step in and regulate.[282] Balancing goes on inside companies as well, where ethics and morals intersect with revenue and profit growth.[283]

The complexity of the regulatory environment and the guess work involved make compliance a challenge for even a diligent company trying to anticipate what the FDA wants. Generally companies are out of compliance to a certain degree.[284] It is when a product is found unsafe or ineffective that issues arise.[285] The prevailing thought is that if a company makes an effort to comply with regulation that effort will keep an unsafe or ineffective product off the market.[286] The discussions and recommendations here are posed in an effort to help strike that balance better by examining safety under a better lens that will aid in determine how much regulation is required.

B. Define the Software Regulation

The FDA needs to clarify some of the confusion, and, of course, it is hoped that the FDA will do so in the FDASIA Report. One commentator suggested it is high time the FDA create an "Office of Software." Developing an Office of In Vitro Diagnostics allowed the FDA develop its expertise in this area,[287] and thus similarly, the FDA could groom its acumen if it had an office with a more dedicated focus.

Just as the accessory rule seems to be giving way and the FDA has already recognized that software requires more than an all-purpose approach, it would be wise for the FDA to define new classifications for mobile medical apps that are more tailored to the characteristic of the

[282] *Id*.
[283] *Id*.
[284] *Id*.
[285] *Id*.
[286] *Id*.
[287] Danzis, *supra* note 10, at 29.

application rather than the intended use.[288] The MDDS rule classifying all MDDS software as Class I is a good start in defining categories. Similar rules or classifications are needed.

Rather than squeeze mobile medical apps into the existing medical device schema, it may be prudent to have a new medical device regulatory framework specific to mobile medical apps, and perhaps even for the broader context of software. Better definitions would be helpful. Developers need to understand when their applications will be regulated as a medical device.[289] Can a more definite line be drawn between a health product versus a medical product? Asking for a completely new regulatory scheme just for mHealth products is probably a bit too aggressive and fanciful to expect of the FDA. While a new scheme may be ideal, but unlikely, a realistically achievable suggestion is to have better definitions.

Information apps, as defined above, probably should not even be considered medical devices. Since essentially the same information has been available on the Internet without regulation, the mere portability of this information on one's hand held device should not invite new regulation. Certainly information apps should not be regulated.[290] Beyond this exempt threshold, however, the level of regulation needs to be defined.

Apps for general health, wellness and lifestyle monitoring may be unassuming, but may pose higher risk than believed. Perhaps these should not be exempted as some commentators argue.[291] Because many health and wellness apps can go beyond what the manufacturer *intends*, these likely need some regulation. Perhaps a low level akin to Class I devices at a minimum.

Diagnostic apps span a wide spectrum such that they obviously require multiple classifications to delineate the appropriate regulatory regime for each category. Although many diagnostic apps could be considered Class I, there are certainly apps whose functionality goes

[288] *Id*.
[289] Krouse, *supra* note 18, at 756.
[290] Krouse, *supra* note 18, at 756.
[291] *Id*.

beyond basic clinical or basic disease management analysis.[292] Undoubtedly there will be diagnostic apps that require either 510(k) approval or PMA clearance. The FDA needs to provide more specific guidance as to diagnostic app classification and more specific direction on what data is required in regulatory submissions so that application developers will have a better understanding of the FDA's expectations on such products.[293] What would be helpful in developing better definitions is if the FDA take a step back and examine the principles that bear on consumer safety that lead to the development of current regulations.

C. TARGET THE FOCUS ON PRINCIPLES UNDERLYING SAFETY

The primary focus with regard to safety in determining what level of regulation should be required has been on the performance of mobile medical apps in relation to their intended use. Discussion of access is given short shrift. Safety considerations necessarily have to change when the power of healthcare treatment moves from physicians' hands to the hands of consumers. In addition, actual use requires at least as much attention as intended use because safety issues will arise through what actually occurs in the marketplace as opposed to theoretical expectations of what a manufacturer purportedly "intended." While not sufficiently part of the regulatory dialogue, consumer access and actual use have led to self-treatment and the unauthorized practice of medicine, which has culminated in marketplace interposition. Regulators need to target their discussions on consumer access, actual use and marketplace interposition in order to rethink regulation.

1. CONSUMER ACCESS

Unless one is a physician, the general consumer needs a prescription to purchase a traditional medical device, except for a few medical devices that have become available over-

[292] Danzis, *supra* note 10, at 29.
[293] *Id*.

the-counter and can be found at drug stores.[294] That being said, there is no equivalent to a pharmacy for medical devices. Gatekeeping is up to the device companies.[295] In contrast, mobile medical apps are readily available, literally at hand, in the application store of one's smartphone. They can be immediately downloaded, often for free and some for a fee. Moreover, mobility has given consumers far greater access to mobile medical apps than consumers previously had with traditional medical devices.

Discussions regarding FDA regulation necessarily focus on the device itself, but more attention also needs to be given to consumer access, otherwise the system cannot be properly improved. Consumer access cannot be ignored without undermining the purpose of the regulation in the first place – safety. One commentator suggests the FDA should put the onus on application stores to prevent mobile medical apps from being marketed without FDA approval.[296] This appears to complicate the relationship between the FDA and the developer by inserting a middleman. It seems misplaced to foist gatekeeping on a middleman, who then would have to endure a regulatory burden not previously felt. Further, it would transform an app store into a medical device pharmacy. Equally important, placing a regulatory evaluation requirement on a market participant like an application store rather than the FDA might lead to arbitrary or incorrect denial of the developer's product. Such measures might stifle innovation.

This is not to say that consumer access should be unbridled with no gatekeeping mechanisms erected. Some threshold may be desirable. With traditional medical devices, once approved for a particular indication of use, the FDA identifies whether the medical device may be marketed by prescription only or over the counter.[297] If the medical device is prescription

[294] Telephone Interview with Anil Bhalani, *supra* note 6.
[295] Correspondence with Anil Bhalani, *supra* note 62.
[296] Krouse, *supra* note 18, at 763.
[297] Correspondence with Anil Bhalani, *supra* note 62.

only, it is up to the company that received approval to be the gatekeeper.[298] There are no pharmacies for medical devices. The company may choose to sell only to physicians or through a distribution network that provides the company some assurance that the product is only reaching physicians or those receiving physician approval.[299] The FDA leaves it up to the company that is getting the medical device approved to determine how to manage the prescription requirement, with an FDA enforcement action as the potential penalty if the company fails to ensure compliance.[300]

Perhaps rather than the app store, it is the manufacturer or developer that is putting the mobile medical app on the market who needs to consider a mechanism to check for physician or prescription authorization before allowing download of the mobile medical app. The advice here is acknowledge that technological advancement has changed consumer access, and thus a concomitant paradigm shift is needed in order to reexamine whether the current or forthcoming regulation addresses not only the technological developments but the practical realities as well.

2. ACTUAL USE

Related to consumer access is the concept of *actual use*. This is in contrast to *intended use*. As noted earlier, it appears the FDA is becoming more aware that it is questionable whether the principle of intended use still makes sense when applied to a product that is deployed for an intended purposes of the manufacturer as expressed in its product claims. However, this does not account for use of a product in ways beyond what the manufacturer expressly intended. It also does not account for use of a product in a way that a manufacturer contemplates but does not expressly state.

[298] *Id*.
[299] *Id*.
[300] *Id*.

Take, for example, the scale mentioned earlier in the software "level of concern" discussion where a scale posed no harm to a person simply using it for general wellness purposes, but if the person is required to notify his/her doctor when s/he exceeds a certain weight and fails to do so because the scale displayed an incorrectly low weight, the person may experience a moderate or high risk. [301] Assume the manufacturer *intended* the scale for general health and wellness. Assume further that the scale is classified as a Class I medical device being deemed to pose a low level of risk to humans. The *actual use* – of monitoring for a health condition to signal when to notify a physician – however, poses a higher health risk. Does "intended use" properly address patient safety?

The disparity may also exist with mobile medical apps. Consider the Instant Heart Rate app by Azumio, Inc., for example.[302] It is a heart rate monitor that measures one's pulse.[303] It uses the built-in camera on a smartphone to track color changes on the fingertip that are directly linked to one's pulse.[304] Azumio, Inc. claims this is the same technique that medical pulse oximeters use.[305] Further, Azumio, Inc. touts Instant Heart Rate as a "health and fitness" app.[306] As of March 12, 2012, the Android version alone of Instant Heart Rate has been downloaded over 10 million times and rated 4.4 out of a 5.0 scale by over 107,979 users.[307]

Presumably Azumio, Inc.'s *intended use* is general health and wellness. In fact, Google and Apple, Inc. categorize the Instant Heart Rate app as "Health & Fitness."[308] Based on this, Instant Heart Rate is not a medical device at all. If so, it is likely a Class I medical device. Heart

---

[301] Thompson, *A Call for Clarity*, *supra* note 8 at 38.
[302] *See* Android Apps on Google Play, available at https://play.google.com/store/apps/details?id=si.modula.android.instantheartrate&hl=en (last visited July 28, 2013).
[303] *Id*.
[304] *Id*.
[305] *Id*.
[306] *Id*.
[307] *Id*. listing installs as 10,000,000-50,000,000.
[308] *See, Id.*, *see also*, Instant Heart Rate – Heart Rate Monitor by Azumio Free, available at https://itunes.apple.com/us/app/instant-heart-rate-heart-rate/id409625068?mt=8 (last visited July 28, 2013).

monitors, however, are Class II medical devices.[309] Pulse Oximeters are also Class II medical devices.[310] With tens of millions of people having Instant Heart Rate readily available on their smartphones, it is not hard to imagine some people using Instant Heart Rate as a heart monitor. Again, does "intended use" properly address patient safety? A traditional heart monitor requires Class II approval. If Instant Heart Rate is not a medical device at all, just "intended" for health and wellness, despite also being a heart monitor, then it does not have to comply with any FDA medical device requirements.

The iStethoscope app by The Undercover Scientist further illuminates this discord. The iStethoscope turns a smartphone into a stethoscope so that one can listen to a heartbeat and view heart waveforms.[311] Apple, Inc. categorizes the iStethoscope in the App Store as "Medical."[312] The developer, however, stated in the description that iStethoscope is "intended to be used for entertainment purposes and as a demonstration of the technology."[313] Can this be? It has a higher category (Medical) than Instant Heart Rate (Health & Fitness), but it is promoted for a lesser purpose – not for general health or wellness, but for amusement. Despite it being a "Medical" category, does "entertainment" allow it to escape regulation? Under this rubric iStethoscope is not a medical device at all. Does this safeguard consumers?

The current regulatory terrain for medical devices with its focus on intended use, not actual use seems to allow a loophole for mobile devices because there is no gatekeeping through prescriptions. The intended use with medical devices is similar to the concept of label claims

[309] *See* Product Classification results for "heart monitor" search on FDA web site showing each of 8 results listed as Class 2, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/TextResults.cfm (last visited July 28, 2013); Product Classification open search is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm?db=PCD&id=DQA (last visited July 28, 2013).
[310] *See* Product Classification results for "pulse oximeter" search on FDA web site showing 4 out of 5 results listed as Class 2, and one, fetal pulse oximeter, listed as Class 3, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/TextResults.cfm (last visited Aug. 10, 2013).
[311] iTune Preview, iStethoscope Free, By undercover scientist software, available at https://itunes.apple.com/ca/app/istethoscope-free/id383008092?mt=8 (last visited Aug. 4, 2013).
[312] *Id*.
[313] *Id*.

with drugs and biologics – the product claims must coincide with approved uses of the device or drug. There are strict requirements on what a drug developer may and may not state in its promotional materials with regard to an approved drug.[314] That industry, however, limits the availability of pharmaceuticals through prescriptions and pharmacies. Furthermore, in the drug and biologic markets there is ongoing heated public discussion regarding concern over promotion of off-label use.[315] In fact, in recent years very fierce and high stake litigation has ensued over off-label promotion of drugs.[316]

There is no public discussion with regard to off-label use of mHealth products and less discussion regarding off-label use of medical devices compared to the prevalence of off-label concern in the pharmaceutical industry.[317] Rather, with mHealth the FDA seems more concerned with the intended use as promoted by the manufacturer. It may be that mHealth manufacturers or other parties do not actually promote "off-label" uses for mHealth products whereby the discussions have not yet arisen. This further highlights the concern here that the FDA should pay more attention to actual use of mHealth products, which may be different from the uses expressed in the product's promotional materials.

Does medical device regulation turn a blind eye to actual use? The above examples reveal the impact of actual use. A manufacturer may *intend* the app to be used for general health and wellness, i.e., the manufacturer may *intend* to market a non-medical device that it believes

---

[314] George Lasezkay, Professor of Law, Pharmaceutical Law & Policy Class Lecture at the University of San Diego School of Law (Feb. 7, 2013) (on file with author).
[315] *Id.*
[316] *See, e.g.*, WLF v. Friedman, 13 F.Supp.2d 51, 62-75 (D.D.C. 1998), WLF v. Henney, 56 F.Supp. 81 (D.D.C. 1999), US v. Caronia, 703 F.3d 149 (2d Cir. December 3, 2012).
[317] There are enforcement actions with regard to off-label medical devices, however, the pharmaceutical industry experiences a far greater magnitude of exposure. For example, device maker AtriCure settled with the US Department of Justice ("DOJ") for $3.76 million and device company Estech settled for $1.4 million in 2010. Anita Slomski, *Off-Label Use of Medical Devices: Out of Bounds*, PROTO, Summer 2010, available at http://protomag.com/assets/offlabel-use-of-medical-devices-out-of-bounds (last visited Aug. 10, 2013). Whereas GlaxoSmithKline settled for $3 billion, Abbott Labs settled for $1.6 billion, and Pfizer settled for $546 million in 2012 for DOJ off-label charges. George Lasezkay, Professor of Law, Pharmaceutical Law & Policy Class Lecture at the University of San Diego School of Law (Feb. 7, 2013) (on file with author).

poses little harm to consumers. This assumes a noble intent. No doubt some may release a product with the hope or motivation that consumers will use it at a higher level, while actually purporting an intent in their product claims for a lower level use.

Regardless of a sincere intent or clandestine intent, the actual use may give rise to a different level of risk to the consumer. This is not to say the manufacturer should be liable for any subsequent harm. In fact, The Undercover Scientist requires would-be iStethoscope users to acknowledge a disclaimer in order to activate the application: "…By activating iStethoscope you…agree that the developers of this application will not be held liable for any use of this device, software and output from the software that results in equipment malfunction, unlawful behavior, or misdiagnosis of any medical condition."[318] The Undercover Scientist may safeguard itself with a disclaimer, but does this safeguard the user? This is not a discussion regarding liability. It is a discussion of risk assessment. What is meant here is that the risk of injury a consumer faces is more connected to actual use rather than intended use. Consumer access and actual use further lead to self-treatment and the unauthorized practice of medicine.

3. MARKETPLACE INTERPOSITION

Marketplace interposition has arisen because concepts such as consumer access, actual use, self-treatment and the unauthorized practice of medicine, are lacking in regulatory debate. Marketplace interposition is where commerce, in this case technological advancement, encourages society to tacitly permit self-treatment and unauthorized practice of medicine through consumer access and actual use.

Interposition is a legal principle whereby a state exercises it sovereign power and disregards the authority of the federal government if the state believes the federal government

[318] iStethoscope activation screen on iPhone (screen capture photograph on file with author).

action is unconstitutional or exceeds the powers granted to the federal government. However, the US Supreme Court does not acknowledge this doctrine.[319]

What is meant here by "Marketplace Interposition" is that it is the commercial marketplace that is effectively rejecting the federal prohibition against self-treatment and rejecting state prohibition of the unauthorized practice of law. Commercial access and widespread adoption of the technologies and mHealth products that bestow on an individual new abilities to provide medical care to one's self and others essentially creates, or interposes, a right of self-treatment and condones lay people engaging in some measure of the practice of medicine. Society is permitting the behavior, in effect, not enforcing the prohibition against self-treatment or prohibiting the unauthorized practice of medicine. This effectively interposes a new right to self-treatment and permission for lay people to practice medicine.

As noted earlier, mobile devices can now make actual diagnoses and increasing availability to consumers creates the dilemma that many may use mobile medical apps for self-diagnosis and treatment.[320] As also noted, at least according to one survey 35% of US adults have used online sources to determine a medical condition they or someone else had and 38% of these individuals believed they could treat the disease or condition without a physician.[321] No doubt they did, or at least tried.

Americans had a right to self-treatment until the government took it away in 1914.[322] Up until then, citizens could purchase any medication they wanted from any pharmacy without a

[319] *See*, Cooper v. Aaron, 358 U.S. 1 (U.S. 1958). *See also, Interposition Doctrine Law & Legal Definition*, US Legal, Inc., US LEGAL.COM (2010-2013) available at http://definitions.uslegal.com/i/interposition-doctrine/ (last visited July 28, 2013).
[320] Krouse, *supra* note 18, at 738.
[321] Fox, *supra* note 26, at 2.
[322] Sheldon Richman, *The Right to Self-Treatment*, THE FUTURE OF FREEDOM FOUNDATION (Jan. 1, 1995), available at http://fff.org/explore-freedom/article/selftreatment/ (last visited July 28, 2013); *see also* Kevin A. Carson, *The Right to Self-Treatment*, MUTUALIST BLOG: FREE MARKET ANTI-CAPITALISM (May 11, 2005), available at http://fff.org/explore-freedom/article/selftreatment/ http://mutualist.blogspot.com/2005/05/right-to-self-treatment.html (last visited July 28, 2013); Dave Pollard, *The Wisdom of Patients (and the Right to Self-Treatment)*,

prescription or oversight from a physician.[323] However, society apparently believed the masses needed protection against themselves, and thus US citizens lost the right to self-treatment almost 100 years ago.[324]

Americans have a right to autonomy, whereby one may refuse medical treatment.[325] Denizens also have a right to self-determination, whereby patients may direct the treatment they wish to receive on their own accord or through a proxy via power of attorney.[326] Neither of these rights, however, allow a person to provide medical care to one's self. At present, there is no right to self-treatment in the United States. Although government has not intentionally restored the right to self-treatment, technology seems to be putting it back in the commoners' hands.

MHealth products might also be used on another person, for example, one using his/her smartphone app to diagnose or treat a spouse or child. Just as one is prohibited from self-treatment, one may not treat another without risking the unauthorized practice of medicine. Unauthorized practice of medicine happens when one provides medical advice or renders treatment without a professional license.[327] The unauthorized practice of medicine is a crime in every state.[328] When one provides care to one's self or another, a deeper question then becomes: what is the "practice of medicine?"[329] While definitions vary state to state, a person typically engages in the practice medicine when she or he attempts to diagnose or treat an illness or injury,

---

HOW TO SAVE THE WORLD (May 6, 2005), available at http://howtosavetheworld.ca/2005/05/06/the-wisdom-of-patients-and-the-right-to-self-treatment/ (last visited July 28, 2013).

[323] Richman, *supra* note 322.

[324] *Id*.

[325] *See* Cruzan v. Director, Missouri Department of Health, 110 S. Ct. 2841, 111 L.Ed. 2d 224 (1990). The United States Supreme Court determined a competent person has a constitutionally protected liberty interest to refuse medical treatment. The Court concluded that the U.S. Constitution grants a competent person a constitutionally protected right to refuse lifesaving medical treatment including nutrition and hydration.

[326] *Right to Autonomy and Self-Determination*, US Legal, Inc., US LEGAL.COM (2010-2013), available at http://healthcare.uslegal.com/patient-rights/right-to-autonomy-and-self-determination/ (last visited July 28, 2013).

[327] *What is the Unauthorized Practice of Medicine?*, FINDLAW (2013) available at http://healthcare.findlaw.com/patient-rights/what-is-the-unauthorized-practice-of-medicine.html (last visited July 28, 2013).

[328] *Id*.

[329] *Id*.

prescribes medication, conducts surgery, or declares that she or he is a doctor.[330] Now that mobile medical apps can actually make diagnoses, an even more vexing question is: who is practicing medicine? Is it the smartphone owner, the manufacturer who created the app, the seller or the device itself? The point here is not to identify culprits guilty of the unauthorized practice of medicine. These questions are posed to stimulate cogitation and discourse.

Health education has been on the rise ever since the advent of managed care. Constant pressure to decrease healthcare costs has engendered extensive conversation in medical and legal circles regarding self-care and the need for lay people to become more active participants in their medical care.[331] Society seems to want consumers to provide some measure of healthcare to themselves, and likely to others, in the case of a spouse, child or other dependent. Government and regulation are slowly warming up to this paradigm. Even the FDA acknowledges mobile devices are staples of modern convenience.[332] Technological advancements have allowed commerce to surpass government, putting healthcare capabilities into commoners' hands. Society seems to embrace it. This is marketplace interposition.

Marketplace interposition is real and cannot be ignored if practical discussions are to be had regarding the appropriate level of regulation in mHealth. Society wants access and demands mobility.[333] Some commentators argue for less regulation for certain diagnostic apps that presuppose a person is receiving medical attention.[334] The reality is that the risk of injury is higher for lay people operating without physician oversight. Some measure of regulation is necessary.

---

[330] *Id*.
[331] *See generally*, *How Self-Care Can Help Firms Cut Health Bills*, 94-10 COMPENSATION AND BENEFITS FOR L. OFF. 2 (Oct. 1994); Michael H. Cohen, *A Fixed Star in Health Care Reform: The Emerging Paradigm of Holistic Healing*, 27 ARIZ. ST. L.J. 79 (Spring 1995); David I. Shalowitz and Michael S. Wolf, *Shared Decision-Making and the Lower Literate Patient*, 32 J.L. MED. & ETHICS 759 (Winter 2004).
[332] Pollard and Cormier, *supra*, note 153 at 18.
[333] *See CTIA and Harris Interactive*, PRWEB, *supra*, note 38.
[334] *See* Danzis, *supra* note 10, at 29.

Furthermore, how much healthcare should a lay person be allowed to practice? It will take more than this article to answer questions of this magnitude. As noted earlier, of the mHealth product types reviewed, diagnostic apps pose gray areas. Regulators can improve the landscape if they increase their focus on diagnostic apps and target their discussions on consumer access, actual use, self-treatment and unauthorized practice of medicine. Perhaps when the FDA releases the FDASIA Report the essence of one or more of these concepts will be seen in new proposed regulation to promote innovation. In the meantime, a few practical suggestions are offered here.

D. STREAMLINE THE FRAMEWORK FOR MOBILE MEDICAL APPS

Regulation has its place to ensure safety. A balance is needed not to stifle innovation. The FDA is criticized for having a slow and difficult approval process that weakens the economy by chilling investment and crippling innovation.[335] There appears to be some validity to this argument. With regard to medical devices in general, time to approval has increased, the number of approvals has decreased, and investment in medical device companies dropped 37% from 2007 to 2011.[336]

The solution that clarifies when mobile medical apps become regulated medical devices also needs to be designed to bring about approvals faster and cheaper. Applications are often developed by very small companies, sometimes with only two people.[337] They cannot afford extensive and protracted clinical trials. Similarly, the industry is moving so quickly, as displayed by the rapidly increasing number of mHealth apps and ever-increasing adoption of smartphones, developers, not to mention professional and lay consumers, cannot wait for the plodding FDA regulatory approval process. What also may occur is that developers might sidestep seeking

[335] Andrew Pollack, *Medical Treatment, Out of Reach*, N.Y. TIMES (Feb. 9, 2011), http://www.nytimes.com/2011/02/10/business/10device.html?pagewanted=1&_r=0& pagewanted=all (last visited Apr. 7, 2013).
[336] *Id*.
[337] McAuliffe, *supra* note 223.

approval, whether deliberately or unintentionally, which defeats the purpose of the regulations – to ensure safety.

Thus, in redesigning the approval process, the FDA needs to keep pace with the dynamics of the mHealth industry. The FDA has made some gesture in this direction with the launch of the Medical Device Innovation Initiative in February 2011, purportedly to give priority review to the newest medical technologies and devices. However, this program's "Innovative Pathway" has been criticized as not being significantly different from the current medical device regime and the FDA, itself, admitted this is "not a new regulatory pathway."[338] The FDA suggests approval times might decrease by 50%, but it is an open question whether mobile medical apps will even be eligible for the Innovative Pathway.[339] Thus, again, a more effective approach would be to establish an approval process specifically for mobile medical apps. A few methods proposed here that the FDA could implement to improve the process would be to implement a preliminary review assessment, institute an abbreviated approval process and, at a minimum, reduce the review backlog.

1. PRELIMINARY REVIEW ASSESSMENT

As noted earlier, the FDA indicated it intends to exercise discretion as to whether it will regulate a mobile medical app.[340] Perhaps to avoid the uncertainty that developers face, the FDA could have a pre-clearance process whereby a developer submits design specifications of an mHealth app in development so the FDA may render a preliminary assessment. This review could inform the developer (1) if the product is a medical device, (2) whether the app requires regulation, and (3) what level. Such an approach could eliminate time and effort spent after the

[338] U.S. Food & Drug Admin., Questions and Answers About the Medical Device Innovation Initiative (Feb. 8, 2011), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm242068.htm (last visited Apr. 7, 2013).
[339] Krouse, *supra* note 18, at 758.
[340] Danzis, *supra* note 10, at 27.

fact by manufacturers having to respond to FDA warning letters. Moreover, preliminary assessment would not only provide direction to developers, but might also encourage developers to "ask permission" first, rather than proceed and "beg forgiveness" later.

At present, developers and manufacturers have to assess for themselves what might be required. Many companies engage regulatory affairs specialists with medical device experience to advise them on requirements.[341] If a company has the resources to hire a regulatory specialists, a preliminary review assessment could be conducted in about four hours.[342] Assume for this exercise a going rate of $250 per hour for regulatory medical device specialists.[343] It would then cost about $1,000 for such a review. The peril with this approach is that a regulatory affairs specialist is exercising his or her experience to anticipate what the FDA would require. While this is a common approach, a better solution as proposed here is the FDA to implement a preliminary review assessment, and preferably for less than $1,000. This would give developers a more clear and confident path with the advice coming directly from the FDA. This would likely increase compliance.

2. ABBREVIATED APPROVAL

Another approach is an accelerated approval process. Accelerated approval is a familiar concept to the FDA. The drug industry enjoyed significant advances with the accelerated approval processes implemented under the Hatch-Waxman Act of 1984 for generic drugs.[344] This regulatory regime saved drug companies substantial costs in developing generic drugs, which further translated into lower drug prices for consumers and insurance carriers.[345] The biologics industry hopes to see similar advancement and cost savings with biosimilars under the

[341] Telephone Interview with Anil Bhalani, *supra* note 6.
[342] *Id*.
[343] *Id*.
[344] LAURENCE J. KOTLIKOFF, STIMULATING INNOVATION IN THE BIOLOGICS INDUSTRY: A BALANCED APPROACH TO MARKETING EXCLUSIVITY 10 (Sept. 2008), *available at* http://people.bu.edu/kotlikof/New%20Kotlikoff%20Web%20Page/Kotlikoff_Innovation_in_Biologics21.pdf.
[345] *Id*.

accelerated approval regime promulgated by the Biologics Price Competition and Innovation Act of 2009.[346] This regime was enacted into law with the passage of Obamacare and given effect by the US Supreme Court when it upheld Obamacare on June 28, 2012.[347]

Since the FDA has accelerated approval processes in the drug and biologic arenas, the FDA already has experience implementing expedited review programs. An accelerated approval process might reduce costs, which is especially important considering mobile app developers tend to be very small companies. Equally important, expedited approval might help regulation keep up with innovation.

3. INTERNAL EFFICIENCY

The two previous suggestions are essentially new programs, however, the FDA could improve the process just by addressing its existing efficiency. At present, it takes the FDA 90 days or more to review a 510(k) submission.[348] This may seem like a short period of time if one compares this to review of a patent application at the US Patent and Trademark Office, which may take years.[349] The difference here, however, is that one is typically already practicing the invention, with products on the market as "patent pending," while waiting, and hoping, for a patent to issue. Whereas a medical device the manufacturer is waiting for FDA approval in order to put the product on the market. A skilled regulatory affairs specialist can prepare a 510(k) in about a week.[350] Why, then, does the FDA need 90 days to review it?[351]

Reducing the backlog may take some internal management to reduce unnecessary work, find efficiencies, and coordinate cross-departmental functions to facilitate scheduling and create

---

[346] JUDITH A. JOHNSON, CONG. RESEARCH SERV., RL 34045, FDA REGULATION OF FOLLOW-ON BIOLOGICS 1 (2010).
[347] Nat'l Fed'n of Indep. Bus. v. Sebelius, *supra* note 218
[348] Correspondence with Anil Bhalani, *supra* note 62.
[349] Dennis S. Fernandez & James T. Huie, Strategic Balancing of Patent and FDA Approval Processes to Maximize Market Exclusivity, 7 ASIA PAC. BIOTECH NEWS 998, 998 (2003), available at http://www.iploft.com/PTO-FDA.pdf (last visited Aug. 3, 2013).
[350] Correspondence with Anil Bhalani, *supra* note 62.
[351] *Id*.

harmony.[352] This is a practical, realistic and worthwhile effort. If regulatory review could be reduced to 30 or even 60 days, it would really inspire industry participants and improve the perception of the FDA.[353] It would also likely increases compliance.

While regulation of medical devices is necessary to ensure safety, the inevitable increase in mHealth and consumer access requires a more defined, targeted and streamlined regulatory scheme for mobile devices in order to keep pace with this quickly evolving technology.

VI. CONCLUSION

This article explored the current and evolving FDA regulatory landscape of the mHealth business. Particular attention was given to the emerging but unclear stance of the FDA with regard to the applicability of the current medical device regulatory regime as it applies to smartphones, software applications and adapters, as well as potential new FDA medical device regulation that may be forthcoming in light of the FDASIA.

This article reviewed the overlapping layers of analyses in the current regulatory regime, starting with the threshold question of whether a smartphone, application or adapter is a medical device at all. It is understandable now that determining whether a product is a medical device is key because other inquires come into play, such as what level of FDA regulation is required, whether compliance with HIPAA is necessary for protection of patient information, and whether the product might be taxed as a medical device.

With regard to FDA regulation, when an object is determined to be a medical device, one must analyze the device against (1) the FDA classification scheme, (2) what control measures are pertinent, (3) the level of concern of any relevant software, and (4) the FDA's guidance on mobile medical apps. Some of these inquiries are overlapping, leading to unnecessary duplication.

---

[352] *Id*.
[353] *Id*.

Another important discussion here was the uncertainly encountered with the FDA's broad, draft, but not final, guidance and the FDA's overture to exercise enforcement discretion. There is a need for a more defined, targeted and streamlined regulatory scheme.

The FDA could do a better job defining when enforcement discretion will be exercised. In doing so, market participants could better predict when compliance is required.

This article recommended a more targeted focus on the concepts of consumer access actual use, self-treatment and the unauthorized practice of medicine. Current principles such as "intended use" do not properly address the underlying regulatory purpose of ensuring safety. Consumers are availing themselves of healthcare tools, including mHealth products, to provide medical treatment to themselves and others. Legislators need to consciously and critically examine the intersection of the unauthorized practice of medicine with the growing circumstance that society encourages consumers to provide healthcare to themselves or others.

Discussions regarding FDA regulation must unavoidably emphasize the device itself, but a more targeted examination needs to acknowledge the effects of consumer access and actual use. Intended use may not make sense with regard to mHealth products because they may be used in ways that the manufacturer may not have intended as provided in the product claims.

The presence of consumer access, actual use, self-treatment and the unauthorized practice of medicine along with the lack of these concepts in public discussion have wrought the phenomena referred to here as marketplace interposition – when commerce encourages society to tacitly permit self-treatment and unauthorized practice of medicine through consumer access and actual use. Marketplace interposition punctuates the need for regulators to reexamine their efforts under a different lens. It is recommend that the legislative calculus consider a more targeted focus on the concepts consumer access, actual use, self-treatment, and the unauthorized practice of medicine. Each bears on patient safety. These cannot be ignored if practical

discussions are to be had regarding the appropriate level of regulation. Safety cannot be ensured by looking at just the device. Targeting the right concepts will yield better solutions.

This article also recommended streamlining the regulations for simplicity and consistency. The regulatory landscape could be streamlined if the medical device classification system governed the regulatory scrutiny without other duplicative and overlapping considerations, such as exceptions to classification as they relate to control requirements and levels of concern for software. Other streamlining measures proposed here were a preliminary review process to allow developers to receive a perspective from the FDA before a product is developed or put on the market and an accelerated approval process to move regulatory review along quicker. Another streamlining measure is simply to find internal efficiency at the FDA in order to reduce the backlog on medical device review. Further FDA guidance is expected as a result of the charge from Congress under the FDASIA for the FDA to implement measures to promote innovation while maintaining safety, however, it is unknown at present whether such new measures will improve mHealth regulation or exacerbate the existing burden.

While regulation of medical devices is necessary to ensure safety, the inevitable increase in mHealth and consumer access requires a more defined, targeted and streamlined regulatory scheme for mobile devices in order to keep pace with this quickly evolving technology. One must proceed cautiously in light of the unclear and evolving regulatory terrain. Undoubtedly, more discussion is forthcoming.