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# THE MHEALTH CONUNDRUM: SMARTPHONES & MOBILE MEDICAL APPS—HOW MUCH FDA MEDICAL DEVICE REGULATION IS REQUIRED?[*]

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*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") for mobile medical applications. Commentators have remarked that the FDA's guidance is complex and unclear. 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. This Article explores the current FDA regulatory scheme for mobile medical applications and adapters for mobile devices designed to provide mobile healthcare, or "mHealth," and provides recommendations on how to improve the FDA regulatory environment. 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.*

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**TABLE OF CONTENTS**

## 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 transmission to and from these devices has generated a demand for convenience from healthcare providers and consumers.[1] This heightened demand has garnered the attention of device and software developers wishing to capitalize on the growing mobile health market.[2] Greater activity in "the use of mobile telecommunications in healthcare," or "mHealth,"[3] has drawn the attention of regulators, which has spawned debate over Food and Drug Administration ("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 FDA with regard to smartphones, software applications, and adapters. The current regulatory regime consists of several overlapping analyses that device developers and device manufacturers need to conduct with regard to their products. A threshold question for these industry participants is whether a smartphone, application, or adapter is a medical device.[4] Determining whether a product is a medical

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[1] Tatiana Melnik, *There's an App for That! The FDA Offers a Framework for Regulation Mobile Health*, J. HEALTH CARE COMPLIANCE, Sept.–Oct. 2011, at 55.

[2] Patricia Mechael & 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.

[3] Deborah Runkle, *The mHealth Revolution*, SCITECH LAW (Winter/Spring) http://www.americanbar.org/content/dam/aba/publications/gp_solo_magazine/july_august/gpsolo_issue_2013_july_august_30_4.authcheckdam.pdf.

[4] Vernessa T. Pollard & Chandra Branham, *FDA Medical Device Requirements: A Legal Framework for Regulating Health Information Technology, Software, and Mobile Apps*, THOMSON REUTERS/ASPATORE, 2011 WL 5833341, 2 (Nov. 2011).

device is key because if it is not, then medical device regulations are not applicable.

With regard to FDA regulation, if the object at issue is a medical device, the developer or manufacturer must evaluate various layers of analysis including any approval from the FDA that may be required before lawfully putting the device on the market. The first inquiry considers under which one of the three FDA classifications the object belongs—Class I, Class II, or Class III—based on the potential health risks to the public.[5] These classifications designate the level of control needed in order to provide the FDA with reasonable assurance of the product's safety and effectiveness.[6] The regulatory control requirements a medical device must meet are typically determined by its classification. Often, however, the control requirements placed on a medical device do not completely align with the classification scheme.[7] Hence, developers and manufacturers must also consider whether FDA control measures are pertinent.[8] 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. Further inquiry arises when software and applications are involved. Apart from its classification, if a device contains software, developers and manufacturers must consider which FDA "level of concern" the software presents to users.[9] Then, if an application is for a medical device or causes a general device to become a medical device, the software must be evaluated against the FDA's recent guidance on

[5] *Id.* at 3.

[6] *Regulatory Controls (Medical Devices)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (last updated Apr. 11, 2013).

[7] Telephone Interview with Anil Bhalani, Principal RA Consultant, Extomed, LLC (June 28, 2013).

[8] *Id.*

[9] *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, U.S. FOOD & DRUG ADMIN. (May 11, 2005), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm.

mobile medical applications.[10] These multiple and overlapping inquiries present burdensome complexity for developers and device manufacturers.

The FDA tends to provide broad guidance to medical device regulation.[11] Because guidance is so broad, commentators indicate that the regulatory terrain is uncertain with regard to mobile medical application developers.[12] For example, the FDA has stated that it will exercise discretion as to whether it will enforce certain regulations when regulating mobile medical applications that may present a low risk, yet it fails to explain when it will exercise such discretion.[13] 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.

Complicating the inquiry into what regulations are pertinent for a particular product 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 had with traditional

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[10] *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD & DRUG ADMIN. et al. 7–8 (Sept. 25, 2013), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulation and Guidance/GuidanceDocuments/UCM263366.pdf (initially issued in draft form on July 21, 2011 entitled "Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications" [hereinafter "FDA Draft Guidance for Medical Apps"], which was more recently revised and issued in final form on September 25, 2013) [hereinafter "FDA Final Guidance for Medical Apps"]; *Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN. et al., (July 21, 2011), http://www.genomicslawreport.com/wp-content/uploads/2013/03/FDA-mHealth-Draft-Guidance.pdf.

[11] Telephone Interview with Anil Bhalani, *supra* note 7.

[12] *See generally* Bradley Merrill Thompson et al., *A Call for Clarity: Open Questions on the Scope of FDA Regulation of mHealth*, MHEALTH REG. COAL. (Dec. 22, 2010), *available at* http://mhealthregulatorycoalition.org/wp-content/uploads/2010/12/mrcwhitefinal122210.pdf (describing how certain software with specifically defined features has been regulated as a medical device, but that current FDA guidance has "not finalized several rules that would establish basic guidelines for the regulation of software" which then leads to uncertainty regarding how some software might be regulated).

[13] Scott D. Danzis & Christopher Pruitt, *Rethinking the FDA's Regulation of Mobile Medical Apps*, SCITECH LAW, Winter/Spring 2013, at 26, 27.

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? Consumer access instigates 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 article device. At present, the FDA looks at how a manufacturer intends its product to be used.[14] It is questionable whether the FDA principle of "intended use" still makes sense when applied to a product that is deployed for an intended purpose of the manufacturer as demonstrated in its product claims, but is utilized in a way that is possibly unintended or unexpected by the manufacturer.

The current regulatory landscape for medical devices, with its focus on intended use rather than actual use, seems to provide a loophole for mobile devices because there is no gatekeeping through prescriptions or pharmacies for mobile medical applications.[15] Moreover, public discussion does not demonstrate concern over off-label use with mHealth products, as is prevalent in the pharmaceutical industry.[16] 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

[14] Pollard & Branham, *supra* note 4, at 3.

[15] Telephone Interview with Anil Bhalani, *supra* note 7.

[16] George Lasezkay, Professor of Law, Pharmaceutical Law & Policy Class Lecture at the University of San Diego School of Law (Feb. 7, 2013) (lecturer's notes on file with author).

into a phenomenon referred to here as "marketplace interposition." Marketplace interposition occurs 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 recommends a more targeted focus on consumer safety, which is the central purpose behind all FDA regulation. The concepts behind marketplace interposition all bear on patient safety. These cannot be ignored if practical discussions are to be had regarding the appropriate level of regulation. Simply looking at the device cannot ensure safety. Targeting the right concepts pertaining to how a device is used will yield better solutions.

In light of the various overlapping inquiries required when evaluating a product under medical device regulation, this Article recommends streamlining the regulations for simplicity and consistency.

Congress also recognizes the need to improve the regulatory landscape.[17] Congress recently charged the FDA, under the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA"), with the task of implementing measures that will promote innovation while maintaining safety.[18]

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 commonplace in today's society, mobile telephones capable of viewing websites and data through

[17] *See* Food and Drug Administration Safety and Innovation Act, 112 Pub. L. No. 144, 126 Stat. 993 (2012).

[18] *Id.* § 618(a).

various cellular networks, so called "smartphones," only began to emerge in 1997 when Stockholm Smartphone released the Sony Ericsson GS88.[19] Then Research In Motion came along with BlackBerry devices in 1999, which gained wide popularity shortly after the turn of the century.[20] Soon thereafter, Apple, Inc. entered the mobile phone business when it launched the first iPhone on June 29, 2007.[21] That same month, Apple announced that third parties could develop applications to run on the iPhone.[22] This announcement opened the door for the mobile applications market,[23] and it has been flourishing ever since. As of January 2013, there were over 775,000 iPhone applications,[24] about the same for Android phones (estimated to have reached one million by June, 2013),[25] and about 100,000 applications for BlackBerries.[26]

In addition to the ubiquity of mobile applications is the pervasiveness of mobile phones. As of September, 2013, 91% of adults in the United States owned a mobile phone and 55% owned a smartphone.[27] Moreover, also as of September, 2013, 74% of

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[19] *History*, STOCKHOLM SMARTPHONE, http://www.stockholmsmartphone.org/history/ (last visited Mar. 30, 2013).

[20] *The History of the Blackberry*, BBGEEKS (Apr. 15, 2008), http://archive.is/3Cln (accessed by searching for "BBGeeks" in the Internet Archive Index).

[21] *iPhone 2G*, IPHONE HISTORY, http://www.iphonehistory.com/iphone-2g/ (last visited Mar. 30, 2013).

[22] Press Release, Apple Inc., iPhone to Support Third-Party Web 2.0 Applications (June 11, 2007), *available at* http://www.apple.com/pr/library/2007/06/11iPhone-to-Support-Third-Party-Web-2-0-Applications.html.

[23] 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).

[24] Sam Costello, *How Many Apps Are in the iPhone App Store*, ABOUT.COM, http://ipod.about.com/od/iphonesoftwareterms/qt/apps-in-app-store.htm (last visited Mar. 31, 2013).

[25] Dan Rowinski, *Google Play Will Beat Apple App Store to 1,000,000 Apps*, READWRITE (Jan. 8, 2013), http://readwrite.com/2013/01/08/google-play-to-hit-1-million-apps-before-apple-app-store.

[26] 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.

[27] Joanna Brenner, *Pew Internet: Mobile*, PEW INTERNET (Jan. 31, 2013), http://pewinternet.org/Commentary/2012/February/Pew-Internet-Mobile.aspx.

U.S. adults had either a tablet or "e-reader."[28] The rest of the world revealed a similar profile. The International Telecommunications Union of the United Nations reported that when the global population reached 7 billion people in 2011, there were approximately 6 billion mobile phone subscriptions worldwide.[29]

Mobile applications have noticeably migrated into the healthcare industry.[30] 81% of U.S. adults use the Internet and of these, 72% reported to have searched online for health information in 2012, thus, approximately 59% of all U.S. adults access health information online.[31] Furthermore, 31% of mobile phone owners are reported to use their phones for health or medical information.[32] Manhattan Research determined that 64% of physicians used smartphones in their daily lives, personally and professionally, by the end of 2011, and it is estimated that as of 2013, 81% of physicians use smartphones.[33] This research indicates that consumers want healthcare information, mobile phones are becoming pervasive, and physicians are also gravitating to smartphones, which have much greater capabilities than traditional mobile phones. The pervasiveness of mobile devices has brought about the mobile health industry.

The proliferation of mobile phones has caught the attention of global health experts, developers, innovators, and entrepreneurs.[34] Collectively, these players have formed a movement called "mobile health," or "mHealth," to capitalize on the potential mobile devices have to deliver healthcare.[35] Mobile health applications are integral to mHealth because they facilitate the provision of healthcare compared to standard and common hand-held

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[28] *Id.*

[29] Mechael & Struble, *supra* note 2.

[30] Krouse, *supra* note 23, at 738.

[31] SUSANNAH FOX & MAEVE DUGGAN, HEALTH ONLINE 2013 (Jan. 15, 2013), *available at* http://pewinternet.org/~/media//Files/Reports/PIP_HealthOnline. pdf.

[32] Susannah Fox, *Pew Internet: Health*, PEW INTERNET (Dec. 16, 2013), http://www.pewinternet.org/Commentary/2011/November/Pew-Internet-Health.aspx.

[33] MOBIHEALTHNEWS, WIRELESS HEALTH: STATE OF THE INDUSTRY 2009 YEAR END REPORT 5 (2009), *available at* http://mobihealthnews.com/wp-content/Reports/2009StateoftheIndustry.pdf.

[34] Mechael & Struble, *supra* note 2.

[35] *Id.*

machines.[36] The advent of mobile health applications has led to interesting phenomena. Although healthcare providers have been using various software packages for many years to assist in their medical determinations, mobile devices can now make actual diagnoses.[37] The mHealth industry also provides software applications for healthcare consumers to use.[38] The increasing availability to consumers creates the problem that many may use these applications for self-diagnosis and treatment.[39] In fact, 35% of U.S. adults report having tried, at least once, to determine online, whether by computer or mobile phone, what medical condition they or someone else was experiencing.[40] 38% of these adults reported that they believed it was something they could remedy without professional medical attention.[41]

Access to mHealth may be an innovative way to provide healthcare in developing countries where healthcare is sorely lacking, but in highly regulated countries like the United States,[42] unfettered access to healthcare tools raises the concern of when this crosses the line into practicing medicine and, thus, regulation of the mHealth tool is appropriate. CTIA-The Wireless Association ("CTIA"),[43] an "international association for the wireless telecommunications industry," and Harris Interactive, a global custom marketing research firm,[44] conducted a recent survey that revealed that 78% of U.S. citizens are interested in mobile health solutions.[45] While about 40% of the respondents indicated that

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[36] *See* Krouse, *supra* note 23, at 738.
[37] *See id.*
[38] *Id.* at 737.
[39] *Id.*
[40] FOX & DUGGAN, *supra* note 31, at 2.
[41] *Id.*
[42] Krouse, *supra* note 231, at 738.
[43] The letters C-T-I-A originally stood for "Cellular Telecommunications Industry Association," and, between 2000 and 2004, they stood for "Cellular Telecommunications and Internet Association" but now these letters are simply just part of the name of the organization, "CTIA."
[44] *CTIA and Harris Interactive Release New National Study; Reveals How Teens Are Shaping & Reshaping Their Wireless World*, PRWEB (Sept. 12, 2008), http://www.prweb.com/releases/CTIA-teen-cell-phone/92008/prweb1322754.htm.
[45] MOBIHEALTHNEWS, *supra* note 33, at 2.

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.[46] If mHealth supplants professional medical attention, the need for regulation is obvious.[47] Patient safety is at risk.[48] Therefore, it is essential that a device work properly and be used properly 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.[49] For example, Glen Stream, the president of the American Academy of Family Physicians, acknowledges and endorses the "explosion" of mobile medical apps.[50] He purports to be an "iPhone guy," utilizing twenty or so medical or health apps, stating, "People want to be empowered to take care of their health."[51] 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."[52]

A recent report revealed that 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.[53] The increase in spending on healthcare is also remarkable. The United States spent $256 billion

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[46] *Id.* at 2–3.
[47] Krouse, *supra* note 23, at 738.
[48] *Id.*
[49] *Id.* at 739.
[50] Laura Ruane, *Smartphone apps now playing doctor*, USA TODAY (Aug. 8, 2012), http://usatoday30.usatoday.com/tech/news/story/2012-08-05/smartphones-health/56764686/1.
[51] *Id.*
[52] *Id.*
[53] 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.

on healthcare in 1980.[54] By 1990 the dollars spent reached $714 billion.[55] By 2010 this number almost reached $2.6 trillion.[56]

Access to mHealth presents a considerable opportunity for savings in the healthcare industry. In 2009, Verizon Wireless estimated mobile broadband solutions saved nearly $6.9 billion in healthcare costs through improved productivity.[57] Further, increased productivity is expected to save $27.2 billion by 2016.[58] 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%.[59]

With such potential savings, presumably from several sources like increased productivity of healthcare providers, reduced time and effort for both the patient and the provider potentially translating into better health and fewer office visits and procedures for patients, it is understandable why there is so much attention on mHealth. The regulatory environment, as will be seen, is not properly equipped 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 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's current regulatory requirements for medical devices. mHealth products are often comprised of software and

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[54] 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).
[55] *Id.*
[56] *Id.*
[57] MobiHealthNews, *supra* note 33, at 5.
[58] *Id.*
[59] *Id.*

sometimes include sensors or attachments for a mobile device. The products, 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.

A product that meets the definition of a medical device falls within the purview of the FDA, and is then subject to regulation before and after it is marketed.[60] 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 . . . ."[61] If the device in question is not a medical device, then no FDA regulation applies. If it is a medical device, then one must evaluate several layers of regulation to determine whether certain regulations apply and whether the developer or manufacturer meets those regulations in offering the product to the public.

### A. *Intended Use*

A significant threshold inquiry for determining if an article is a medical device is whether the product in question is intended to diagnose or treat a disease or condition.[62] "Intended use" is a critical element in determining FDA regulation.[63] If an article, like software, is *intended* to be used for medical purposes, then the FDA considers it a medical device.[64] On the other hand, an article

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[60] Krouse, *supra* note 23, at 745.

[61] 21 U.S.C. § 321(h) (2012); *see also Is The Product a Medical Device?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm (last updated Feb. 8, 2013) (setting forth the basic definition of a medical device and distinguishing it from other FDA regulated products such as drugs).

[62] Danzis & Pruitt, *supra* note 13, at 27–28.

[63] *Id*.

[64] *Id*.

is not considered a medical device if it is intended to promote or encourage general health or wellness;[65] for example, an application for diet or exercise information.[66]

Thus, the initial question is whether the mHealth product is intended for general health or wellness or whether it is intended to diagnose or treat a disease or condition.[67] The distinction is not always black and white. Along the spectrum, general health and wellness may begin to bleed 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. At what point does managing weight rise to the level of treating 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.[68] A company presents this in its submission for approval to the FDA.[69] When the FDA approves the medical device, it makes public the indication of use.[70] Consider, for example, cough medicine. The indication of use is "coughing, sore throat . . . etc."[71] These are the *indications* for which the product is approved to treat as reflected in the submission documents and subsequent FDA approval.[72] The *intended* use is "to treat an infection."[73]

The FDA derives "intent" from the product's promotional claims.[74] Promotional claims revealing the intended use may be

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[65] *Id*.
[66] Krouse, *supra* note 23, at 760.
[67] Pollard & Branham, *supra* note 4, at 3.
[68] Interview with Linda Moore, Director of Operations and Regulatory Affairs, StatRad, LLC, in Poway, Cal. (Aug. 5, 2013) (notes on file with author).
[69] Correspondence from Anil Bhalani, Principal RA Consultant, Extomed, LLC (Aug. 2–7, 2013) (on file with author) [hereinafter Correspondence with Anil Bhalani].
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] Danzis & Pruitt, *supra* note 13, at 27.

found on a product label, in "advertising materials, or oral or written statements by manufacturers or their representatives."[75] So, manufacturers generate the intended use for their products based on how they promote the product to the public. If the intent is to promote health, the appliance is not a medical device.[76] If the intent is for medical use, then the appliance is a medical device. But where does the line for health purposes end and the line for medical purposes begin? Although intended use is still a primary focus of FDA regulation, technology may have already evolved to a point where a different paradigm is warranted. At present, the principle of intended use drives much of the subsequent regulatory inquiry. If the intended use is a medical purpose, the article constitutes a medical device, which then requires the developer to evaluate what class of injury might arise from that use.

B. *Medical Device 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.[77] Medical devices are assigned a classification based on the level of control needed in order to provide the FDA with reasonable assurance of the product's safety and effectiveness.[78] If a device represents a very low risk of injury, it is considered Class I and does not require any premarket approval.[79] While most Class I devices are exempt from premarket notification requirements and regulations for good manufacturing practices,[80] 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

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[75] FDA Final Medical App Guidance, *supra* note 10.

[76] Danzis & Pruitt, *supra* note 13, at 27.

[77] *Id*.

[78] *Medical Devices, Regulatory Controls, Introduction*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (last updated Apr. 11, 2013).

[79] Danzis & Pruitt, *supra* note 13, at 27.

[80] *General and Special Controls*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (last updated Apr. 11, 2013).

tracking the device's activity.[81] Bandages, examination gloves, and hand-held surgical instruments are examples of Class I devices.[82]

Devices that present an intermediate level of risk of injury to people are considered Class II.[83] The FDA's perspective is that for Class II devices "general controls alone are insufficient to . . . assur[e] . . . safety and effectiveness."[84] 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.[85]

New medical devices are typically subject to a "Premarket Notification" under Section 510(k) of the FDCA.[86] The FDA requires a 510(k) Premarket Notification when one is "[i]ntroducing a device into commercial distribution (marketing) for the first time."[87] "Most Class I devices and some Class II devices are exempt from the 510(k) Premarket Notification" requirement.[88] The premarket notification is sometimes colloquially referred to simply as "510(k)."

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 equivalent" to another Class II device already on the market.[89] An appliance that is already legally on the market is called a "predicate device."[90]

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[81] Krouse, *supra* note 23, at 746–47; *see also General and Special Controls*, *supra* note 80.

[82] Krouse, *supra* note 23, at 746.

[83] Danzis & Pruitt, *supra* note 13, at 27.

[84] *General and Special Controls*, *supra* note 80.

[85] *Id*.

[86] Danzis & Pruitt, *supra* note 13, at 27.

[87] *Premarket Notification (510k)*, *When a 510(k) is Required*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationand Guidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm#when (last updated Jan. 3, 2014).

[88] *Premarket Notification (510k)—21 CFR Part 807 Subpart E*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm#510k (last updated Mar. 5, 2013).

[89] Danzis & Pruitt, *supra* note 13, at 27.

[90] *Medical Devices, How to Find a Predicate Device, Introduction*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/

Establishing substantial similarity provides the FDA reasonable assurance that the device is safe and effective.[91] The FDA reviews the submission to determine whether the documentation demonstrates that the proposed medical device is substantially similar to another already marketed device.[92] If the FDA agrees, it provides a letter of substantial equivalence to the manufacturer authorizing the commercial distribution of the product.[93] Powered wheelchairs, infusion pumps, and surgical drapes are examples of Class II devices.[94]

High-risk devices are Class III.[95] These are devices that either sustain human life or present an unreasonable risk of injury to humans.[96] Because of the risks involved, the FDA does not believe that general or special controls are sufficient to assure safety and effectiveness.[97] The FDA requires general controls and premarket approval ("PMA") for Class III devices.[98] 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.[99] In such cases, a manufacturer is generally required to perform complex, extensive, and expensive clinical trials[100] to produce scientific data that demonstrates the device is safe and effective for its proposed use.[101] The company must submit the results in a PMA application to the FDA to review

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HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm (last updated Dec. 20, 2013).

[91] *510(k) Clearances Overview*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm (last updated Jan. 17, 2014).

[92] *Premarket Notification (510k)—21 CFR Part 807 Subpart E*, *supra* note 88.

[93] *Id.*

[94] Krouse, *supra* note 23, at 747.

[95] *Id*.

[96] *General and Special Controls*, *supra* note 80.

[97] *Id*.

[98] *Id*.

[99] *Premarket Approval (PMA)—21 CFR Part 814*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm#510k (last updated Mar. 5, 2013).

[100] Danzis & Pruitt, *supra* note 13, at 27.

[101] *General and Special Controls*, *supra* note 80.

and approve before the company may commercialize the product.[102] Pacemakers, artificial heart valves, and breast implants are examples of Class III devices.[103]

C. *Quality System Regulation*

Regardless of classification, every medical device manufacturer is required to comply with the FDA's Quality System Regulation ("QSR").[104] The QSR specifies the special controls and performance standards required.[105] The purpose of the QSR is to maintain a certain level of quality and consistency in the manufacturing process so that products meet FDA specifications[106] in order to assure the safety and effectiveness of finished products.[107]

The QSR describes what is required, but it does not describe how to go about meeting those requirements. This is another example of unclear medical device regulation. 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 QSR.[108] In

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[102] Danzis & Pruitt, *supra* note 13, at 27.

[103] *See Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Non-Significant Risk Medical Device Studies*, U.S. FOOD & DRUG ADMIN., *available at* www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf.18.1.

[104] Interview with Linda Moore, *supra* note 68; Food and Drugs, Quality System Regulation, 21 C.F.R. § 820, *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1 (last updated June 1, 2013).

[105] Correspondence with Anil Bhalani, *supra* note 69. The FDA quality systems for regulated products are also called current good manufacturing practices ("cGMPs"). *See Medical Devices, Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/ (last visited Apr. 28, 2011).

[106] *See Medical Devices, Quality Systems (QS) Regulation/Medical Device Good Manufacturing Practices*, *supra* note 105.

[107] *See Introduction to Regulation of Medical Devices: Quality Systems Regulation, and Good Manufacturing Practice*, STAN. BIODESIGN, *available at* http://www.stanford.edu/group/biodesign/regulatory/materials/quality_slides.pdf (last visited Aug. 10, 2013).

[108] *See* Correspondence with Anil Bhalani, *supra* note 69.

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

D. *Performance Standards*

To satisfy special controls, manufacturers are required to adhere to certain performance standards.[109] Similar to the QSR, the FDA's guidance on performance standards provides little direction. First, the guidelines on performance standards are not mandatory, but a company must have internal procedures in place and related documentation that are sufficient to demonstrate safety and effectiveness if the FDA were to audit or investigate the company or the product.[110] Performance standards give the FDA an indication of the quality and consistency of the manufactured item. A company may develop its own standards that it believes sufficiently evidence that the manufacturing process produces a safe and effective product.[111]

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.[112] The FDA, however, does not mandate ISO standards.[113] Nonetheless, the FDA has come to recognize as acceptable some ISO standards and some standards from other organizations, such as the International Electrotechnical Commission, the Association for the Advancement of Medical Instrumentation, Underwriters Laboratories, and the Canadian Standards Association.[114] As

[109] *See id.*
[110] *See id.*
[111] *See id.*
[112] *Standards: What is a standard?*, ISO, *available at* http://www.iso.org/iso/home/standards.htm (last visited Aug. 3, 2013).
[113] *See* Correspondence with Anil Bhalani, *supra* note 69.
[114] *See id.*

resources for manufacturers, the FDA posts on its website a number of FDA recognized standards.[115]

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."[116] If no recognized standard is implemented, the company will have to justify the criteria it used before the FDA and hope that the FDA accepts the internally crafted standards.[117] 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,[118] the FDA considers software to be a device if it is intended to diagnose or treat a disease or condition.[119] The FDA addressed software products in a draft policy document in 1989.[120] In it, the FDA expressed its perception that "computer products . . . are intended to involve competent human intervention before any impact on human health occurs" and that a computer program poses less risk to patients because a medical provider can use clinical judgment to evaluate and interpret the computer system's output.[121] The FDA, however, withdrew this draft policy in 2005.[122] In 2011, the FDA stated it

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[115] *Recognized Consensus Standards*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?id=27652 (last updated Aug. 5, 2013).

[116] *See* Correspondence with Anil Bhalani, *supra* note 69.

[117] *See id.* Other countries have similar standards requirements and have similarly adopted certain standards as adequate to demonstrate safety and effectiveness. *Id.*

[118] *See* 21 U.S.C. § 321(h) (Supp. 2010).

[119] Danzis & Pruitt, *supra* note 13, at 27.

[120] *See id*. The document was entitled "FDA Policy for the Regulation of Computer Products 11/13/89 (Draft)." *Id.*

[121] *See id*.; *see also* FDA Policy for the Regulation of Computer Products 11/13/89 (Draft) 3.

[122] *Id.*

could not adopt a single software or computer policy to address every kind of software or computer driven medical device.[123]

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").[124] According to the FDA, the types of software being regulated are "software components, parts, or accessories, or are composed solely of software."[125] Even software alone may be a "software device."[126] Furthermore, the FDA indicates the guidance pertains "to software devices regardless of the means by which the software is delivered to the end user[.]"[127] Therefore, this also applies to mobile medical applications.[128]

Similar to, but separate from, the three-class classification system for medical devices, the FDA requires developers to consider a three tiered "level of concern" over software from a risk standpoint: major, moderate, and minor.[129] "Major level of concern" is where failure or a latent flaw in the software "could directly result in death or serious injury to the patient or operator."[130] "Moderate level concern" is when minor injury to the patient or operator could occur.[131] "Minor concern" is one in which software failure is unlikely to cause injury.[132] 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

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[123] Medical Device Data Systems, 76 Fed. Reg. 8637, 8638 (Feb. 15, 2011).

[124] *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, U.S. FOOD & DRUG ADMIN. (May 11, 2005), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm. The FDA updated this guidance in 2011.

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] Krouse, *supra* note 3, at 749.

[129] *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, *supra* note 124, at 5.

[130] *Id.*

[131] *Id.*

[132] *Id.*

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.

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.[133] For example, a person using a weight scale for wellness purposes may not experience harm if the scale displays an incorrect weight.[134] 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.[135]

There is no formally declared "final" policy.[136] The Software Device Guidance is still only in "proposed" form.[137] Despite this proposed state, the industry follows this as is if it were a formal regulation, and the FDA treats it as such.[138] Even with just proposed guidance, the FDA has classified a number of software products as Class I and Class II medical devices.[139] Laboratory information systems ("LIS"), for example, are categorized as Class I.[140] Picture archiving and communications systems ("PACS") are ranked as Class II.[141]

As of February 15, 2011, there is, at least, a final rule on what is called Medical Device Data System ("MDDS")[142] software. MDDS software, which is now classified as Class I, is a product that transfers, stores, converts, or displays medical device data without providing analysis, alarms, or active patient monitoring.[143] The FDA issued this final rule on its own volition to downgrade

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[133] Thompson et al., *supra* note 12, at 11–13.
[134] *Id*. at 38.
[135] *Id*.
[136] Interview with Linda Moore, *supra* note 68.
[137] *Id*.
[138] *Id*.
[139] Danzis & Pruitt, *supra* note 13, at 27.
[140] *Id*.
[141] *Id*.
[142] Medical Device Data Systems, 21 C.F.R. § 880.6310 (2014).
[143] Danzis & Pruitt, *supra* note 13, at 27.

MDDS software from its previous classification of Class III, which generally requires premarket approval, down to Class I, which typically requires only general controls.[144] The MDDS software classification is a narrow category, covering only those functions that fit within its definition.[145]

F. *Accessories*

Many software programs and some mobile applications are considered "accessories" to medical devices under the FDA's "accessory rule."[146] An accessory is an article that is targeted at and sold directly to consumers for use with a parent device.[147] These accessories are generally subject to the same regulation as the parent device.[148]

There is also the concept of a "component" under FDA regulation.[149] An accessory can be differentiated from a component; consumers purchase accessories, whereas manufacturers purchase components.[150] The critical distinction is that the manufacturer of a program does not bear the regulatory burden for components it makes, but the manufacturer must bear the burden of meeting FDA requirements for accessories it makes.[151]

This Article primarily focuses on accessories. Whether the item at issue is a software program, like a mobile medical app or an adapter that attaches to a smartphone, these products are sold

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[144] *See* 21 C.F.R. § 880.6310.

[145] Danzis & Pruitt, *supra* note 13, at 27.

[146] *Accessory Regulation in mHealth*, EPSTEIN BECKER & GREEN, P.C., (May 10, 2011), http://mhealthregulatorycoalition.org/wp-content/uploads/2010/06/mrcaccessguiddraft.pdf.

[147] Bradley Merrill Thompson, *FDA Regulation of Mobile Health*, http://mobihealthnews.com/wp-content/pdf/FDA_Regulation_of_Mobile_Health.pdf (last visited July 27, 2013).

[148] Danzis & Pruitt, *supra* note 13, at 27.

[149] Thompson, *supra* note 145, at 3.

[150] *Id*.

[151] *Id*. 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. An accessory manufacturer, however, must meet FDA regulations because the accessory gets sold directly to consumers. *Id*.

separately from the smartphone. Consumers purchase programs, apps, and adapters directly and then install them in or attach them to their smartphones. As a result, the accessory rule is pertinent to this Article.

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 also fail.[152] 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.[153] 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.[154] 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.[155]

None of these methodologies—classification, software level of concern, quality systems, performance standard—however, provides clear regulation on medical software.[156] Consequently, developers still face uncertainty as to whether their software is a medical device, and, if so, what level of regulation is required.[157] Not only

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[152] Danzis & Pruitt, *supra* note 13, at 28.

[153] *Id*.

[154] *Id*.

[155] *Mobile Medical Applications Draft Guidance*, 76 Fed. Reg. 50,231, 50,233 (Aug. 12, 2011). In a Federal Register notice dated 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." *Id.* Thus, it seems the FDA is considering a lower regulatory standard for such accessories.

[156] Telephone Interview with Anonymous, CEO of U.S. medical device company (Aug. 7, 2013).

[157] Krouse, *supra* note 23, at 752. This has serious financial implications for mobile medical application developers because, for example, the fees for 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. Devices: General Hospital and Personal Use Devices; Reclassification of

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.[158] It further recognized 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 others require less regulatory oversight.[159] 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.[160]

In the Draft Medical App Guidance, the FDA set forth a proposed framework for regulating certain software applications that perform or enable critical diagnostic or treatment activities.[161] The FDA specified in the draft guidance that this "narrowly-tailored approach" only covers the mobile medical apps it describes.[162] The draft guidance laid out a number of concepts to help determine which mobile applications the FDA intends to

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Medical Device Data System, 73 Fed. Reg. 7,502 (Feb. 8, 2008) (codified at 21 C.F.R. pt. 880).

[158] Vernessa T. Pollard & Joseph W. Cormier, *FDA Issues Draft Guidance Regarding Mobile Medical "Apps,"* 16 CYBERSPACE L. 18, 18 (Aug. 2011).

[159] *Id.*

[160] *See generally* FDA Draft Guidance for Medical Apps, *supra* note 10 (providing background on how the FDA views the industry and setting forth some definitions, the proposed scope of the guidance, insight into the FDA's regulatory approach and requirements, and series of examples to further explain the guidance).

[161] Pollard & Cormier, *supra* note 158, at 18.

[162] FDA Draft Guidance for Medical Apps, *supra* note 10, at 12.

regulate.[163] It also described which persons or entities would be treated as "manufacturers" for purposes of these regulations.[164]

First, the Draft Medical App Guidance pertained to a "mobile platform," which is any off-the-shelf commercial handheld platform, whether or not it has wireless connectivity capabilities."[165] Examples of mobile platforms are personal digital assistants, tablets, and smartphones.[166] Another important concept is a "mobile application," which is a software application that can either run on a mobile platform or a web-based software application that is customized to run on a mobile platform but is actually executed on a server somewhere else.[167]

Moreover, the Draft Medical App Guidance indicated the FDA would regulate only a subset of applications.[168] It concerned those that "meet the definition of a medical device *and* [either] (1) are used as an accessory to a 'regulated medical device' *or* (2) transform a mobile platform into a 'regulated medical device.'"[169] The FDA calls these "mobile medical apps."[170]

First, a mobile medical app must meet the threshold question of whether it is a medical device.[171] Then one of two conditions needs to be satisfied. If the mobile medical app is a medical device and is also an accessory to another regulated medical device, then the

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[163] Pollard & Cormier, *supra* note 158, at 18. For example, the Draft Medical App Guidance provides several definitions for the apps and devices intended to be regulated. FDA Draft Guidance for Medical Apps, *supra* note 75, at 7–8. It summarizes the FDA's regulatory approach. *Id*. at 12–13. It also provides some examples of apps intended to be regulated under this guidance. *See id*. at 18–20.

[164] FDA Draft Guidance for Medical Apps, *supra* note 10, at 8. A "manufacturer," for example, is "any person who manufactures, prepares, propagates compounds, assembles, or processes a device by chemical, physical, biological, or other procedure," including, among other things, those who repackage or change "the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture." *Id*. at 8 n.7; *see generally* 21 CFR §§ 803.3, 806, 807.

[165] FDA Draft Guidance for Medical Apps, *supra* note 10, at 7.

[166] *Id.*

[167] *Id.*

[168] *Id.* at 5.

[169] Danzis & Pruitt, *supra* note 13, at 27.

[170] *Id.*

[171] Pollard & Branham, *supra* note 4, at 2.

Draft Medical App Guidance applied. The Draft Medical App Guidance may also have applied 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.[172] As with many other electronic machines, the FDA considers a smartphone off-the-shelf hardware.[173] 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. So, it is important to understand the impact of installing a mobile medical app.

Appendix A of the Draft Medical App Guidance included three non-exhaustive lists of examples of mobile medical apps.[174] A mobile medical app (1) controls or extends a medical device, such as remotely accessing vital sign readings of patients at home, (2) transforms a mobile platform into a traditionally regulated medical device through attachments or sensors, such as turning a smartphone into an electronic stethoscope, or (3) allows a user to enter patient-specific data and generate patient-specific outcomes using algorithmic methods or processes.[175]

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."[176] A manufacturer could be an entity or a person who

[172] Telephone Interview with Anil Bhalani, *supra* note 7.

[173] Interview with Linda Moore, *supra* note 68.

[174] FDA Draft Guidance for Medical Apps, *supra* note 10, at 9.

[175] Danzis & Pruitt, *supra* note 13, at 28. *See generally* FDA Draft Guidance for Medical Apps, *supra* note 10, at 18–20. According to the Draft Medical App Guidance, this last type includes applications that provide an index or score, calculate dosage for a specific medication or radiation treatment, or offer recommendations to aid a clinician with a diagnosis. *Id.* at 19. 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. *Id.* at 20.

[176] FDA Draft Guidance for Medical Apps, *supra* note 10, at 9.

creates, designs, develops, labels, or modifies a software system to perform as a mobile medical app.[177] This does not apply to those who just distribute a mobile medical app, like retailers and distributors who do not conduct any manufacturing activities.[178] The FDA proposes four broad categories of mobile medical apps in the Draft Medical App Guidance that it intended to scrutinize under its usual medical device schema: (1) applications that display, store or transmit patient-specific medical device data in its original format ("Original Format Apps"); (2) applications that control the intended use, function, modes, or energy sources of a connected medical device ("Control Apps"); (3) applications that transform a mobile platform into a traditional regulated medical device ("Transforming Apps"); and (4) applications that create alarms, recommendations, or new information by analyzing or interpreting medical device data ("Creating Apps").[179]

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.[180] As noted earlier, Class I entails general controls for medical devices, which requires manufactures to register their companies, list their products, conform quality systems, and provide the FDA with adverse event reporting.[181]

A Control App is considered an accessory to the device to which it connects or extends, i.e., the "parent" device.[182] These apps are required to meet the regulation applicable to the parent device.[183] For example, if the parent device is a Class II medical device, the Control App manufacturer must meet these same Class II requirements.[184]

Transforming Apps "are required to meet the controls that would apply to the resulting medical device if it were manufactured

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[177] *Id.*
[178] *Id.* at 8–9.
[179] *Id.* at 13–15.
[180] Pollard & Cormier, *supra* note 158, at 20.
[181] *Id.*
[182] *Id.*
[183] *Id.*
[184] *Id.*

independent of the mobile platform."[185] For example, a Transforming App that transforms a mobile platform into an electronic stethoscope would have to meet the requirements for electronic stethoscopes, which, in this example, are regulated as Class II devices.[186]

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.[187] 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 such guidance is intended only to cover these categories.[188] It is uncertain how an app that does not fall into of one these four categories is to be regulated.

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.[189] Enforcement discretion means that the FDA will reserve, but not exercise, the option to pursue enforcement action against a mobile medical app manufacturer for violating the FDCA and its regulations.[190] The FDA indicated that mobile applications that "automate common medical knowledge available in medical literature" to allow individuals to self-manage a disease or condition should receive discretion.[191] Other mobile apps that are supposed to receive discretion are those that log,

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[185] *Id.*
[186] *Id.*
[187] *Id.*
[188] FDA Draft Guidance for Medical Apps, *supra* note 10, at 12.
[189] Melnik, *supra* note 1, at 56.
[190] FDA Draft Guidance for Medical Apps, *supra* note 10, at 4.
[191] Pollard & Cormier, *supra* note 158, at 3.

track, or store personal data, but are not essential to patient diagnosis, treatment, or safety.[192]

The scope of the Draft Medical App Guidance was limited. The FDA explicitly stated that the guidance did not cover certain areas. The guidance did not delve into applications that analyze, process, or interpret medical data from multiple medical devices.[193] The FDA explained that it would issue separate guidance for this.[194] The draft guidance also failed to address wireless safety, classification or premarket submission requirements, quality system requirements, and software that implements quality systems.[195] Again, the FDA purported it would address these areas with future guidance.[196]

The Draft Medical App Guidance received considerable criticism.[197] While the mobile app industry was generally pleased to hear that the FDA would exercise enforcement discretion toward some apps, the FDA failed to delineate where the threshold of enforcement discretion occurs.[198] In fact, the Draft Medical App Guidance generated more questions than answers.[199] For example, while the FDA suggests most mobile medical apps will fall under Class I, which are typically exempt from premarket review, or Class II, which typically requires 510(k) 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.[200]

On September 25, 2013, however, the FDA issued what is purportedly the final guidance document on this subject, entitled "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff" [hereinafter "Final Medical App Guidance"].[201] Noticeably, the FDA took industry feedback on the

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[192] *Id.*
[193] *Id.*
[194] *Id.*
[195] *Id.*
[196] *Id.*
[197] Danzis & Pruitt, *supra* note 13, at 28.
[198] *Id.*
[199] *Id.* at 29.
[200] Pollard & Cormier, *supra* note 158, at 3.
[201] FDA Final Guidance for Medical Apps, *supra* note 10.

Draft Medical App Guidance because the Final Medical App Guidance offers greater detail on the types of apps the FDA intends to regulate, a new section that tries to identify what applications the FDA *will not* regulate, and a greater number of appendices with more explicit examples than the Draft Medical App Guidance.[202] In fact, the FDA provides three pages of examples in the new Appendix A of mobile apps that are not medical devices according to the FDA and therefore not subject to regulation.[203]

The FDA has also reorganized the apps it intends to regulate from the four categories described earlier into three categories: gone are the Original Format Apps described above, which are now conceptually captured in the new Appendix A as apps that will not be regulated.[204] Still present, in essentially the same form, are the Control Apps and Transforming Apps, but with the Creating Apps now recharacterized as "Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations."[205] The guidance further states that "[t]hese types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved."[206] The non-exhaustive lists of examples of mobile medical apps has moved from Appendix A to Appendix C with some more detailed descriptions and possible product codes that may be applicable to such devices.[207] The addition of possible product codes in the examples may help developers and manufacturers determine whether a new product might fall into one of these examples.

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[202] *See generally id*.
[203] *Id.* at 20–22.
[204] *Id.*
[205] *Id.* at 13–15.
[206] *Id*. at 15.
[207] *Id.* at 26–28.

Some commentators consider the Final Medical App Guidance "good news for the health care community."[208] Nonetheless, the final guidance instigated similar criticism as its draft counterpart.[209] For example, Bradley Merrill Thompson, the general counsel for the mHealth Regulatory Coalition, stated, "[T]he final guidance is fundamentally like the proposed guidance, and omits some very important areas."[210] A few items that Thompson noted are lacking are "the definition of what are regulated; disease intended uses compared to unregulated, wellness intended uses; and the exact meaning of an accessory to a medical device."[211] Moreover, there is an expanded discussion in the Final Medical App Guidance regarding FDA enforcement discretion[212] and a new Exhibit B giving examples of mobile apps over which the FDA intends to exercise enforcement discretion.[213] This, unfortunately, enlarges the "murky territory left up to FDA's discretion . . . ."[214] Consequently, some of the earlier unknowns persist.

Commentators have not yet remarked on a new twist in the definition of a "mobile medical app" in the Final Medical App Guidance, which is the conspicuous addition of the words "is intended."[215] Now a mobile medical app is defined as "a mobile app that meets the definition of a [medical device] and either *is intended* [1] to be used as an accessory to a regulated medical device; or [2] to transform a mobile platform into a regulated medical device."[216] This introduces a new ambiguity, because it is

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[208] Peter Blenkinsop et al., *FDA Final Guidance on Mobile Medical Applications*, LIFE SCIENCES NOW (Nov. 22, 2013), http://lifesciencesnow.com/fda-final-guidance-on-mobile-medical-applications/.

[209] Greg Slabodkin, *FDA Final Mobile Medical App Guidance Mirrors 2011 Draft*, FIERCE MOBILE HEALTHCARE (Sept. 23, 2013), http://www. fiercemobile healthcare.com/story/fda-final-mobile-medical-app-guidance-mirrors-2011-draft/2013-09-23.

[210] *Id.*

[211] *Id.*

[212] FDA Final Guidance for Medical Apps, *supra* note 10, at 16–18.

[213] *Id*. at 23.

[214] Diana Manos, *3 Surprises in FDA's Mobile Medical Apps Final Guidance*, GOV'T HEALTH IT (Nov. 6, 2013), http://www.govhealthit.com/news/3-surprises-fdas-mobile-medical-apps-final-guidance.

[215] FDA Final Guidance for Medical Apps, *supra* note 10, at 7.

[216] *Id.* (emphasis added).

not whether the device actually is used as an accessory or actually transforms a mobile platform, but whether the developer or manufacturer *intended* the device to do so. Whether this or other uncertainties will be addressed in future guidance remains to be seen. The FDA has noted it will issue additional guidance.[217]

Congress seems to have provided some motivation for the FDA to develop and implement more specific direction to the marketplace when it passed the Food and Drug Administration Safety and Innovation Act ("FDASIA") on January 3, 2012.[218] 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 applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[219] This report (the "FDASIA Report") was due in July, 2013.[220] Perhaps the marketplace will soon have greater clarity. As of the date of this Article, however, the FDA has not yet published this congressionally mandated report.[221] There is no indication as to why this is the case. Despite the legislated timeframe, it could be months or even years before the FDA actually responds or takes action.[222] Until the FDASIA Report is posted, interested parties must glean insight from the guidance documents and related discussions.

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[217] Pollard & Cormier, *supra* note 158, at 3.

[218] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144 (2012).

[219] *Id.* at § 618(a).

[220] *Id.* (stating that the report is due "[n]ot later than 18 months after the date of enactment of this Act," which was July 3, 2013).

[221] *Reports and Plans Mandated by FDASIA*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm (last updated Aug. 20, 2013) (showing four reports mandated by the FDASIA, but not the specific report referenced here that is mandated by Section 618 of the FDASIA).

[222] Interview with Linda Moore, *supra* note 68.

What is apparent from pre-existing guidelines 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) the corresponding control measures; (4) quality systems; (5) the 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 would 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 reviewed briefly below.

### H. *HIPAA Privacy and Security*

While the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") is not core to this Article's discussion on FDA regulation, the use of mobile devices for healthcare raises serious HIPAA issues regarding privacy and security.[223] Congress passed HIPAA in 1996 to, among other things, require protection and confidential handling of protected health information.[224] "Protected health information" ("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.[225] The entry of mobile devices into healthcare has brought new issues

[223] HIPAA as it relates to mHealth could warrant its own separate article.

[224] *Health Insurance Portability and Accountability Act*, CALIFORNIA DEPT. OF HEALTH CARE SERVICES, http://www.dhcs.ca.gov/formsandpubs/laws/hipaa/Pages/1.00%20WhatisHIPAA.aspx (last visited July 27, 2013).

[225] 45 C.F.R. § 160.103 (2014).

of privacy and security with regard to patient information.[226] HIPAA requires healthcare providers to implement and maintain certain privacy and security measures with regard to PHI.[227] Mobile communications are not secure because communication between the users goes through a third party's system, the telecommunication data carrier.[228] Moreover, professional communications may be audited by the U.S. Department of Health and Human Services.[229]

The issue is that communications between a patient and physician are protected under HIPAA.[230] 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.[231] Security measures, such as authentication and encryption, are needed in order to safeguard PHI.[232] Typical commercial mobile communications lack security protocols unless the designer specifically incorporates them into the device.[233] Nonetheless, electronic measures do not eliminate liability and responsibility. A survey conducted by the Ponemon Institute[234] revealed that 96% of healthcare organizations reported securities breaches often as a result of a lost mobile device.[235] Fines are imposed on HIPAA violations with penalties increasing under new HIPAA rules that went into effect on March 26, 2013.[236]

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[226] Jim Sheldon-Dean & Vidya Phalke, PhD, *Healthcare Going the Mobile Way!*, METRICSTREAM, INC. (Feb. 19, 2013), *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.

[227] Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, § 201(a)(3)(B)(ii) (1996).

[228] *Id.* § 221.

[229] *Id.* § 262.

[230] Runkle, *supra* note 3, at 31.

[231] *Id.* at 30.

[232] *Id.*

[233] Sheldon-Dean & Phalke, *supra* note 226.

[234] Ponemon Institute is an organization that conducts independent research on "privacy, data protection and information security polic[ies]." *See* PONEMON INSTITUTE, www.ponemon.org (last visited July 27, 2013).

[235] Runkle, *supra* note 3, at 31.

[236] Sheldon-Dean & Phalke, *supra* note 226.

There are other implications as well, but HIPAA requires a separate discussion to do them justice. It is simply raised here to note the convergence of these two federal schemes, HIPAA and FDA regulation, within the context of mHealth.[237]

I. *Taxation of Smartphones as Medical Devices*

The Patient Protection and Affordability Care Act ("PPACA"), known colloquially as "Obamacare," was signed into law by President Obama on March 23, 2010.[238] After a bustle of controversy and challenge, the Supreme Court upheld PPACA with a 5-4 vote on June 28, 2012.[239] PPACA is partially subsidized through a new 2.3% excise tax imposed on medical devices.[240] 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.[241]

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.[242] The 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) . . . ."[243]

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[237] *See generally* Runkle, *supra* note 3 (discussing the increase in physician use of smartphones, how HIPAA applies to data that a doctor or clinic receives on or from a patient and communications between a doctor and patient and that survey reports reveal data breaches often occur from lost mobile phones).

[238] *See* PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010), *amended b*y Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (codified in scattered sections of 26 and 42 of the U.S. Code).

[239] Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).

[240] 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/.

[241] *Id.*

[242] Letter from Fred Upton et al., Committee on Energy and Commerce, to Margaret A. Hamburg, MD, Commissioner, U.S. Food and Drug Administration (Mar. 1, 2013), *available at* http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/letters/030113FDAsmartphones.pdf.

[243] *Id*. at 2.

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.[244] 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."[245] This tax applies to medical devices sold after December 31, 2012.[246]

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.[247] This IRS deference to the FDA has the effect of transforming the FDA into a government tax agent.[248] 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 as to whether smartphones and tablets are medical devices for tax purposes,[249] and thus speculation ensued.

The tax situation is troublesome because the excise tax is imposed regardless of whether the manufacturer makes a profit.[250] Further, most device companies are relatively small, typically with 50 or fewer employees.[251] To accommodate this tax, companies may need to cut costs or pass the cost on to consumers.[252] This begs the question of whether a healthcare savings is actually achieved.

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[244] Katie McAuliffe, *Don't Allow Medical Device Taxation on Smartphones, Tablets and Apps*, THE HILL (Mar. 7, 2013, 10:15 PM), http://thehill.com/blogs/congress-blog/healthcare/286923-dont-allow-medical-device-taxation-on-smartphones-tablets-and-apps.

[245] *See Medical Device Excise Tax: Frequently Asked Questions*, INTERNAL REVENUE SERVICE, http://www.irs.gov/uac/Medical-Device-Excise-Tax:-Frequently-Asked-Questions (last updated May 22, 2013).

[246] *Id.*

[247] McAuliffe, *supra* note 244.

[248] *Id*.

[249] *Id*.

[250] *Id*.

[251] *Id*.

[252] *Id*.

The logical conclusion is that smartphones should not be taxed as medical devices. The FDA is familiar with smartphones. Smartphones are standard devices now, like computer monitors and keyboards.[253] 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.[254] No one needs a prescription to buy a smartphone or a tablet. Therefore, a standard mobile device ought not to be a medical device for purposes of the PPACA tax. If a mobile medical app transforms a standard mobile device into a medical device, just the app should be subject to the tax, not the off-the-shelf device.

This discussion reveals the federal landscape and 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 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. [255]

## IV. SMARTPHONE MHEALTH PRODUCTS

The three categories of mobile medical apps that the Final Medical App Guidance discusses are still merely a subset of mobile medical apps.[256] This leaves out a variety of mHealth products. 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

[253] Telephone Interview with Anil Bhalani, *supra* note 7.

[254] *Id*.

[255] 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 article.

[256] *See* FDA Final Guidance for Medical Apps, *supra* note 10, at 12.

are designed to work with a standard hand-held 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 (hereinafter "information apps").[257] 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.[258]

Second, there are applications that perform a diagnostic function (hereinafter "diagnostic apps"). This type of product performs a calculation or analysis and computes a result or determination.[259] This process is typically conducted by a user who inputs certain data into the application; the process and diagnosis is then rendered without the mental step of human intervention.[260]

The third type of product is applications that allow the smartphone to control an unattached medical device (hereinafter "control apps").

The fourth category includes attachments, sensors, or other devices that attach to or adapt 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 (hereinafter "adapters"). As noted, the FDA categorizes these as "accessories" under the "accessory rule."[261] For purposes of this discussion, an accessory, in the sense of a physical article, will be called an "adapter" to designate a physical item that attaches to the

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[257] Krouse, *supra* note 23, at 741.

[258] *See id.* (explaining how informational applications allow users to look up medical information and other reference materials similar to looking up information on a website or in a book).

[259] *See id.* at 743 (explaining how some applications now process information and arrive at decisions that were traditionally mental processes that medical professionals conducted).

[260] *Id*.

[261] *See generally* EPSTEIN BECKER & GREEN, P.C., *supra* note 146 (discussing the FDA accessory rule and when accessory regulation is implicated in mHealth technologies such as in classification and substantiation of claims of accessories).

smartphone; not to be confused with the principle of "accessory" under the FDA's accessory rule, which includes physical articles and software. The following is an analysis of FDA regulation on each of these four categories of smartphone mHealth products.

### 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.[262] The FDA regulates none of these sites. Information apps provide the same access, but 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, but is more akin to general health and wellness, and perhaps should be free from regulation.

### B. *Diagnostic Apps*

A diagnostic app is an application that performs a calculation or function and computes a result or determination without human intervention, aside from entering the data. Diagnostic apps appear to fall within the FDA's definition of a mobile medical app according to the Final Medical App Guidance because these applications allow a user to enter patient-specific data, apply an algorithm or formulae, and then output patient-specific results.[263] Accordingly, the FDA presumably intends to regulate diagnostic apps under its medical device regime of Classes I–III.[264] This may

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[262] *See Medical Information Sites: The Pick of the Best Medical Information Sites on the Net Today*, NETTOP20.COM, http://medical.nettop20.com/ (last visited Apr. 4, 2013) (listing some of the most popular and highest-rated Internet sites for medical information).

[263] Danzis & Pruitt, *supra* note 13, at 27.

[264] *Id.* at 29.

seem reasonable; however, diagnostic apps have varying capabilities and, thus, represent varying levels of risk to consumers.[265]

It would make better sense to regulate diagnostic apps that pose little health risk to consumers 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.[266]

1. *Clinical Analysis by Diagnostic Apps*

Some commentators contend that basic clinical analysis programs simply automate well-understood, nonproprietary clinical algorithms and, thus, present a relatively low risk to consumers.[267] The rationale behind this perspective is that physicians not only understand how to use the information that such programs generate, but they are also familiar with the algorithms and calculations utilized in these applications, and, thus, would be able to recognize incorrect results, and could arrive at his or her own mentally derived diagnosis.[268] This allows for "competent human intervention," which the FDA prefers per its draft software policy.[269]

In such event, the FDA perceives that competent human intervention provides sufficient safeguard against the diagnostic application leading to medical error.[270] So it appears there is relatively low risk with such diagnostic apps. This presupposes that a doctor or other healthcare professional is involved in the process. If the operator is a layperson with no medical training or medical education, the "competent human intervention" may be deficient.

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[265] *Id.*
[266] *Id.*
[267] *Id.*
[268] *See id.* (describing the "competent human intervention" principle the FDA included in its 1989 draft software policy that physicians are knowledgeable enough to recognize an incorrect result that a software program might generate).
[269] *Id.* at 27 (noting that in 2005, the FDA withdrew the 1989 draft policy without comment).
[270] *Id*. at 29.

Software applications that deploy simple, automated, well-understood, nonproprietary clinical algorithms have been present on the Internet for years without regulation.[271] In fact, the FDA had an oncology drug-dosing calculator on its own website.[272] Other federal government websites offer similar medical calculators. For example, the National Heart, Lung, and Blood Institute, offers a "10 Year Heart Attack Risk Calculator."[273] The National Institute of Diabetes and Digestive and Kidney Diseases offers a glomerular filtration rate calculator for children and another for adults.[274] The U.S. Department of Veterans Affairs offers a calculator for cirrhosis and end stage liver disease as well as other similar clinician tools.[275] Being available on the Internet, these calculators are open to the general public.

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 by Diagnostic Apps*

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.[276] An example of a disease management diagnostic app is one that "helps heart disease patients create a diet based on published nutritional guidelines."[277] Commentators think that such apps should receive

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[271] *See id.*

[272] *Id.*

[273] *Risk Assessment Tool for Estimating Your 10-year Risk of Having a Heart Attack*, NAT'L HEART, LUNG, & BLOOD INST., http://cvdrisk.nhlbi.nih.gov/calculator.asp (last updated May, 2013).

[274] *GFR Calculators*, NAT'L INST. OF DIABETES & DIGESTIVE & KIDNEY DISEASES, http://nkdep.nih.gov/lab-evaluation/gfr-calculators.shtml (last updated Apr. 25, 2012).

[275] *Algorithms, Screens, Toolkits*, U.S. DEP'T OF VETERANS AFFAIRS, http://www.hepatitis.va.gov/provider/tools/ (last updated Dec. 9, 2013).

[276] Danzis & Pruitt, *supra* note 13, at 29.

[277] *Id.*

FDA enforcement discretion because they are intended to operate in tandem with oversight from a healthcare provider and are not meant to encourage a patient to self-treat or self-diagnose.[278] Disease management diagnostic apps may pose a low risk to a patient under care. Because these apps can meaningfully improve public health, perhaps they should be subject to lower scrutiny.

Nonetheless, lower scrutiny on such apps 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 layperson uses the disease management app without physician supervision. Should a different regulation apply based on the user? 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 by Diagnostic App*

Another diagnostic app is a program that downloads medical device data and utilizes the data for basic disease management.[279] Health data analysis diagnostic apps might perform charting, trending, or basic disease-management analysis of data obtained from a medical device, such as a blood pressure cuff or glucose monitor.[280] As noted earlier, MDDS software "transfer[s], store[s], convert[s], or display[s] medical device data without providing analysis, alarms, or active patient monitoring" and such software falls in Class I due to its low risk.[281]

Although the MDDS rule is a narrow category,[282] one commentator suggests 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

[278] *See id.* (explaining that basic disease management applications pose a low risk because a healthcare professional is typically overseeing a patient that is a user of such application and therefore if an application is intended to be used in conjunction with medical care it should warrant enforcement discretion).

[279] *Id.*

[280] *Id.*

[281] *Id.* at 27.

[282] *Id*.

attention,[283] and therefore should be entitled to FDA 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?

Suppose a product receives enforcement discretion, i.e., is exempted from medical device requirements because a patient is being overseen by a doctor. Does this same product then require different regulation when used by a consumer who is without a physician? This question cannot be answered by just examining the device and the manufacturer's intended use of it.

4. *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."[284] Mobile applications that control a medical device are considered "accessories" and are generally subject to the same regulation as the parent device.[285] The aspect of control unequivocally implicates the FDA's concern that if the accessory failed, the parent device might fail as well. 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 Final Medical App Guidance further indicates that a control app is subject to medical device regulation because a control app will connect to a medical device for purposes of controlling the device.[286] Pursuant to the accessory rule, a control app is subject to the same regulation as the parent device.

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[283] *See id.* at 29 (explaining that applications that perform these functions are downloading the data from a regulated medical device and that a medical professional is supervising the use of that data such that enforcement discretion is justified).

[284] *See generally* EPSTEIN BECKER & GREEN, P.C., *supra* note 146 (explaining the FDA accessory rule and when accessory regulation is implicated in mHealth products).

[285] *Id*. at 2.

[286] FDA Draft Guidance for Medical Apps, *supra* note 10, at 13–14.

5. *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. For example, the Schosche myTrek and the Polar WearLink+ allow one to track and upload one's vital signs to his or her iPhone or Android phone.[287] The iHealth BP3 and the Withings BPM are two blood pressure monitoring adapters that allow one to monitor, track, and store blood pressure readings.[288] Sanofi's IBGStar blood glucose meter tracks one's glucose, carbohydrate intake, and the dosage of insulin to be taken.[289] 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.[290] The following table illustrates adapters that allow smartphones to give eye exams, take ultrasounds, and replace stethoscopes.[291]

| 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 |

[287] Daniel P., *Smartphones and tablets as medical devices*, PHONEARENA.COM (Sept. 3, 2011, 2:42 PM), http://www.phonearena.com/news/Smartphones-and-tablets-as-medical-devices_id21791.

[288] *Id.*

[289] *Id.*

[290] Ruane, *supra* note 50.

[291] Daniel P., *supra* note 287.

Many more adapters are in development. For example, 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.[292] CellScope[293] is developing an otoscope that also attaches to a 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.[294]

These and other consumer-oriented devices are part of an established and growing trend that is revolutionizing healthcare.[295] 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."[296] An alternative approach is that many adapters may be able to satisfy the lower regulatory requirements of Class II or by doing a 510(k) notification if, for example, a blood pressure cuff adapter is substantially similar to a standard, pre-existing blood pressure cuff.[297] 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.[298] AliveCor's Heart Monitor, for example, has been the subject of several clinical trials.[299]

These and other similar advancements show there is a critical mass building in mHealth. Regulation could use an upgrade so that

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[292] Ruane, *supra* note 50.

[293] A San Francisco-based company.

[294] Ruane, *supra* note 50.

[295] *See Smartphone Medicine*, REPERTOIRE, http://www.repertoiremag.com/Article.asp?Id=3980 (last visited Apr. 7, 2013).

[296] Danzis & Pruitt, *supra* note 13, at 27.

[297] *Id.* at 28.

[298] Ruane, *supra* note 50.

[299] *Id.*

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, then, should the product be regulated? Does the same product warrant two different regulatory requirements based on whether a healthcare practitioner is involved? This would complicate matters further. 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 REGULATION

It is unclear under which situations mobile medical apps are subject to the FDA's 501(k) and PMA regimes.[300] Further, these medical device regulations were created during a time when technologies were developing at a slower pace and were less accessible to consumers.[301] It is 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.[302] By 2015, it is estimated that 500 million people worldwide will use mobile medical apps on their smartphones.[303] Regulation needs to improve. 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,

[300] *See generally* Thompson et al., *supra* note 12 (explaining that it is fundamental to business planning and innovation for companies and investors to understand "whether a given product requires some sort of premarket clearance or approval from the FDA").

[301] Krouse, *supra* note 23, at 763.

[302] *Id.*

[303] Ralf-Gordon Johns, *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.

cosmetics, and products that emit radiation."[304] Ensuring safety must be carefully balanced with how much regulation is necessary.[305] Manufacturers, and people in general, want to be free of regulation.[306] However, when people or loved ones are injured, they want the government to step in and regulate the activity that caused injury.[307] Balancing goes on inside companies as well, where ethics and morals intersect with revenue and profit growth.[308]

The complexity of the regulatory environment and the guesswork involved make compliance a challenge for even a diligent company trying to anticipate what the FDA wants. Generally companies are out of compliance to some degree because 100% compliance with all FDA regulation is difficult to achieve.[309] It is when a product is found unsafe or ineffective that issues arise.[310] 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.[311] 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 determining how much regulation is required.

### A. *Define the Software Regulation*

The FDA needs to clarify some of the confusion pointed out in this Article. The FDA really should capitalize on its opportunity to do so in the FDASIA Report. It is high time the FDA creates an "Office of Software."[312] For example, developing an Office of In Vitro Diagnostics allowed the FDA to develop its expertise in the areas of fertility and reproduction,[313] and thus similarly, the FDA

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[304] *About FDA*, FDA.GOV, http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last updated Sept. 19, 2013).
[305] Correspondence with Anil Bhalani, *supra* note 69.
[306] *Id.*
[307] *Id.*
[308] *Id.*
[309] *Id.*
[310] *Id.*
[311] *Id.*
[312] Danzis & Pruitt, *supra* note 13, at 29.
[313] *Id.*

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 characteristics of the application rather than the intended use.[314] 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 would be prudent to have a new medical device regulatory framework specific to mobile medical apps, and perhaps even for the broader context of software. Clearer definitions would be helpful. Developers need to understand when their applications will be regulated as a medical device.[315] The FDA should draw a more definite line between a health product and a medical product. Asking for a completely new regulatory scheme just for mHealth products is probably a bit too aggressive, and it would be fanciful to expect the FDA to do so. While a new scheme may be ideal, but unlikely, it is achievable for the FDA to devise and implement better definitions.

Information apps, as defined above, should not even be considered medical devices. Because 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.[316] Beyond this exemption 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.[317] Because many health and wellness apps can go beyond what the

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[314] *Id.*
[315] Krouse, *supra* note 23, at 756.
[316] *Id.*
[317] *Id.*

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 beyond basic clinical or basic disease management analysis.[318] 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.[319] What would be helpful in developing better definitions and distinguishing health products from medical products, and products that require regulation from those that do not, is if the FDA examined the principles that bear on consumer safety.

### B. *Target the Focus on Principles Underlying Safety*

The primary focus with regard to safety 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. The FDA needs to consider consumer access, actual use, and marketplace interposition in order to improve regulation.

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[318] Danzis & Pruitt, *supra* note 13, at 29.
[319] *Id.*

1. *Consumer Access*

Unless one is a physician, who is able to purchase traditional medical devices directly, the general consumer needs a prescription to purchase a traditional medical device, except for a few medical devices that have become available over-the-counter and can be found at drug stores.[320] That said, there is no pharmacy equivalent for medical devices. Gatekeeping is up to the device companies.[321] 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 or sometimes 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 that the FDA should put the onus on application stores to prevent mobile medical apps from being marketed without FDA approval.[322] 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

[320] *See* Telephone Interview with Anil Bhalani, *supra* note 7 (explaining the prescription requirement the FDA imposes on some medical device in order for consumers to obtain access to them).

[321] *See* Correspondence with Anil Bhalani, *supra* note 69 (explaining that pharmacies act as gatekeepers for the pharmaceutical industry to vet a consumer's prescription for a drug, thereby confirming physician approval, but there are no equivalents to pharmacies for medical devices and, thus, companies must implement internal mechanisms to vet a consumer's prescription).

[322] Krouse, *supra* note 21, at 763–64.

denial of the developer's product. Such measures have the potential to 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.[323] If the medical device is prescription only, it is up to the company that received approval to be the gatekeeper.[324] 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.[325] 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.[326]

The manufacturer or developer needs to consider a mechanism to check for physician or prescription authorization before allowing download of the mobile medical app. It is the manufacturer or developer, rather than the app store, who is putting the mobile medical app on the market. The onus should not be on the app store. The advice here acknowledges that technological advancement has changed consumer access, and therefore 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 purpose of the manufacturer as expressed

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[323] Correspondence with Anil Bhalani, *supra* note 69.
[324] *Id.*
[325] *Id.*
[326] *Id.*

in its product claims.[327] 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.

Consider, for example, the scale mentioned earlier in the software "level of concern" discussion. The scale posed no harm to a person simply using it for general wellness purposes, but if the person is required to notify his doctor when 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.[328] 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*—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.[329] It is a heart rate monitor that measures one's pulse.[330] It uses the built-in camera on a smartphone to track color changes on the fingertip that are directly linked to one's pulse.[331] Azumio, Inc. claims this is the same technique that medical pulse oximeters use.[332] Further, Azumio, Inc. touts Instant Heart Rate as a "health and fitness" app.[333] 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.[334]

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[327] See discussion *supra* Part III.A.

[328] Thompson et al., *supra* note 12, at 38.

[329] *See Android Apps*, GOOGLE PLAY, https://play.google.com/store/apps/details?id=si.modula.android.instantheartrate&hl=en (last visited July 28, 2013) (displaying the Instant Heart Rate app, its maker, its category, some screen images from the app, the product description, some rating data and comments).

[330] *Id.*

[331] *Id.*

[332] *Id.*

[333] *Id.*

[334] *Id.* The listing installs as 10,000,000–50,000,000. *Id.*

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."[335] Based on this, Instant Heart Rate is not a medical device at all. If it were, it is likely a Class I medical device. Heart monitors, however, are Class II medical devices.[336] Pulse Oximeters are also Class II medical devices.[337] 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.[338] Apple, Inc. categorizes the iStethoscope in the App Store as "Medical."[339] The developer, however, stated in the description that iStethoscope is "intended to be used for entertainment purposes and as a demonstration of the technology."[340] 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

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[335] *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).

[336] *Product Classification*, FDA.GOV, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/TextResults.cfm (last visited July 28, 2013) (listing each of the eight results as Class 2 when searching "heart monitor").

[337] *See Product Classification*, FDA.GOV, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/TextResults.cfm (last visited Aug. 10, 2013) (listing four out of five results as Class 2, and one, fetal pulse oximeter as Class 3 when searching "pulse oximeter").

[338] iStethoscope Free, *iTunes Preview*, APPLE.COM, https://itunes.apple.com/ca/app/istethoscope-free/id383008092?mt=8 (last visited Aug. 4, 2013).

[339] *Id.*

[340] *Id.*

it to escape regulation? Under this rubric iStethoscope is not a medical device at all. This highlights that consumers may not be adequately safeguarded against all apps.

The current regulatory terrain for medical devices with its focus on intended use, not actual use, provides 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 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.[341] 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.[342] In fact, in recent years, very fierce and high stake litigation has ensued over off-label promotion of drugs.[343]

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.[344] Rather, with mHealth, the FDA seems more concerned with the intended use as promoted by the manufacturer. mHealth manufacturers or other parties may not actually promote "off-label" uses for mHealth products whereby

[341] George Lasezkay, Professor of Law, Pharmaceutical Law & Policy Class Lecture at the University of San Diego School of Law (Feb. 7, 2013) (lecturer's notes on file with author).

[342] *Id.*

[343] *See, e.g.*, United States v. Caronia, 703 F.3d 149 (2d Cir. 2012); Washington Legal Found. v. Henney, 56 F. Supp. 81 (D.D.C. 1999); Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 62–75 (D.D.C. 1998).

[344] 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 U.S. 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, http://protomag.com/assets/offlabel-use-of-medical-devices-out-of-bounds. 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, *supra* note 341.

the discussions have not yet arisen. This further highlights the concern 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.

Medical device regulation inadvertently turns 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 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 that the intent of their product is 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."[345] 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

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

and unauthorized practice of medicine through consumer access and actual use.

Interposition is a legal principle whereby a state exercises its sovereign power and disregards the authority of the federal government if the state believes the federal government action is unconstitutional or exceeds the powers granted to the federal government. However, the U.S. Supreme Court does not acknowledge this doctrine.[346]

"Marketplace interposition" means that the commercial marketplace is effectively rejecting the federal prohibition against self-treatment and rejecting state prohibition of the unauthorized practice of medicine. 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, by 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.[347] As also noted, at least according to one survey, 35% of U.S. 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.[348] No doubt they did, or at least tried.

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[346] *See* Cooper v. Aaron, 358 U.S. 1 (1958) (the Supreme Court reinstated a plan of desegregation rejecting the claim that state officials had no duty to obey federal court orders explaining that federal constitutional rights "can neither be nullified openly and directly by state legislators or state executives or judicial officers[.]"); *see also Interposition Doctrine Law & Legal Definition*, US LEGAL.COM, http://definitions.uslegal.com/i/interposition-doctrine/ (last visited July 28, 2013).

[347] Krouse, *supra* note 23, at 738.

[348] FOX & DUGGAN, *supra* note 31, at 2.

Americans had a right to self-treatment until the government took it away in 1914.[349] Up until then, citizens could purchase any medication they wanted from any pharmacy without a prescription or oversight from a physician.[350] However, society apparently believed the masses needed protection against themselves, and, thus, U.S. citizens lost the right to self-treatment almost 100 years ago.[351]

Americans have a right to autonomy, whereby one may refuse medical treatment.[352] 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 power of attorney proxy.[353] 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 may use his or 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

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[349] Sheldon Richman, *The Right to Self-Treatment*, THE FUTURE OF FREEDOM FOUNDATION (Jan. 1, 1995), *available at* http://fff.org/explore-freedom/article/selftreatment/; *see also* Kevin A. Carson, *The Right to Self-Treatment*, MUTUALIST BLOG: FREE MARKET ANTI-CAPITALISM (May 11, 2005), http://mutualist.blogspot.com/2005/05/right-to-self-treatment.html; Dave Pollard, *The Wisdom of Patients (and the Right to Self-Treatment)*, HOW TO SAVE THE WORLD (May 6, 2005), http://howtosavetheworld.ca/2005/05/06/the-wisdom-of-patients-and-the-right-to-self-treatment/.

[350] Richman, *supra* note 349.

[351] *Id.*

[352] *See* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 621, 110 S. Ct. 2841 (1990). The United States Supreme Court determined a competent person has a constitutionally protected liberty interest to refuse medical treatment. *Id.* 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. *Id.*

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

medicine happens when one provides medical advice or renders treatment without a professional license.[354] The unauthorized practice of medicine is a crime in every state.[355] When one provides care to one's self or another, a deeper question then becomes: what is the "practice of medicine?"[356] While definitions vary state to state, a person typically engages in the practice of medicine when she or he attempts to diagnose or treat an illness or injury, prescribes medication, conducts surgery, or declares that she or he is a doctor.[357] 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.[358] 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 is slowly warming up to this paradigm. Even the FDA acknowledges mobile devices are staples of modern convenience.[359] Technological advancements have allowed commerce to surpass government, putting healthcare capabilities

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

[355] *Id.*

[356] *Id.*

[357] *Id.*

[358] *See generally How Self-Care Can Help Firms Cut Health Bills*, 94 COMPENSATION AND BENEFITS FOR L. OFF. 2 (1994); Michael H. Cohen, *A Fixed Star in Health Care Reform: The Emerging Paradigm of Holistic Healing*, 27 ARIZ. ST. L.J. 79 (1995); David I. Shalowitz & Michael S. Wolf, *Shared Decision-Making and the Lower Literate Patient*, 32 J.L. MED. & ETHICS 759 (Winter 2004).

[359] Pollard & Cormier, *supra* note 158, at 18.

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.[360] Some commentators argue for less regulation for certain diagnostic apps that presuppose a person is receiving medical attention.[361] The reality is that the risk of injury is higher for lay people operating without physician oversight. Some measure of regulation is necessary.

Another question is how much healthcare a layperson should be allowed to practice. As noted earlier, of the mHealth product types reviewed, diagnostic apps pose gray areas.[362] 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.

*4. 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.[363] 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.[364]

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[360] *See CTIA and Harris Interactive*, *supra* note 44.

[361] *See* Danzis & Pruitt, *supra* note 13, at 29.

[362] *See supra* Part IV.B.

[363] 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.

[364] *Id.*

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.[365] 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, that 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 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."[366] 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.[367] Again, a more effective approach would be to establish an approval process specifically for mobile medical apps. The FDA could implement a preliminary review assessment, institute an abbreviated approval process and, at a minimum, reduce the review backlog to improve the process. The following paragraphs detail these approaches.

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[365] McAuliffe, *supra* note 244.

[366] *Questions and Answers About the Medical Device Innovation Initiative*, U.S. FOOD & DRUG ADMIN. (Feb. 8, 2011), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm242068.htm.

[367] Krouse, *supra* note 23, at 758.

a. *Preliminary Review Assessment*

As noted earlier, the FDA indicated it intends to exercise discretion as to whether it will regulate a mobile medical app.[368] To avoid the uncertainty that developers face, the FDA could develop 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) at what level. Such an approach could eliminate time and effort spent after the 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.[369] If a company has the resources to hire a regulatory specialist, a preliminary review assessment could be conducted in about four hours.[370] Assume for this exercise a going rate of $250 per hour for regulatory medical device specialists.[371] 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 for 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.

b. *Abbreviated Approval*

Another approach is an accelerated approval process. Accelerated approval is a familiar concept to the FDA. The drug

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[368] Danzis & Pruitt, *supra* note 13, at 27.
[369] Telephone Interview with Anil Bhalani, *supra* note 7.
[370] *Id.*
[371] *Id.*

industry enjoyed significant advances with the accelerated approval processes implemented under the Hatch-Waxman Act of 1984 for generic drugs.[372] This regulatory regime saved drug companies substantial costs in developing generic drugs, which further translated into lower drug prices for consumers and insurance carriers.[373] The biologics industry hopes to see similar advancement and cost savings with biosimilars under the accelerated approval regime promulgated by the Biologics Price Competition and Innovation Act of 2009.[374] This regime was enacted into law with the passage of PPACA and given effect by the U.S. Supreme Court when it upheld PPACA on June 28, 2012.[375]

Because 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 would reduce costs as it has done in the drug industry, 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.

c. *Internal Efficiency*

The two previous suggestions are essentially new programs, however, the FDA could improve the process by simply addressing its existing inefficiency. At present, it takes the FDA 90 days or more to review a 510(k) submission.[376] This may seem like a short period of time if one compares this to review of a patent application at the U.S. Patent and Trademark Office, which may

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[372] Laurence J. Kotlikoff, *Stimulating Innovation in the Biologics Industry: A Balanced Approach to Marketing Exclusivity*, B.U. (Sept. 2008), http://people.bu.edu/kotlikof/New%20Kotlikoff%20Web%20Page/Kotlikoff_Innovation_in_Biologics21.pdf.

[373] *Id.*

[374] JUDITH A. JOHNSON, CONG. RESEARCH SERV., FDA REGULATION OF FOLLOW-ON BIOLOGICS (Apr. 26, 2010), http://primaryimmune.org/ advocacy_center/pdfs/health_care_reform/Biosimilars_Congressional_Research_Service_Report.pdf.

[375] *See* Nat'l Fed'n of Indep. Bus. (NFIB) v. Sebelius, 132 S. Ct. 2566 (2012).

[376] Correspondence with Anil Bhalani, *supra* note 69.

take years.[377] While the patent is pending, the product is typically already on the market. Unlike a product whose patent is pending, manufacturers of medical devices have to wait for FDA approval before they can place their product on the market. A skilled regulatory affairs specialist can prepare a 510(k) in about a week.[378] Why, then, does the FDA need 90 days to review it?[379]

Reducing the backlog may take some internal management to reduce unnecessary work, find efficiencies, and coordinate cross-departmental functions to facilitate scheduling and create harmony.[380] This is a practical, realistic, and worthwhile effort. If regulatory review could be reduced to 30–60 days, it would motivate industry participants to increase compliance efforts and improve the perception of the FDA.[381]

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 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

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[377] Dennis S. Fernandez & James T. Huie, *Strategic Balancing of Patent and FDA Approval Processes to Maximize Market Exclusivity*, ASIA PAC. BIOTECH NEWS (2003), http://www.iploft.com/PTO-FDA.pdf.

[378] Correspondence with Anil Bhalani, *supra* note 69.

[379] *Id.*

[380] *Id.*

[381] *Id.*

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.

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 examine their efforts under a different lens. It is recommended that the legislative calculus consider a more targeted focus on the concepts of consumer access, actual use, self-treatment, and the unauthorized practice of medicine. Each concept 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. 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.