THE FDA GUIDANCE DOCUMENT FOR MEDICAL MOBILE APPS AND ITS IMPACT ON INNOVATION: BRINGING THE PROMISE OF A NEW WAY TO LOOK AT MEDICINE CLOSER, OR PUSHING IT FURTHER?

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INTRODUCTION

Six years after the launch of the iPhone, it is almost impossible to conceive what our lives would be like without our mobile devices.1 And, regardless of your field of interest, chances are “there’s [at least] an app for that.”2 According to Portio Research, 1.2 billion people used mobile apps worldwide in 2012 and approximately 4.4 billion people will be using mobile apps by 2017.3 While the total number of apps currently out on the market is hard to calculate, there are over 1,600,000 mobile apps only between Apple’s App Store and Google’s Play Store.4 Mobile apps are no longer limited to games, but have also become players in fields such as education and medicine. The World Health Organization defines mobile health as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring

* Case Western Reserve University School of Law, JD 2015. I would like to thank Professor Raymond Ku and Professor Ruqaijah Yearby for their guidance and encouragement, as well as the editors of JOLTI for their support during the publication process.


2. THERE’S AN APP FOR THAT, Registration No. 4091498 (a trademark owned by Apple implying that for any task or purpose, there is an app for that task or purpose).


The FDA Guidance Documents for Medical Mobile Apps and its Impact on Innovation

There are currently over 43,000 healthcare related apps in the iTunes store alone, and, according to Research2Guidance, 500 million people will be using healthcare mobile applications in 2015 globally. This Note critiques the guidance document released by the Food and Drug Administration (“FDA”) in connection with the medical mobile apps it intends to regulate and the regulations that govern medical mobile apps. Specifically, the main argument of this Note is that, while the document is clearly a step in the right direction, significantly more guidance, focused on the characteristics of this new field, such as the rapid change of mobile technology, and on the transformational impact on healthcare of health IT in general and mHealth in particular, should follow soon. Part I provides an overview of the guidance document, with a focus on the FDA’s attempt to find the right balance between regulating apps that could potentially be harmful, and trying to promote innovation. Part II reviews the FDA regulations for medical devices in general, which the FDA used in its guidance document for medical mobile apps. Part III discusses ambiguities in the guidance document, the difficulties mobile app developers may encounter in trying to comply with it, the huge gap between the ability of conventional medical device manufacturers and that of medical mobile app manufacturers to go through the premarket approval process, and how the way the FDA intends to regulate medical mobile apps may ultimately impact innovation in the field. Part IV looks at potential solutions to improve the current regulations and strike the balance between ensuring safety and supporting innovation, and argues for a change in the way the FDA approaches regulation of mobile medical apps, which should incorporate a clear reflection of a field that is constantly evolving at a very fast pace, with very different players than the traditional medical device manufacturers, and for which a 40-year old framework is simply outdated.

I. THE PROBLEM: MOBILE APPS AS MEDICAL DEVICES

A. Mobile Apps.

The Federal Food, Drug, and Cosmetic Act defines a medical 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, or … intended to affect the structure or any function of the body.”

Before the world could even comprehend the idea of mobile apps as medical devices, the first mobile apps were built by handset manufacturers and carriers, and were part of the pre-installed software stack. And while people who bought the same headset used to have the same exact device, no two people today have the same exact mobile phone because as soon as they get the device they are able to customize it based on their needs, interests and preferences. Nowdays, most of us also know someone who has built or is thinking about building an app. The change was driven by how mobile devices have evolved in terms of technology advancements, by manufacturers understanding the importance of giving access to the internal design of handsets, and by the emergence of proprietary platforms such as iOS and Android, on which developers can freely create apps not just for smartphones, but for a plethora of mobile devices. With over “one billion active smartphones and tablets [currently being active] globally, … [analysts] expect [the number] to reach two billion in 2014.”

Using mobile health related apps was a natural progression for today’s consumers, who have been leveraging the Internet for years to look up medical information online. According to Pew Internet and America Life Project, 81% of American adults use the Internet, and 72% of Internet users looked online for health related information within the past year. As of April 2012, 19% of smartphone owners had downloaded an app specifically to track or manage health. We use our mobile devices to connect to our friends, our families, our business partners, so using them to connect to our healthcare providers and manage our health is only logical. As concluded by the GSM Association “[mHealth] solutions can help healthcare providers deliver better, more consistent, coordinated and more efficient healthcare, where and how it is needed, increase access to health services to remote or under-served communities and empower individuals

to manage their own health more proactively and effectively.”

By 2017, according to Research and Markets, half of the 3.4 billion smartphone or tablet users worldwide will use mobile health apps.

“[T]he use of mobile devices in the delivery of healthcare and in obtaining healthcare knowledge [has become] ubiquitous.” In light of the Affordable Care Act, mobile devices are also one of the most promising tools in achieving an important goal of Accountable Care Organizations, by reinforcing the best behavior in patients, reducing costs, and shifting the focus from just treatment to wellness and prevention. Mobile devices and the mobile apps they allow us to use are ideally suited to take healthcare outside of the hospital environment and begin a new age of remote medicine that has the potential to drive healthcare costs down while empowering the patients to become engaged in their health and wellness.

In 2012, there were 828 companies in the high tech medical device industry, generating over $60 billion, and employing over 88,000 people, and the top three companies (Medtronic, General Electric, and St. Jude Medical) controlled 32% of the market share. By contrast, according to the Wall Street Journal, the average app developer today is 29 years old or younger, 40% of app developers work alone, while 27% work at 2-3 person firms, with 34% making less than $15,000 from app development, 65% making less than $35,000, and only 12% making $100,000 or more.


15. Paul De Muro, Mobile Medical Applications and the Affordable Care Act, THE LUND REPORT (Dec 2, 2013), http://www.thelundreport.org/content/mobile-medical-applications-and-affordable-care-act (arguing that “under health reform, facilitated by the Affordable Care Act, (ACA) many can envision that mobile medical apps will become increasingly important in this new patient-centered care environment).


18. Id.

On September 25, 2013, the FDA released its final guidance document pertaining to mobile medical apps it intends to regulate. While the FDA acknowledges that “[m]obile apps are unleashing amazing creativity, and [it] intend[s] to encourage these exciting innovations,” its guidance regarding mobile medical apps may slow down or deter the very innovation it intends to encourage. A summary of the guidance is provided below.

Most analysts welcomed the newly released guidance, as it brought much needed clarity compared to the draft guidelines released by the FDA back in 2011. Morgan Reed, the executive director for the Association for Competitive Technology said that the new guidelines prove that the FDA “recognized that they aren’t going to tell us how to innovate.” In theory, this should be good news for app developers and for the industry in general. However, the FDA applied the same approach it used in regulating medical devices in general to medical mobile apps, which could prove problematic and counterproductive in the long run. Part III discusses this in detail.

1. Apps That Are Not Medical Devices

The apps included under this category are apps that “could be used in a healthcare environment, in clinical care or patient management, but are not considered medical devices.” Since these apps are not considered medical devices, the FDA will not regulate them. The list of examples included in the guidance document by the FDA indicates that the apps most likely to fall under this category are educational and informational, and are “not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.” For example, these types of apps provide users and healthcare professionals with access to medical literature as well as commonly used reference information, can be training tools for healthcare providers, or help patients interact with their healthcare providers via different communications mechanism, as long as they are not intended specifically for medical use. If it simply informs or


24. *Id.*

25. *Id.*
educates, a healthcare related mobile app is not considered a medical
device, and the FDA will not regulate it.

2. Apps That Are Medical Devices but over Which the FDA Will
   Exercise Enforcement Discretion

   In the case of apps that may be considered medical devices, but pose a
low risk to patients, the FDA does not intend to enforce the requirements
under the Food, Drug and Cosmetic Act.26 These types of apps go beyond
information or education, and are mostly apps that allow patients to self-
manage their conditions, organize information related to their health, and
communicate with their health care providers, as well as apps that automate
simple tasks for health care providers.27 The key characteristic of the apps
included in this category is that they do not provide “specific treatment or
treatment suggestions.”28 Classified under this category are apps that track
the user’s use of medication or medical devices, collect data from these
medical devices (either electronically or data the use inputs manually),
track health episodes such as asthma attacks and hospitalizations, and
provide reminders and means to communicate with the user’s healthcare
providers. In using the apps that fall under this category, the user is
exposed to no risk or a minimal amount of risk, so the FDA will only
exercise enforcement discretion.

3. Apps That Are Medical Devices and over Which the FDA Will
   Exercise Regulatory Authority

   The FDA stated that it would focus its oversight on “medical mobile
apps that meet the definition of device in the Federal Food, Drug and
Cosmetic Act29 and are intended to transform a mobile device into a
medical device regulated by the FDA, or be used as an accessory to a
medical device regulated by the FDA.”30 The FDA explained that “[the]
intended use of a mobile app determines whether it meets the definition of
a ‘device.’”31 The intended use may be shown, for example, by “labeling
claims, advertising matter, or oral or written statements by [the persons
legally responsible for the labeling of devices], or by the circumstances that

26. Id. at 16
27. Id.
28. Id.
medical 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, or intended to affect the structure or any function
of the body of man or other animals ….”).
30. FDA, MOBILE MEDICAL APPLICATIONS GUIDANCE FOR INDUSTRY AND FOOD AND
31. Id.
the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.” 32 Therefore, the FDA will consider a mobile app a medical device if it performs the functions of a medical device. If an app performs a medical function (diagnosing or recommending a treatment for example), then the app is a medical device and therefore subject to FDA’s oversight.

In its guidance document, the FDA divided the types of medical mobile apps that will be subject to its oversight into three categories. 

*Mobile apps that are extensions of a medical device* are those mobile apps that connect to an existing medical device in order to control the device or display, analyze, or transmit patient-specific medical device data. 33 Such an app would be, for example, a mobile app that controls the inflation and deflation of the blood pressure cuff of a traditional blood pressure monitor. 

*Mobile apps that transform the mobile platform into a medical device through the use of attachments, sensors or display screens* will be required to “comply with the device classification associated with the transformed platform.” 34 Such an app would be, for example, a mobile app that performs the role of a blood glucose meter with a use of an attachment capable of reading blood glucose strips. 

*Mobile apps that become a regulated medical device (software) by performing patient-specific analysis, providing diagnosis, or treatment recommendations* are apps that are “similar to or perform the same function as those types of software devices that have been previously cleared or approved.” 35 Such an app would be, for example, a mobile app that uses patient-specific parameters to calculate or create a dosage plan for radiation therapy.

The FDA was responsive to the comments it received regarding the draft guidance published in July 2011, and, after collecting and analyzing input, it included multiple examples for each category, 36 to help app manufacturers navigate the guidance document and identify which category their apps will fall under. 37 In brief, the FDA will only regulate mobile apps that would qualify as medical devices, either on their own or in combination with an existent medical device. These apps will have to go through the same review system as the one the FDA has been employing for regular medical devices since 1976. Part II looks at the review system for medical devices.

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33. FDA, *supra* note 30, at 8.
34. *Id.* at 9.
35. *Id.*
37. Manos, *supra* note 22 (“[T]he guidance is chock full of anecdotes that provided better clarity”).
II. FDA REGULATIONS FOR MEDICAL DEVICES

The FDA has defined three classes of regulatory control for medical devices under the Federal Food, Drug, and Cosmetic Act. As indicated by the guidance document, mobile medical apps that will be subject to FDA’s oversight will be assigned to one of the three classes described below.

A. Class I

Medical devices classified under Class I are subject only to general controls. While general controls apply to all three classes, they are the only level of control that applies to medical devices in Class I. General controls for medical devices include device registration and listing, labeling requirements, records and reports, as well as good manufacturing practices. While general controls also include a requirement for premarket notification, FDA has exempted almost all Class I devices, with the exception of devices referred to as Reserved Devices, from the premarket notification requirement. General controls also mean that the manufacturer has to abide by the good manufacturing practice (“GMP”) requirements set forth in Title 21 of the Code of Federal Regulations.

Mobile apps that qualify as Class I devices will thus be subjected to general controls alone, and the vast majority will be exempt from the premarket notification requirement. A premarket notification, also referred to as a 510(k), “is a premarketing submission made to FDA to demonstrate that the device to be marketed is safe and effective by proving substantial equivalence (SE) to a legally marketed device (predicate device) that is not subject to Premarket Approval (PMA).” The document issued by the FDA with regard to mobile medical applications lists premarket notification under general controls required for Class I devices, without

38. 21 C.F.R. § 860.3(c) (2007).
39. 21 C.F.R. § 860.3(c)(1) (2007) (“A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness of injury”).
40. FDA, General Controls for Medical Devices (May 13, 2009), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm.
41. 21 C.F.R. § 807.81 (2007).
42. FDA, Medical Device Exemptions 510(k) and GMP Requirements (Jan. 20, 2014), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm.
43. 21 C.F.R. § 820 (2007).
44. FDA, How to Find a Predicate Device (Dec. 20, 2013), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm.
specifying the fact that most mobile medical apps that would be considered Class I devices would also be exempt from the premarket notification requirement.

The only indication that the premarket notification for Class I devices may not be an absolute requirement is the fact that it is listed as a stand-alone requirement for mobile medical apps in Class II.45 However, a medical mobile app in Class I may still be considered a reserved device, for which the premarket notification will not be waived. The FDA Modernization Act of 1997 explains in section 206 that “the exception … does not apply to any [C]lass I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any [C]lass I device that presents a potential unreasonable risk of illness or injury.” 46 Such devices remain subject to premarket notification. The mobile app manufacturer must consult the list of reserved devices to make sure the mobile app does not require premarket notification.

**B. Class II**

Medical devices classified under Class II are subject to general controls, special controls and premarket notification.47 Through the premarket notification, “[s]ubmitters must compare their 510(k) device to a similar legally marketed U.S. device.”48 The similar device is called a “predicate device,”49 and it can be a device that was marketed before May 28, 1976, a device cleared under the 510(k), a device that was down-classified from Class III to Class I or II, or a 510(k) exempt device.50 The predicate device does not have to be identical to the device in question. What the 510(k) must establish is substantial equivalence with the predicate device, which can be accomplished by analyzing the “intended use, design, energy used or delivered, materials, performance, safety, safety,

47. 21 C.F.R. § 860.3 (2007) (“A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance”).
48. FDA, *supra* note 44.
49. *Id.*
50. *Id.*
effectiveness, labeling, biocompatibility, standards, and other applicable characteristics.”

Grandfathered devices are those devices that were marketed prior to May 28, 1976, have not been significantly modified since then, and “for which a regulation requiring a premarket approval (PMA) application has not been published by FDA.”

C. Class III

Medical devices classified under Class III are subject to premarket approval. These are the highest risk devices. Any new device that was not marketed before 1976 or that cannot claim substantial similarity with a predicate device is automatically a Class III device as well. This is regardless of the level of risk posed by the device. A wholly innovative device that addresses issues traditional devices did not or were not able to address, would thus be classified as Class III, simply because of its novelty, even if it poses no risk or a minimal amount of risk for the patient.

Premarket approval is a great thing both for patients and for manufacturers. It ensures patients are using a device that has been thoroughly tested and deemed safe by the FDA, and it shields manufacturers from legal action. In 2008, the Supreme Court in Riegel v. Medtronic stated that medical device manufacturers are immune from liability for personal injuries as long as the FDA approved the device before it was marketed and it meets the Agency’s specifications. The Supreme Court’s decision in Riegel does not impact devices that were approved through the 510(k) process, but only those that got FDA premarket approval.

III. REGULATING MEDICAL APPS AS MEDICAL DEVICES

A. Problems with the Current Regulation

1. Mobile Apps as Class I Medical Devices

For the average app developer, consulting and understanding the steps he/she needs to follow to determine whether the app he is building will be regulated or not, and what he needs to do to abide by the FDA regulations may not be so easy, despite the newly released guidelines. Consider Breathometer, one of the first breathalyzers for smartphones. The portable device connects to any smartphone and “can transform your smartphone

51. Id.
52. Id.
53. 21 C.F.R. § 860.3 (2007) (“A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls … would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury”).
into a breathalyzer within seconds — helping you monitor your alcohol consumption, giving you the power to make smarter decisions when drinking.”

The keychain-sized device “plugs into the phone’s headphone jack and can connect to both Android and Apple apps [providing] … a way for people to check whether they’re too drunk to drive home.”

According to the FDA breath-alcohol test systems are medical devices. Breathometer qualifies as a medical app that will be the focus of FDA oversight. It is a mobile app that “transforms a mobile platform into a regulated medical device by using attachments, display screens, sensors, or other such methods.” Breathometer also qualifies as a Class I medical mobile app, subject to general controls, and it would also appear that it qualifies as a reserved medical device. Therefore, under the general controls specifications, Breathometer appears to be among the devices that are not exempted from the premarket notification requirement and will have to obtain the 510(k) clearance. Breathometer Inc. has registered Breathometer with the FDA, with the product code DJZ, which indicates under the “submission type” field that the device is subject to enforcement discretion.

There are two problems with how the guidelines for mobile medical apps apply to an app like Breathometer. First, the guidance document for mobile apps for which FDA intends to exercise enforcement discretion, “the FDA intends not to pursue enforcement action for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile app that meets the definition of a device in section 201(h) of the FD&C Act.” Thus, the app developer who sees Breathometer’s FDA submission could easily conclude that the FDA does not intend to pursue enforcement action for this category of mobile apps. Yet, a Breathalyzer is a Class I device, and the developer needs to comply with the general controls specified by the FDA. The app developer

57. 21 C.F.R. § 862.3050 (2007) (“A breath-alcohol test system is a device intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication”).
58. FDA, supra note 23, at 8.
59. Id.
62. FDA, CHRH 1741, MOBILE MEDICAL APPLICATIONS GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, 2013 WL 5634256 at *7, n. 18 (2013) [hereinafter MOBILE MEDICAL APPLICATIONS].
who wants to develop an app similar to Breathometer will likely be confused by the fact that the guidance document for medical mobile apps indicates that a mobile breathalyzer of this type would be the focus of the FDA’s regulatory oversight,\(^{63}\) while a search in the FDA’s database will reveal that the FDA seemingly only exercises enforcement discretion for medical devices with the product code DJZ.\(^{64}\)

The problem arises from the use of the term “enforcement discretion” by the FDA with two different meanings. In the first instance, as explained by the guidance document for medical mobile apps, enforcement discretion means that the FDA “does not intend to enforce requirements under the FD&C Act.”\(^{65}\) In the second instance, as used by the FDA under the DJZ product code, it means that the FDA will exercise enforcement discretion only with regards to the premarket notification requirement for some devices in Class I and Class II that qualify as “reserved devices.” While it appears that breathalyzers and other medical devices initially deemed “reserved devices” require 510(k) clearance, in December, 2011, the FDA released a guidance document instructing FDA staff that it intends the down-classification and exemption from the 510(k) requirement for a series of devices whose “safety and effectiveness … is sufficiently well established and they have sufficiently controlled risks that general controls are sufficient and a 510(k) review is not necessary.”\(^{66}\) Devices under product code DJZ were among those the FDA intends to take off the “reserved devices” list through an amendment.\(^{67}\) This confusion could lead the app developer to market his application, without complying with any of the general controls necessary for Class I, and thus violate the FDA’s guidance document for medical mobile apps.

A second problem is that, while the FDA intends to exempt devices such as breathalyzers from the premarket notification requirement, the list of “reserved devices” on the FDA’s website still includes all the devices originally listed in the “reserved device” category, indicating that all the “reserved devices” have to comply with the premarket notification requirement. If the app developer chooses this venue of research, he will likely go through the 510(k) clearance process, despite the fact that the FDA no longer enforces it for this type of devices. Given the profile of the average developer,\(^{68}\) and the type of resources available to the average

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63. Id. at *9 (providing that apps which transform the mobile platform into a regulated device are amongst the focus of FDA regulatory oversight).

64. FDA, Product Classification Database, supra note 61.

65. FDA, Mobile Medical Applications, supra note 62, at *10 (2013).


67. Id.

68. See supra Part I.
developer, this could either impose an unnecessary burden on the developer, or completely dissuade him from developing and marketing the app.

The Breathometer/breathalyzer example illustrates an instance where the information in the guidance document for medical mobile apps is insufficient and can lead the app manufacturer, who is the ultimate recipient of the document, to either waste resources or ignore the FDA’s requirements for the class of devices the app belongs to. The inconsistency of the term “enforcement discretion” and the lack of clarity in the newly released guidance document for medical mobile apps can thus lead to undesirable results that can ultimately discourage innovation. In the example of the mobile Breathalyzer, if the information provided by the FDA in the guidance document and on its website were consistent and clear, the general controls required under Class I should be fairly easily complied with by any app manufacturer. The system is more complicated for Class II devices, for which “general controls alone are insufficient to provide reasonable assurance of [their] safety and effectiveness.”

2. Mobile Apps as Class II Medical Devices

Mobile medical apps such as an electronic stethoscope or an ECG controlled through a mobile device would be classified as Class II devices. The manufacturers of the apps would thus have to go through the 510(k) clearance process before they are able to market the mobile medical apps. And while the process has been in place for a while and may appear to be streamlined for traditional medical devices, the same may not be true for mobile medical apps. Given the various new parameters mobile devices are able to track and use (such as location, spatial positioning, and a whole set of data that they can obtain in real time by connecting to the Internet wherever the user may be), the manufacturers of medical mobile apps that can incorporate and take advantage of them will likely not be able to easily find a predicate device. The process is lengthy, difficult, and expensive, and substantial similarity, while not requiring an identical device, can be difficult to prove.

A 2010 study by Stanford University and the National Venture Capital Association showed that “the average total cost … to bring a low- to moderate-risk 510(k) product from concept to clearance was approximately $31 million, with $24 million spent on FDA dependent and/or related activities.” For the traditional medical device manufacturer, big companies like Phillips or Omron, this would be part of the cost of doing

69. 21 C.F.R. § 860.3 (2007).
70. FDA, MOBILE MEDICAL APPLICATIONS, supra note 62, at *10 (2013).
business. But going back to the average app developer, this is unattainable for most, and improbable even if they manage to secure investment. According to a report by research-focused investment bank Rutberg & Company, between January and August 2013, fifty companies in mHealth have managed to attract venture capital funding of $310 million\(^\text{72}\), a significant increase from the same period in 2012. Still, this averages approximately $6 million per company, a number that is nowhere close to the expenses estimated by Stanford in connection with getting the FDA’s 510(k) clearance. While acknowledging the tremendous innovation that comes from startups in this field, Rajiv Chand, Managing Directors and Head of Research at Rutberg & Company cautions “that it is very difficult to grow companies within the sector and that although several companies are emerging as breakout leaders, most are struggling with adoption and/or revenue growth.”\(^\text{73}\)

Even considering that the financial obstacle could be surpassed, demonstrating substantial similarity could prove as much of a hurdle in the case of mobile medical apps. In a field that is constantly changing, time is of the essence. And the 510(k) can not only be a very difficult process, but it can also stretch past the 90 days the FDA estimates are necessary to determine substantial equivalency.\(^\text{74}\)

MIM, the first mobile medical app to get FDA approval,\(^\text{75}\) provides the perfect example. It took the company two and a half years to get FDA 510(k) clearance for an iOS viewer for CT and MRI images.\(^\text{76}\) While the company had gone through the 510(k) process before for different non-mobile devices, without any difficulties, tackling the 510(k) for a mobile medical device proved to be a different story.\(^\text{77}\) Not only did the FDA close the company’s submission for lack of “substantial equivalence to a predicate device,” although the company had used as predicate device one of their own viewing software,\(^\text{78}\) but the app “got bumped up to Class 3 Premarket Approval which is the same classification as high risk devices,

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73. *Id.*


76. *Id.*

77. *Id.*

78. *Id.*
like implants.” The company resubmitted the 510(k) application, worked towards addressing the FDA’s concerns, and eventually got the FDA clearance a year and a half after resubmitting. While interoperability and wide reach are essential in mHealth, the manufacturers of MIM decided to stick with iOS and not release an Android version as well, despite the fact that Android currently dominates the market. The decision was based on how difficult it was to get FDA clearance for the iOS app, and “it became a time and resource issue.”

Over the past ten years, the FDA has cleared about 100 mobile apps through the 510(k) process, and according to the FDA it has taken on average 67 days for an app to get clearance. This seems to be good news, given that the time for clearance was almost 30 days below the estimated 90 days, but the FDA does point out that the duration of the clearance process “depends on the complexity and functionality of the app.” While these numbers are encouraging at first sight, Stanford’s survey points out that technology companies in the US have experienced on average a wait time between 10 and 31 months to obtain the 510(k) clearance.

Mobile devices have brought about a variety of exciting new possibilities for patient care and wellness, but new can also be problematic in terms of conquering the 510(k). Introducing whole new functions that were not available on a predicate device, such as monitoring parameters in the user’s proximity, and taking them into account when giving the user feedback, can make it difficult for the app manufacturer to be able to claim substantial similarity with an existent predicate device. This also means, as proven by MIM’s example, that many app developers could find themselves walking a very fine line between having their device classified as a Class II or Class III device, not because of a high-risk app, but because of the novelty of the app’s features and capabilities.

3. Mobile Apps as Class III Medical Devices

Premarket approval (PMA) is the answer to a better, safer device. The overarching approach applied for medical devices in general encourages the right behavior, but there is a caveat. It only “speaks” to the traditional

79. Id.
81. Wodajo, supra note 75.
83. Id.
84. Id.
85. Makower, supra note 71, at 22.
manufacturer of medical devices – the big corporations such as Medtronic, Phillips etc. While especially in light of the Supreme Court’s decision in *Riegel*, medical device manufacturers are encouraged to go after premarket approval, the process is complicated and expensive. As part of the premarket approval process, manufacturers are required to submit clinical data supporting the application and the process of gathering this data requires the types of financial and logistic resources that the average app developer does not possess.

Getting PMA approval is a time consuming process, which can be a major obstacle for a technology company. According to Stanford University’s study, while the FDA reported PMA review time is 9 months, it took survey participants on average 54 months to obtain PMA approval from the FDA. According to the same study, “the average total cost from concept to approval [for a PMA] was $94 million, with $75 million spent on stages linked to the FDA.”

By definition, Class III equals innovation – any new device that has not been marketed and does not have a predicate device would be classified as a Class III device. It also provides the ideal scenario for a business to be innovative – innovation will be rewarded once the device obtains the premarket approval and becomes immune to legal action for personal injury, which has put a huge number of manufacturers out of business (see silicone implants, or facial prosthetics in the 1980s and 1990s). But companies leading the space of traditional medical devices are large corporations. Any start-up that develops mHealth apps would probably love to go after premarket approval and benefit from the protection offered by the decision of the Supreme Court in *Riegel*, but the vast majority simply cannot. For the average app developer, premarket approval is a prohibitive process and, in virtually all situations, not a real option.

**B. Effects of FDA Regulation on Innovation**

While the FDA stated that it intends to foster innovation in the promising field of medical mobile apps, the guidance regarding mobile apps does not live up to that goal. It is great news that the FDA does not intend to regulate certain types of health related mobile apps, but the document it released in September 2013 applies a medical device “cookie-cutter” approach to mobile medical apps, which is hardly the type of solution that will encourage app developers to innovate. As history proves, many times it is not big corporations that drive innovation, but start-ups. Microsoft, Apple and Google were all started by a handful of people in a garage office. The game-changers in the field of mobile medical apps can be anybody from a computer-science college student, to a doctor, or a small

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86. *Id.* at 23.
87. *Id.* at 28.
company with a couple of employees. Almost none of these app developers would have the necessary resources to go through the lengthy and exorbitant premarket approval process.

Mobile medical apps would likely be classified as a Class III device simply because of the degree of innovation manufacturers are able to incorporate, not because they are all life-threatening devices. A mobile app that would control a pacemaker, or other implantable devices, would most likely qualify as a Class III device and would have to undergo the PMA process. But what should qualify a mobile medical app as a Class III device should only be the level of risk to patients, not its sheer novelty. In the current approach employed by the FDA, which “emphasizes risk over benefit,” a mobile medical app that would perform the features of a blood pressure monitor, and therefore could go the 510(k) route, but that can also take into account parameters such as humidity, temperature, altitude, and activity level when analyzing the results of your blood pressure readings, would likely have to go through the PMA process. Just because a predicate device couldn’t employ these features at the time, should not be reason enough to delay the timely development of such medical mobile apps that would not only be an incredible improvement on existent traditional medical devices, but could also provide patients with vital life-saving information in a timely manner. What are the consequences if there is no change? App developers would either be tempted to cut features, so they could go after the 510(k) clearance and avoid the PMA, or not develop the medical app at all, as the PMA would appear as an insurmountable hurdle. The end user is the one who stands to lose the most.

In an interview with the Baltimore Sun, Chris Bergstrom, Chief Strategy and Commercial Officer with mobile medical app developer WellDoc, pointed out that developers will have to decide “whether they want to seek FDA approval for something that will diagnose or help treat a disease, or if they will develop something geared towards entertainment and wellness.” Similarly, Orrin Franko, doctor, app developer and founder of the Journal of Mobile Technology in Medicine, told USA Today that “app developers with products that are not strictly medical … may avoid making medical claims in their marketing in order to skip the FDA process.” The financial incentives are pointing developers away from


going after FDA approval, as “going from zero to mobile application is often not the most straightforward, or even worthwhile, road.”92

Technology is fast moving and the FDA is historically the opposite of that. That is one of the reasons that created the confusion regarding enforcement discretion and how it would apply in the case of breathalyzers discussed in Part II.93 The initial draft released by the FDA in 2011 brought more confusion than clarity.94 The agency did manage to clarify some of the confusion with the newly released document (it clarified FN 13 that referred to apps over which FDA would exercise enforcement discretion as mobile medical apps; it provided more examples for each category of apps, and changed its opinion regarding some apps that perform basic clinical analysis such as an Apgar score app, which under the draft guidance would have been regulated, but under the final guidance document will not).95 However, it took the FDA two years to come up with the final document, and the biggest flaw of the document is that it treats apps as it would traditional medical devices, without taking into account the particularities of the industry.

Mobile medical app developers spoke before the House Subcommittee on Health and Technology in June 2013 about the obstacles they face, especially from a regulatory standpoint, warning Congress that “[w]ith the possibility of unintended consequences disproportionately affecting small businesses, it’s important for Congress to move carefully when making changes that affect health care mobile technologies.”96 As the final


92. Chris Wiltz, Pick a Good Problem: Mobisante’s Approach to Mobile Health, MOBILE DEVICE AND DIAGNOSTIC INDUSTRY ONLINE (Nov. 5, 2013), http://www.mddionline.com/article/pick-good-problem-mobisantes-approach-mobile-health (providing author’s suggestion for developing an mHealth application or device within the small space granted by the FDA).

93. The decision to take a number of devices off the reserved devices list was reached in 2011, but it still hasn’t been made the law, which explains why all those devices still appear on the reserved list indicating that 510(k) clearance is required.

94. Scott D. Danzis & Christopher Pruitt, Rethinking the FDA’s Regulation of Mobile Medical Apps, 9 THE SCITECH LAWYER, no. 3, 2013, at 26, http://www.cov.com/files/Publication/56c8d97e-4432-4623-b81c-1230545cc204/Presentation/PublicationAttachment/cb8b13fe-9b8f-4de4-b8d3-15096d3b25be/Rethinking_the_FDA’s_Regulation_of_Mobile_Medical_Apps.pdf (describing the FDA’s historic policies on software and puts forth draft guidance on mobile medical apps, suggesting a balance regulatory approach).

95. Id.

96. Chris Wiltz, Medical App Developers Tell House Committee of Major Challenges, MOBILE DEVICE AND DIAGNOSTIC INDUSTRY ONLINE (Jul. 2, 2013), http://www.mddionline.com/article/medical-app-developers-tell-house-committee-major-challenges (relating content from when mobile medical app developers spoke before the House Subcommittee on Health and Technology about challenges they face bringing their products to fruition).
document had not been released yet, the small business representatives stressed during the same meeting the “immediate need for clear, comprehensive FDA guidance.” 97 Once the document was released, health IT groups welcomed it, but also pointed out its flaws.

Joel White, Executive Director of the Health IT Now Coalition, explained that “many app developers are not opposed to regulation, but they believe the FDA process, [which was created when the floppy disk was around,] doesn’t fit the industry.” 98 The Health IT Now Coalition stated in a news release that the FDA “endorsed an old framework,” 99 and that “the administration and Congress ought to work together on updating the 1970s era law to meet the needs of the 2013 … mobile health community.” 100

The mHealth Regulatory Coalition, while welcoming the much-needed FDA guidance, pointed out that “the final guidance is fundamentally like the proposed guidance [of 2011], and omits some very important areas.” 101 Members of the Digital Health Coalition voiced the same concerns. Marc Monseau, Managing Partner with Mint Collective referred to the questions left unanswered by the document, “[in] particular, … [the lack of] a precise definition of which app will be regulated, [and] … the exact meaning of an accessory to a medical device.” 102 Robert Palmer, Managing Partner with Juice Pharma Worldwide, expressed the same concerns that seem to pervade the mobile medical app field: “potential unintended consequences that could inhibit innovation and add to the time and expense of bringing new apps to market.” 103

A lot of questions still remain. What happens when the manufacturer of a completely new medical mobile app obtains premarket approval, and then releases an update to the app? Does he have to get a 510(k) clearance for every update? What if the new update introduces completely new features that impact the ability to claim substantial similarity? Even when referring to software updates to traditional medical devices, the FDA

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97. Id.
98. Gold, supra note 91.
100. Id.
103. Id.
seemed to indicate that it is difficult to say when a new 510(k) is needed. Mobile apps are different. Frequent updates are a staple of any existing mobile app. Updates are not triggered just by the constant advancement of technology in the field of mobile devices, but also by the ease with which a mobile app can be modified and updated. Traditionally, a modification in a medical device is a process that can take years, while a developer can change a mobile app in a matter of hours. Mobile apps are “updated and created on a daily basis, …[and the] lifecycle [of a mobile app] is dramatically different.”

Treating health-related mobile apps the same as medical devices hampers app developers in the US and foreign app developers who would like to enter the US market. In the end, by blocking or delaying innovation, the ones who will suffer the most will be US consumers. But the Internet provides patients with access to apps that the FDA does not reach. This is a high risk, both for consumers and app developers. Where app developers outside the reach of the FDA become the main provider of mHealth solutions for US patients, and patients end up using apps that are potentially not subject to any kind of safety regulation, consumer safety is a big issue. At the same time, the FDA’s slow response time, lack of transparency, and its increasingly risk-averse attitude towards new products makes it more difficult for US producers to compete with foreign producers, and provides incentives for US companies to launch and market their apps on foreign markets for a quicker and safer return on investment.

While testifying in front of the U.S. House of Representatives in September 2011, Sharon Stevenson, on behalf of the National Venture Capital Association, emphasized that as a consequence of growing regulatory challenges “[w]e are seeing [investors] moving away from [life sciences companies] … [and] sending private investment dollars previously dedicated to U.S. companies to start ups overseas, or [making plans] to commercialize their products outside of the U.S., …as genuine ongoing businesses.” Stevenson cited “the uncertain regulatory environment of the FDA” as the number one factor contributing to the decrease in venture capital investments in the development of new therapies and technologies related to life sciences. The lack of available funding in life sciences has had a significant impact on biotechnology startups especially.

104. See Department of Health and Human Services, Office of Device Evaluation, 510(k) Memorandum #K97-1, Food and Drug Administration: Deciding When to Submit a 510(k) for a Change to an Existing Device (Jan. 10, 1997), available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm (“The major difficulty lies in sorting out which of these changes is significant enough to trigger the need for a 510(k)”).

105. Gold, supra note 91.

106. Makower, supra note 71, at 24-25.

107. See Stevenson, supra note 89.

108. Id.
which, like mobile app development companies, tend to have fewer resources than large players. As a direct consequence of the decline in venture capital investments, “[t]here were only 15 first-time biotech financings nationally in the third quarter of 2012, which continued[d] a year long decline.”\footnote{109} Carl Weissman, the CEO of Accelera\tor, a venture-backed biotech incubator, called 2012 “the saddest period in biotech.”\footnote{110} As exciting as the new field of mHealth is, if the regulatory hurdles discouraged investors from backing biotech companies, the same fate awaits mHealth players, who desperately need funding to be able to take on the “FDA challenge.”

IV. Solutions

While the FDA was praised for not telling us how to innovate,\footnote{111} the FDA has not told us nearly enough about health-related apps to reach the goal of both protecting consumers and supporting innovation. The guidance document should not just mimic the system used for medical devices. While the FDA has had a sinuous history in its attempt to regulate software,\footnote{112} it cannot simply address this using a cookie-cutter approach. There is an argument that following the existing approach allows developers to at least consider how the FDA has treated medical devices in the past, and provided the FDA with a solution to keep its promise and deliver the final document before the end of 2013, the document in its current form should only be a temporary solution. It provided answers to some questions, it clarified some aspects that were not clearly defined in FDA’s 2011 attempt, and it was overall a positive move for the developer community that had dealt with a lot of uncertainty in the recent years, and more questions than answers. And while positive effects such as “more money, resources and energy devoted to the development of mobile apps,”\footnote{113} will soon follow or have already started to show, the FDA will have to embrace and be able to reflect change in order to be able to keep its promise and encourage innovation.

Some stakeholders have suggested that medical mobile apps should be treated as a separate new category with its own rules that take into account the realities of the software development industry. Joel White, executive director of the Health IT Now Coalition suggested that “the government set up a new regulatory framework for mobile health – something like the National Transportation Safety Board – to accommodate the speed, flexibility and innovation on this new marketplace.”\footnote{114} Not everyone agrees


\footnote{110. Id.}

\footnote{111. Manos, supra note 22.}

\footnote{112. See generally Danzis, supra note 94.}

\footnote{113. Digital Health Coalition, supra note 102.}

\footnote{114. Gold, supra note 91.}

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with this approach, though. In a white paper by Epstein Becker & Green, member of the mHealth Regulatory Coalition, the law firm argues that “as technology and the marketplace move toward convergence, [it] would be a terrible time for regulation to move toward divergence.” However, there is no denying that health IT is changing the face of healthcare as we know it, and this change needs to be reflected in the regulatory framework fast.

Before any structural change is implemented, a quick fix would be to elaborate in order to simplify, by expanding right away on the current guidance document and specifying which mobile medical apps would be considered Class II or Class III devices. The Agency should follow the same approach that was used to down-classify some medical device data systems from Class III to Class I, in order to prevent the absurd situation where an innovative mobile medical app that poses no risk to patients would be classified as a Class III device by default because of its novelty and capabilities.

As pointed out by the National Venture Capital Association, the “adoption of a more flexible benefit-risk paradigm [would allow for] differentiation in the level and amount of evidence required.” The NVCA also urges the FDA to adopt a “qualitative framework for benefit-risk assessment … that incorporates robust input from stakeholders, including patients and consumers.” A more flexible risk-benefit paradigm would definitely have a positive impact on the approval process for mobile medical apps as well.

Another option to speed up the process and support developers would be to implement new premarket approval requirements for mobile medical apps, which should be very different than the ones used for traditional medical devices. “[Developers] thrive in an environment in which change is constant …, and changing that culture and environment by imposing regulatory obligations that would dramatically lengthen the product lifecycle would have a tremendous stifling impact [on them].” This field, which is constantly changing and evolving, cannot be forced successfully into a regulatory scheme created over 40 years ago. A possibility to try to close the gap would be to create a version of the 510(k)...


116. Medical Device Data Systems, 76 Fed. Reg. 31, 8637 (Feb. 15, 2011) (codified at 21 C.F.R. § 880) (Reaching the conclusion that “general controls provide a reasonable assurance of safety and effectiveness for this device type,” the FDA reclassified medical device data systems from Class III (subject to premarket approval) to Class I (subject to general controls) on February 15, 2011).

117. See Stevenson, supra note 89.

118. Id.

119. Id.
that is more responsive to the needs and realities of this market, as well as implement a system similar to the Accredited Persons Program used to improve the efficiency and the timeliness of the 510(k), 120 where the accredited partners would be centers that are able to test and approve the apps, in a simpler and faster manner than the premarket approval process used for medical devices. This is an exciting new field, and these are “transformational times in American health care,” 121 which offer a great opportunity for the FDA to “take a decentralized for profit approach to mobile health application approval.” 122

Regardless of how it does it, the FDA will have to start implementing the kind of changes that prove it understands the extraordinary role it plays in the success of modern healthcare, which is more and more focused around e-health.

CONCLUSION

The FDA guidance document for medical mobile apps is a step in the right direction that analysts welcomed. Nevertheless, the field of mHealth requires more guidance specifically tailored to respond to the needs of the players driving this field forward, and ultimately respond to the needs of the modern patient. The guidance document is still too ambiguous and the examples it includes are not enough to answer all the questions app developers might have regarding whether or not the FDA will regulate their apps. This ambiguity may ultimately lead to stifling the innovation the FDA wants to promote, through a self-policing process that, together with the limited resources available to the average mobile app developer, may result in an over-simplification of medical mobile apps or even in developers delaying or deciding not to develop complex medical mobile apps altogether, to the detriment of the end user.

While applying the same approach it took to regulating traditional medical devices to medical mobile apps offered the agency a fast solution to start the conversation about medical mobile apps, the FDA needs to continue this conversation by listening to all stakeholders, including doctors and patients, and working closely with other agencies, such as the FCC, to develop a coherent regulatory framework for mHealth, one that recognizes the significant differences between medical mobile apps and traditional medical devices. Working towards the goal of promoting innovation, while ensuring patient safety, the FDA should provide


121. Wiltz, supra note 96 (quoting Keith Brophy, CEO of Ideomed).

developers not only with the proper regulatory framework, but also with the tools that would help them navigate it, and with solutions realistically tailored to put safe mHealth solutions in the hands of patients in the shortest time possible. Given the novelty of the field and the specific characteristics of mobile apps, the FDA should develop a platform focused on primarily assessing the risks related to medical mobile apps and create the premises to bring in entities with knowledge and expertise in the field of mHealth to evaluate and certify medical mobile apps in a manner that takes into account the realities of this new and exciting field. This would prevent situations where medical mobile apps that pose minimal or no risks to patients would be qualified as Class III medical devices simply because of the novelty of the features they incorporate, and would provide a solution that moves as fast as this new industry does, to the benefit of all players.