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Can You Diagnose Me Now? A Proposal to Modify the FDA's Regulation of Smartphone Mobile Health Applications with a Pre-Market Notification and Application Database Program

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CAN YOU DIAGNOSE ME NOW? A PROPOSAL TO MODIFY THE FDA’S REGULATION OF SMARTPHONE MOBILE HEALTH APPLICATIONS WITH A PRE-MARKET NOTIFICATION AND APPLICATION DATABASE PROGRAM

Stephen McInerney*

Advances in mobile technology continually create new possibilities for the future of medical care. Yet these changes have also created concerns about patient safety. Under the Food, Drug, and Cosmetic Act, the Food and Drug Administration (FDA) has the authority to regulate a broad spectrum of products beyond traditional medical devices like stethoscopes or pacemakers. The regulatory question is not if the FDA has the statutory authority to regulate health-related software, but rather how it will exercise its regulatory authority. In September 2013, the FDA published Final Guidance on Mobile Medical Applications; in it, the Agency limited its oversight to a small subset of medical-related mobile applications, referred to as “mobile medical applications.” For the Final Guidance to be effective, the FDA must continue to work directly with all actors—including innovators, doctors, and patients as the market for mobile health applications continues to develop. This Note argues that the FDA should adopt a two-step plan—a pre-market notification program and a mobile medical application database—to aid in the successful implementation of its 2013 Final Guidance. By doing so, the FDA will ensure that this burgeoning market can reach its fullest potential.

INTRODUCTION 1074

I. MOBILE HEALTH APPLICATIONS 1077

 A. *The Mobile Health Application Paradox* 1078

 B. *Low-Risk vs. Medium- or High-Risk Applications* 1080

II. THE FDCA: FDA’S STATUTORY AUTHORITY OVER MOBILE MEDICAL APPLICATIONS 1083

III. FDA REGULATION OF MOBILE APPLICATIONS 1089

 A. *Early Enforcement of the FDCA for Mobile Applications* 1090

 B. *The FDA’s Mobile Medical Application Guidance Documents* 1091

 1. 2011 FDA Draft Guidance 1091

 2. 2013 FDA Final Guidance 1093

 3. *Ambiguity in the Risk-Based Regulatory Scheme* 1096

IV. THE PROPOSED REFORM 1097

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A. *First Prong: Pre-market Notification Program* 1098
 B. *Second Prong: Mobile Medical Application Database* . . 1104
 CONCLUSION 1106

INTRODUCTION

After being told by her local doctor that she simply suffered from anxiety, Mary was at a loss as to why she still felt sick.¹ Traditionally, Mary’s only option would be to seek a second opinion from another physician. Instead, she turned to a mobile application: HealthTap+. Mary spent two hours on HealthTap+, at which point a doctor who contributed to the site suggested her condition may be a blocked artery.² She soon saw a cardiology specialist, who confirmed the diagnosis and inserted a coronary stent, which may have saved Mary’s life.³

Mary’s story is not unique. More and more people turn to their smartphones and medical-related applications, or mobile health applications for medical advice. The use of mobile health applications is revolutionizing healthcare delivery, both helping doctors treat patients outside of traditional healthcare settings and helping consumers manage their own health. A recent survey of the mobile application market shows at least 40,000 available medical-related apps, with a market size in 2013 estimated at \$6.3 billion.⁴ By 2018, the market size is projected to grow to a staggering \$20.7 billion.⁵

Mobile health applications vary widely in terms of scope and functionality: some are simply medical dictionaries, allowing users to understand health-related terminology,⁶ while others perform a more complex task for the user, such as scanning over-the-counter drug bar codes to check for medication interactions.⁷ These applications also target different consumers. Some applications are

1. Amy O’Leary, *An App That Saved 10,000 Lives*, N.Y. TIMES (Oct. 5, 2013), <http://bits.blogs.nytimes.com/2013/10/05/how-to-save-10000-lives-with-an-app-flatter-doctors/>.

The name “Mary” is used solely for the purposes of this Note.

2. *Id.*

3. *See id.*

4. Scott Rupp, *Mobile Health Apps and Solutions Market Worth \$20.7 Billion by 2018*, ELECTRONIC HEALTH REP. (Dec. 11, 2013), <http://electronichealthreporter.com/hit-news/mobile-health-apps-and-solutions-market-worth-20-7-billion-by-2018/>; Jenny Gold, *FDA Regulators Face Daunting Task as Health Apps Multiply*, USA TODAY (June 27, 2012), <http://usatoday30.usatoday.com/news/health/story/2012-06-22/health-apps-regulation/55766260/1>.

5. Rupp, *supra* note 4.

6. *See, e.g., Taber’s Medical Dictionary with Updates*, iTUNES, <https://itunes.apple.com/us/app/tabers-medical-dictionary/id301866347?mt=8> (last visited Mar. 20, 2015).

7. *See, e.g., Pharmacy On the Go*, CVS PHARMACY, <http://www.cvs.com/promo/promo-LandingTemplate.jsp?promoLandingId=mobile-pharmacy> (last visited Mar. 20, 2015).

geared towards the general public,⁸ some specifically to doctors,⁹ and others to both.¹⁰ The variety and complexity among these types of applications—which can operate on multiple mobile devices, from iPhones or Androids to iPad tablets—highlight the difficulties involved in regulating mobile applications.

Due in part to the novelty of the field and in part to the difficulty of promulgating regulations in general, the federal government has not typically regulated mobile apps. In September 2013, in response to confusion among application developers over regulation of mobile apps, the Food and Drug Administration (FDA or the Agency) published its Final Guidance for Mobile Medical Applications to explain its plans to regulate this quickly evolving industry.¹¹ Under the Food, Drug, and Cosmetic Act (FDCA or the Act), the FDA has the statutory authority to regulate “medical devices,”¹² a term that is broadly defined and includes “mobile medical applications.”¹³ The Final Guidance explained that the FDA will regulate mobile applications with a soft touch, limiting its regulatory oversight to “only those mobile apps that [qualify as] medical devices *and* whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.”¹⁴ The FDA termed this subset of mobile health applications “mobile medical applications.”¹⁵ Ultimately, the FDA is expected to actively

8. See, e.g., *Experience WebMD on the Go Via Your Smartphone or Tablet*, WEBMD, <http://www.webmd.com/mobile> (last visited Mar. 20, 2015) (providing users with an interactive tool to check their symptoms, access drug and treatment information, get first aid tips and check local health listing).

9. See, e.g., *Doximity—Physician Network*, iTUNES, <https://itunes.apple.com/us/app/doximity-physician-network/id393642611?mt=8> (last visited Mar. 20, 2015) (providing healthcare professionals with a tool for HIPAA-secure communication and electronic faxing).

10. See, e.g., *ASTHMAMD*, <http://www.asthmamd.org> (last visited Mar.20, 2015) (allowing users to track their asthma activity and share these activities with their physicians to be included in their medical records).

11. U.S. FOOD & DRUG ADMIN., *MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF* (2013), available at <http://www.fda.gov/downloads/MedicalDevices/. . ./UCM263366.pdf> [hereinafter FINAL GUIDANCE].

12. See 21 U.S.C. § 321(h) (2012).

13. See *infra* text accompanying note 15.

14. FINAL GUIDANCE, *supra* note 11, at 13 (emphasis added).

15. See *id.* “Medical mobile application” (or “medical mobile app”) is a term of art within the Final Guidance to describe applications that the FDA has determined qualify for regulation under its “medical device” regulatory authority. This is not to be confused with the term “medical health application” (or “medical health app”) used throughout this Note as a generic term for any mobile device application that serves a medical or health related function, irrespective of whether the application would qualify for regulation under the FDA’s “medical device” regulatory authority.

regulate less than twenty percent of all mobile health applications.¹⁶

The public response to the FDA's Final Guidance has been mixed. Many experts have lauded the FDA's restrained regulatory approach.¹⁷ Others, however, argue that the rule is still too restrictive on application developers.¹⁸ In February 2014, Senators Marco Rubio (R-Fla.), Deb Fischer (R-Neb.), and Angus King (I-Maine) proposed the Preventing Regulatory Overreach To Enhance Care Technology (PROTECT) Act¹⁹ to limit the FDA's regulatory authority over mobile health applications and to assign oversight of many applications to the National Institute of Standards and Technology (NIST), an agency without regulatory authority.²⁰ More specifically, NIST does not have authorization to actively regulate applications, and would not have the subpoena power necessary to investigate wrongdoing for any non-medical software or to criminally enforce existing regulations.²¹ Thus, even after the FDA issued its 2013 Final Guidance, policy makers continue to disagree as to the proper regulatory approach for mobile health applications.

This Note argues that although the 2013 Final Guidance is a good first step in balancing innovation and protecting users from unsafe mobile health applications, to aid in the successful implementation of the Final Guidance the FDA should adopt a two-

16. *Happtique Announces Inaugural Class of Certified Health Apps*, PR NEWSWIRE (Dec. 2, 2013), <http://www.prnewswire.com/news-releases/happtique-announces-inaugural-class-of-certified-health-apps-234063701.html>.

17. See, e.g., Christina Farr, *Congress Wants to Kick the FDA Out of Digital Health with this New Bill*, VENTUREBEAT (Feb. 26, 2014), <http://venturebeat.com/014/02/26/new-digital-health-bill-proposes-to-undermine-the-fda-draws-mixed-reactions/> ("The September [FDA Final Guidance] was greeted with relief and fanfare . . .").

18. See, e.g., Alison Diana, *Will Most Healthcare Apps Escape FDA Scrutiny?*, INFO. WEEK (Feb. 13, 2014), <http://www.informationweek.com/healthcare/policy-and-regulation/will-most-healthcare-apps-escape-fda-scrutiny/d/d-id/1113812>.

19. In the House of Representatives, Representative Marsha Blackburn (R-Tenn.) proposed similar legislation titled the SOFTWARE Act (H.R. 3303). See Press Release, King, Fischer Introduce Legislation to Protect Jobs, Prevent Overregulation in Growing Health IT Industry (Feb. 10, 2014), available at <http://www.king.senate.gov/newsroom/press-releases/king-fischer-introduce-legislation-to-protect-jobs-prevent-overregulation-in-growing-health-it-industry>.

20. See Farr, *supra* note 17; Press Release, King, Fischer Introduce Legislation to Protect Jobs, *supra* note 19.

21. Under the PROTECT Act, the FDA would retain authority over "medical software." See Stephanie Zeppa & Lauren Lewis, *Mobile Medical App Regulations on the Move —Proposed Bills to Further Alter the Regulatory Landscape of Mobile Medical Applications*, SHEPPARD MULLIN HEALTHCARE L. BLOG (Mar. 31, 2014), <http://www.sheppardhealthlaw.com/2014/03/articles/other/mobile-medical-app-regulations-on-the-move-proposed-bills-to-further-alter-the-regulatory-landscape-of-mobile-medical-applications/>; Farr, *supra* note 17 ("We are extremely concerned that this bill will deregulate a broad swath of medical devices that rely on software and will create opportunities for rampant 'gaming' to avoid regulation.").

pronged approach: (1) a pre-market notification program and (2) a mobile medical application database. The argument will proceed as follows: Part I will examine the breadth of the mobile health application market and explain that in order to be effective, the FDA's regulatory scheme must be able to adjust to an ever-changing market. This ability to evolve is essential to balance consumer safety and innovation. Part II will demonstrate that the FDCA provides clear statutory authority for the FDA to regulate a wide range of mobile health applications. Part III will contend that, while the 2013 FDA Final Guidance is a step in the right direction, it leaves both the FDA and application developers with minimal ability to anticipate future regulatory changes. Finally, Part IV will argue that implementing a pre-market notification program and a mobile medical application database would remove current and future uncertainty and better address safety concerns in this emerging market.

I. MOBILE HEALTH APPLICATIONS

Since the Ericsson GS88 launched in 1997,²² smartphones have developed far beyond simple telephonic functions and transformed into handheld computers. The first smartphones combined the functions of a personal digital assistant (PDA) with a mobile phone.²³ For example, smartphones were equipped with calendars, lists, and other task-oriented applications.²⁴ "Later models added the functionality of portable media players, low-end compact digital cameras, pocket video cameras, and GPS navigation [systems] to form one [unified] multi-use device."²⁵

The true advent of mobile applications ("applications" or "apps," as they are known today) did not occur until shortly after Apple Inc. developed the iPhone in 2007.²⁶ That summer, instead of restricting iPhone application development to its own in-house developers, Apple opened the floodgates for anyone—from a multi-

22. *History*, STOCKHOLM SMARTPHONE, <http://www.stockholmsmartphone.org/history/> (last visited Mar. 20, 2015).

23. See Horace Dediu, *The parable of the PDA: predicting the smartphone's future*, ASYMCO (Dec. 27, 2010), <http://www.asymco.com/2010/12/27/the-parable-of-the-the-pda-predicting-the-smartphones-future/>.

24. See *id.*

25. *Smartphone*, MASHABLE, <http://mashable.com/category/smartphone/> (last visited Mar. 20, 2015).

26. See Alex Krouse, *iPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 731, 734 (2012); 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>.

billion dollar company to a teenager in her parents' basement—to create a mobile application.²⁷ This shift led to the previously unimaginable proliferation of applications that exists in the marketplace today.²⁸ Within the first year, Apple's "App Store" offered 50,000 iPhone applications.²⁹ That number increased to 225,000 in 2010, and as of October 2014 is over 1.3 million.³⁰ Similarly, the App Store's main competitor, Google's Android Market, offers many similar applications for Android smartphones. Today, the Android Market offers over 1.5 million mobile applications.³¹

A. *The Mobile Health Application Paradox*

Mobile health applications present a difficult regulatory dilemma. On the one hand, by increasing the amount of health information available to consumers, these applications can help patients take control of their health and improve the delivery of medical care. For example, the University of Cambridge recently developed an application, Colorimetrix, which allows physicians to remotely monitor their patient's conditions, including diabetes, kidney disease, and urinary tract infections.³² After the patient uses a urine test strip, the application—not the physician—instantly analyzes a picture of the strip and generates a medical report.³³ Subsequently, this medical report and diagnosis can be emailed to a doctor for any necessary prescriptions.³⁴ Applications like Colorimetrix provide an especially useful service for patients in remote areas, where access to physicians is limited and patients may not otherwise receive such treatment.³⁵

27. See Press Release, Apple Inc., *supra* note 26.

28. See Krouse, *supra* note 26, at 733–35 (tracing the history of mobile applications and attributing the increase in mobile apps to a rise in mobile device usage and the development of online app stores).

29. See 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. 20, 2015).

30. *Id.*

31. *Number of Available Android Applications*, APPBRAIN, <http://www.appbrain.com/stats/number-of-android-apps> (last visited Mar. 20, 2015).

32. Mihir Patkar, *New Camera-Centric Smartphone App Puts Healthcare in Your Pocket*, THE DAILY BEAST (Mar. 28, 2014), <http://www.thedailybeast.com/articles/2014/03/28/new-camera-centric-smartphone-app-puts-health-care-in-your-pocket.html>.

33. *Id.* Although reviewed by a physician, the application still plays a vital role in analyzing the urine strip and generating a medical report for the physician to utilize.

34. *Id.*

35. See Darrell West, *How Mobile Devices are Transforming Healthcare*, ISSUES IN TECH. INNOVATION, May 2012, at 1, 8, available at <http://www.insidepolitics.org/brookingsreports/>

However, these benefits also come with risks. Users who rely on applications to partially or completely replace a professional physician may receive substandard treatment as a result. First, the application may issue an inaccurate diagnosis. For example, the iTunes application store is flooded with skin cancer diagnostic applications³⁶ that promise to “save your life!”³⁷ The majority of these applications are relatively inexpensive because they rely on a mathematical algorithm based on self-evaluation (without a clinician) to alert the user of a skin cancer “diagnosis.”³⁸ In a 2013 Journal of the American Medical Association (JAMA) study, a group of University of Pittsburgh dermatologists found that “three out of four smartphone applications incorrectly classified 30 percent or more of melanomas as un concerning.”³⁹ The study concluded that, “reliance on these applications, which are not subject to regulatory oversight, in lieu of medical consultation can delay the diagnosis of melanoma and harm users.”⁴⁰

Second, heavy reliance on medical diagnosis from mobile medical applications removes the possibility of secondary diagnoses. When a patient goes to see a physician for an ailment, the physician examines the patient’s overall health, including temperature, blood pressure, and other routine tests of vital signs.⁴¹ It is not difficult to imagine a situation where a patient goes to the physician for one ailment and leaves with a diagnosis for a second ailment lurking behind the same symptoms. A doctor would readily consider that second ailment, but a mobile app would necessarily miss it. Because mobile apps focus on a particular set of symptoms they may allow ailments to go undetected and undiagnosed.⁴²

mobile_health_52212.pdf (“Digital technology allows people to overcome the limitations of geography in health care and access information at a distance.”).

36. See, e.g., *Skin Prevention – Photo Body Map for Melanoma and Skin Cancer early detection*, iTUNES, <https://itunes.apple.com/us/app/skin-prevention-photo-body/id366657886?mt=8> (last visited Mar. 20, 2015).

37. See *id.*

38. See Iyatomi Hitoshi et al., *An Improved Internet-based Melanoma Screening System with Dermatologist-like Tumor Area Extracting Algorithm*, 32 *COMPUTERIZED MED. IMAGING & GRAPHICS* 566 (2008).

39. Joel A. Wolf et al., *Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection*, 149.4 *JAMA DERMATOL.* 422, 422 (2013).

40. *Id.*

41. See, e.g., *Medical Assistants: Taking the 6 Vital Signs*, EVEREST COLL., <http://medicalassistant.everestcollege.edu/articles/medical-assistants-taking-the-6-vital-signs> (last visited Mar. 20, 2015) (“There are usually six tests you’ll run at the start of every patient visit. They are: 1. Weight, 2. Temperature, 3. Pulse, 4. Blood Pressure, 5. Respiration, 6. Pain.”)

42. See, e.g., Nathaniel R. Carroll, *Mobile Medical App Regulation: Preventing a Pandemic of “Mobilechondriacs,”* 7 *ST. LOUIS U.J. HEALTH L. & POL’Y* 415, 427 (2014), available at <http://>

Today, over ninety percent of Americans have a mobile phone.⁴³ Fifty-six percent of people have smartphones that can utilize the most current mobile health applications.⁴⁴ This figure rose from only nineteen percent just three years ago.⁴⁵ Further, the percentage of the population with constant access to the Internet will continue to increase. Such “connected” Americans plan to use their mobile phones to monitor their health: today, according to a survey by CTIA and Harris Interactive, seventy-eight percent of Americans are interested in mobile health tools⁴⁶ and twenty-three percent believe that mobile health could replace doctor visits entirely.⁴⁷ By 2015, an estimated 500 million people worldwide will use a mobile health app.⁴⁸ This proliferation of use raises two competing concerns with mobile health apps: How can the government (1) promote increased access to mobile health solutions while (2) protecting consumers from the serious risks these applications may present?

B. Low-Risk vs. Medium- or High-Risk Applications

The best way to understand the capabilities of mobile health applications—and the health concerns that may require FDA regulation—is through examples. Some health applications, such as electronic health records or fitness apps, pose a low-health risk.⁴⁹ Other apps, such as those that directly involve diagnosis and treatment of patients, can pose a much higher health risk.⁵⁰ This already blurry conceptual line will likely become even more obscure as technology advances. Moreover, this definitional difficulty creates a regulatory paradox for the FDA.

www.slu.edu/Documents/law/SLUJHP/Archives/Vol7-2/Carroll_Article.pdf (“Many illnesses can manifest the same set of symptoms, but a complete diagnosis requires more than simply checking off boxes in a list; it requires learned intuition.”).

43. Lee Rainie, *Cell Phone Ownership Hits 91% of Adults*, PEW RESEARCH CTR. (June 6, 2013), <http://www.pewresearch.org/fact-tank/2013/06/06/cell-phone-ownership-hits-91-of-adults/>.

44. *See id.*

45. MOBI HEALTH NEWS, WIRELESS HEALTH: STATE OF THE INDUSTRY 2009 YEAR END REPORT 1, 5 (2009), available at <http://mobihealthnews.com/wp-content/Reports/2009StateoftheIndustry.pdf>.

46. *Id.* at 2.

47. *Id.* at 2–3.

48. Kevin Pho, *Health App Users Beware*, USA TODAY (Apr. 2, 2014), <http://www.usatoday.com/story/opinion/2014/04/02/medical-app-fitness-health-fda-technology-column/7224837/>.

49. *See Diana, supra* note 18.

50. *See Pho, supra* note 48.

Low-risk applications generally “store, organize, or track health information, or provide general disease management or health recommendations.”⁵¹ Such apps allow the user (generally the patient) to read about a medical condition or treatment, input his or her own data, and gather resources to make more informed decisions.⁵² Some examples of these applications include:

- **Epocrates**—which allows the user to review drug prescription and safety information, check potentially harmful drug-to-drug interactions, and identify a pill by its physical characteristics (e.g. color, size, etc.) and imprinted symbol.⁵³ Epocrates has more than one million active users, including fifty percent of physicians in the United States.⁵⁴
- **LactMed**—which aggregates all drugs and dietary supplements that may affect breastfeeding, includes information on the levels of such substances in breast milk and infant blood, and lists possible adverse effects in the nursing infant.⁵⁵ LactMed was developed by the National Library of Medicine’s Toxicology Data Network.
- **Microdex Drug Reference**—which purports to contain the “most trusted drug information” of any health and wellness application, including generic names, therapeutic class, black box warnings, dosages, adverse effects, and more.⁵⁶
- **MyFitnessPal**—which maintains a database of over five million foods and allows users to track their daily calorie intake.⁵⁷

Because of the limited capabilities of these apps, there is little risk that a user will be misinformed in a harmful way.

51. Sidley Updates, Sidley Austin, FDA Says it Will Not Actively Regulate Low-Risk Mobile Medical Apps (Oct. 1, 2013), <http://www.sidley.com/FDA-Says-it-will-not-Actively-Regulate-Low-Risk-Mobile-Medical-Apps-10-01-2013/>.

52. See *id.*

53. *Mobile Products*, EPOCRATES INC., <http://www.epocrates.com/mobile> (follow “Features” hyperlink; then follow “Pill ID” hyperlink) (last visited Mar. 20, 2015).

54. *Epocrates*, ANDROID APPS ON GOOGLE PLAY, <https://play.google.com/store/apps/details?id=com.epocrates&hl=en> (last visited Mar. 20, 2015).

55. *LactMed*, iTUNES, <https://itunes.apple.com/us/app/lactmed/id441969514?mt=8> (last visited Mar. 20, 2015).

56. *Free Micromedex Drug Reference*, ANDROID APPS ON GOOGLE PLAY, <https://play.google.com/store/apps/details?id=com.truven.druginfonative.customer> (last visited Mar. 20, 2015).

57. *Calorie Counter & Diet Tracker by MyFitnessPal*, iTUNES, <https://itunes.apple.com/us/app/calorie-counter-diet-tracker/id341232718?mt=8> (last visited Mar. 20, 2015).

In contrast to these low-risk apps, those that aim to replace the decision-making processes normally performed by medical professionals have the potential to present greater health risks, and transform an innocuous mobile device into a medical device that the FDA should monitor.⁵⁸ Some examples of these applications include:

- **Instant Heart Rate**—which takes the user’s heart rate by allowing the user to place her finger over the camera for several seconds.⁵⁹ The application acts as a medical “pulse oximeter” by tracking color changes in the light that passes through the user’s finger.⁶⁰
- **EyeNetra**—which purports to perform an eye exam from the user’s phone.⁶¹ The application, developed by researchers at the Massachusetts Institute of Technology, requires an add-on piece⁶² through which the user is instructed to look; EyeNetra will then indicate if the user is nearsighted, farsighted, or has astigmatism.
- **Isabel App**—which allows the user to enter symptoms and search a database of over 6,000 diseases.⁶³ While “not designed to provide a diagnosis . . . [Isabel will] provide you with a list of likely diagnoses to consider when you have doubt.”⁶⁴
- **iStethoscope**—which allows users to record their heartbeats and see their heart waveforms by “turn[ing] your iPhone into a stethoscope.”⁶⁵ iStethoscope can also display a phonocardiograph or send the recording and images to anyone, like a doctor, through email.

Although it may appear easy to separate these classes of applications, the dividing line between low- and medium- or high-risk applications becomes more complicated by how patients actually

58. See Sidley Update, FDA Says it Will Not Actively Regulate, *supra* note 51.

59. *Instant Heart Rate*, iTUNES, <https://itunes.apple.com/us/app/instant-heart-rate-heart-rate/id395042892?mt=8> (last visited Mar. 20, 2015).

60. *Id.*

61. *Eye Exam? There’s An App For That: Think of Device As “Thermometer for the Eye*, ABC 7 NEWS DENVER (Oct. 4, 2010), <http://www.thedenverchannel.com/lifestyle/health/eye-exam-there-s-an-app-for-that>.

62. The add-on piece costs two dollars. *Id.*

63. *Isabel*, iTUNES, <https://itunes.apple.com/us/app/isabel/id473503904?mt=8> (last visited Mar. 20, 2015).

64. *Id.*

65. *iStethoscope Pro*, iTUNES, <https://itunes.apple.com/us/app/istethoscope-pro/id322110006?mt=8> (last visited Mar. 20, 2015).

use the applications. Some facially low-risk applications provide users with information that informs their subsequent self-treatment, transforming seemingly innocuous applications into medium- or high-risk applications. For example, Cures A-Z is an application that purports to be a “free Comprehensive Medicine specialist in your pocket!”⁶⁶ The application contains a complete list of health conditions and their treatments in order for users to self-manage an illness. While at first glance this application appears to be a low-risk application, this categorization could shift if patients self-diagnose and self-manage their illnesses based on information collected from the application. As one user commented, “this app has provided . . . ways that I can help myself instead of running to the doc . . .”⁶⁷ Thus, patients can use this information not simply for their own knowledge, but to actually diagnose and treat their ailments.⁶⁸ Accordingly, a successful regulatory scheme should not rely on strictly risk-based categories; instead, it should account for the fact that patients may use applications in ways developers did not anticipate.

II. THE FDCA: FDA’S STATUTORY AUTHORITY OVER MOBILE MEDICAL APPLICATIONS

The term “FDA regulated medical device” evokes images of medical hardware, X-ray machines, pacemakers, thermometers, and stethoscopes,⁶⁹ rather than a mobile phone application that reads your heart rate.⁷⁰ The FDCA, nevertheless, grants the FDA the statutory authority to regulate all of these products—both hardware and software intended for use in diagnosing, curing, mitigating, treating, or preventing a disease or other condition⁷¹—as “medical devices.”⁷² The FDA, thus, clearly has regulatory authority over the software used to develop mobile medical applications.⁷³

66. *Cures A-Z*, iTUNES, <http://itunes.apple.com/us/app/cures-a-z/id297648638?mt=8> (last visited Mar. 20, 2015).

67. HayLady1, Comment to *Cures A-Z*, iTUNES, <http://itunes.apple.com/us/app/cures-a-z/id297648638?mt=8> (last visited Mar. 20, 2015).

68. See Krouse, *supra* note 26, at 743.

69. See *generally Is The Product a Medical Device?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm> [hereinafter *Medical Devices*].

70. See *Instant Heart Rate*, *supra* note 59.

71. See 21 U.S.C. § 321(h)(2) (2006).

72. See *id.* § 321(h).

73. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1754 (1996) (explaining that it is “virtually impossible to market a new medical product without FDA’s review and concurrence”); JUDITH A. JOHNSON, CONG. RESEARCH SERV., R42130, FDA REGULATION OF MEDICAL DEVICES 1 (2012), available at <http://>

The FDA's authority to regulate medical devices and software has evolved incrementally. In 1906, Congress created the FDA when it enacted the first major federal law governing therapeutic drugs.⁷⁴ At this point, beyond dental tools, the medical device industry included few products intended for prolonged application to, much less installation in, the human body.⁷⁵ Further, physician tools, limited to instruments like stethoscopes, did not pose risks beyond those associated with careless or untrained use.⁷⁶ As a result, medical devices were not thought to be "appropriate candidates for federal regulation."⁷⁷

During the Great Depression, social advocacy groups pioneered policies designed to protect consumers.⁷⁸ These efforts included the 1938 Food, Drug, and Cosmetic Act (the 1938 Act), which, for the first time, expanded FDA's authority to include the regulation of medical devices.⁷⁹ This expanded authority resulted in mixed success. In some instances, the FDA successfully contested the unproven therapeutic claims made by the creators and marketers of several "quack" devices, like the "Halox Therapeutic Generator" and the "Electreat Mechanical Heart."⁸⁰ However, the FDA still "had no authority to require the manufacturer of any device to prove the safety, much less the effectiveness, of its product."⁸¹ This lack of regulatory authority stymied many of the FDA's efforts to

www.fas.org/sgp/crs/misc/R42130.pdf ("Medical devices regulation is complex, in part, because of the wide variety of items that are categorized as medical devices.").

74. See JAMES HARVEY YOUNG, *THE MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH QUACKERY IN TWENTIETH-CENTURY AMERICA* 54, 242 (1967) (noting that the definition of drug in 1906 law left a large loophole for devices and that as a result, though "[d]evice quackery was ancient in America, . . . not until the 1938 law did the FDA secure authority to act against it."); Rodney R. Munsey, *Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years*, 50 *FOOD & DRUG L.J.* 163, 163 (1995) (noting the link between the rise in "quack medical devices" and congressional consideration of increasing the FDA's regulatory authority).

75. See S. REP. NO. 94-33, at 2-3 (1975) (cataloging some such items).

76. See Merrill, *supra* note 73, at 1801.

77. See *id.*

78. See *The 1938 Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/ucm132818.htm> (last visited May 10, 2015) [hereinafter *The 1938 FDCA*].

79. *Id.*

80. See *United States v. 22 Devices, More or Less, Halox Therapeutic Generator*, 98 F. Supp. 914, 917-18 (S.D. Cal. 1951) (condemning devices as misbranded); *United States v. 6 Devices, "Electreat Mech. Heart,"* 38 F. Supp. 236, 238 (W.D. Mo. 1941) (condemning the "Mechanical Heart" as misbranded); see also *United States v. One Device, Intended for Use as a Colonic Irrigator*, 160 F.2d 194, 200 (10th Cir. 1947) (sustaining action against "Tox-Eliminator").

81. Merrill, *supra* note 73, at 1802-03; see also H.R. REP. NO. 94-853, at 6 (1976); David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and its Substantive Provisions*, 6 *LAW & CONTEMPORARY PROBLEMS* 2, 23 (1939), available at <http://scholarship.law.duke.edu/lcp/vol6/iss1/2> ("It suffices here to say that the principal act prohibited

remove products with no value in the prevention or treatment of disease.⁸²

The FDA began to push for stronger regulatory authority over medical devices in the 1960s with the introduction of highly sophisticated medical technologies.⁸³ The FDA perceived the need for regulatory authority over leg braces and wheel chairs quite differently from artificial joints and heart pacemakers, which presented very different regulatory considerations.⁸⁴ In 1962, the FDA unsuccessfully lobbied Congress for an amendment to the FDCA that would have required pre-market proof of safety and effectiveness for medical devices. As a result of that failure, the Agency was left with only the 1938 Act's minimal enforcement tools.⁸⁵ Despite the failure of that amendment, a consensus grew among healthcare professionals, manufacturers, and FDA officials that the 1938 Act provided an inadequate framework to regulate medical devices.⁸⁶

After nearly a decade of debate on the proper regulatory system,⁸⁷ in 1976, Congress amended the FDCA with the Medical Device Amendments (MDA).⁸⁸ The lengthy amendments⁸⁹ broadly defined a medical device as:

“an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article,

by the statute is the introduction into interstate commerce ‘of any food, drug, device, or cosmetic that is adulterated or misbranded.’ ”).

82. See Merrill, *supra* note 73, at 1803.

83. See *id.*

84. See *id.*

85. See Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99, 106 (1989); Peter Barton Hutt, Richard A. Merrill & Alan M. Kirschenbaum, *The Standard of Evidence Required for Premarket Approval Under the Medical Device Amendments of 1976*, 47 FOOD & DRUG L.J. 605, 609–10 (1992).

86. The FDA successfully used the 1938 Act's expansive definition of “drug” to claim that certain diagnostic medical devices qualified as “new drugs” and required pre-market approval. For example, in *United States v. An Article of Drug . . . Bacto-Unidisk . . .* the Supreme Court upheld the FDA's determination that an antibiotic sensitivity disk, a product that never came into contact with the patient's body, was a “drug” subject to FDA regulation. 394 U.S. 784, 800 (1969); see Merrill, *supra* note 73, at 1805–06.

87. See, e.g., DEF'T OF HEALTH, EDUC. AND WELFARE, STUDY GROUP ON MEDICAL DEVICES, MEDICAL DEVICES: A LEGISLATIVE PLAN (1970) (describing a model for medical device legislation); Theodore Cooper, *Device Legislation*, 26 FOOD DRUG COSM. L.J. 165 (1971) (same).

88. Pub. L. No. 94-295, 90 Stat. 39 (1976) (codified in scattered sections of 21 U.S.C.); see also Gail H. Javitt, *I've Got You Under My Skin—and I Can't Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 49 FOOD & DRUG L.J. 553, 558–59 (1994); Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 FOOD & DRUG L.J. 183, 184 (1994).

89. The 1976 Amendments cover forty-five pages in the Statutes at Large. 90 Stat. 539-83 (1976). By comparison, the entire 1938 Act took up just twenty pages. See 52 Stat. 1040-59 (1938).

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 . . . or intended to affect the structure or function of the body.”⁹⁰

Analysis of this statutory definition often centers on the broad determination of an article’s “intended use.” To determine the intended use, the FDA looks at a product’s “labeling claims, advertising matter, or oral or written statements by [manufacturers] or their representatives.”⁹¹ Generally, an article—including software—is considered a medical device if it is intended for a medical purpose.⁹² The MDA, therefore, granted the FDA expansive regulatory power: the “intended use” modifier statutorily authorizes the FDA to regulate certain products based solely on their manufacturer’s advertising statements.⁹³

The FDA regulates medical devices based on a three-tiered risk analysis.⁹⁴ Under this classification system, the Agency determines the amount of pre-market and post-market regulation required by the FDCA. The three levels of control are:

- **Class I** devices necessitate the least regulatory control.⁹⁵ Producers of Class I devices can generally market those goods without any pre-market review.⁹⁶ Examples of Class I devices include tongue depressors, elastic bandages, and examination gloves.⁹⁷

90. 21 U.S.C. § 321(h) (2012) (emphasis added).

91. 21 C.F.R. § 801.4 (2015).

92. See Scott D. Danzis & Christopher Pruitt, *Rethinking the FDA’s Regulation of Mobile Medical Apps*, 9 THE SCITECH LAW. 3, 2 (2013), available at http://www.cov.com/files/Publication/56c8d97e-4432-4623-b81c-1230545cc204/Presentation/PublicationAttachment/cb8b13fe-9b8f4de4-b8d3-15096d3b25be/Rethinking_the_FDA’s_Regulation_of_Mobile_Medical_Apps.pdf.

93. The regulatory language for medical devices and drugs is identical. However, the level of regulation is much less strict for most devices. *Cf. id.* (explaining that articles intended as health and wellness devices—like treadmills—are not regulated as medical devices).

94. See *Regulatory Controls*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm> (the FDA did not complete the classification process until 1988); see also PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 751 (2d ed. 1992).

95. Class I medical devices are only subject to “general controls” that include registration of the company and device, and tracking the company’s activities. See *Regulatory Controls*, *supra* note 94.

96. See *id.*

97. See *Classification of Medical Devices*, LITRON INC., <http://www.litron.com/Classification-of-Medical-Devices.asp> (last visited Mar. 20, 2015).

- **Class II** devices represent an intermediate level of risk, and the FDA requires manufacturers to submit device-specific “special controls.”⁹⁸ The FDA classified over half of the pre-1976 devices as Class II, including X-ray machines, powered wheelchairs, and acupuncture needles.⁹⁹
- **Class III** devices entail the greatest risk and generally require pre-market approval,¹⁰⁰ a complex and expensive process that obligates the manufacturer to submit clinical data proving the device’s safety and effectiveness.¹⁰¹ This approval process resembles the procedures for new therapeutic drugs, which demonstrates the FDA’s view that medical devices can pose similar dangers to health.¹⁰² Examples of Class III devices include implantable pacemaker pulse generators and endosseous implants.¹⁰³

This three-tiered regulatory approach demonstrates a recognition of the need for a flexible, dynamic approach to medical device regulation.¹⁰⁴ The regulatory scheme “calibrate[s] regulatory requirements to the risks and uncertainties presented by specific devices.”¹⁰⁵ To this end, the MDA also gives the FDA the authority to set good manufacturing practice requirements for medical devices,¹⁰⁶ to ban worthless and dangerous products from the market,¹⁰⁷ and to require notification, replacement, or refund by makers of defective products.¹⁰⁸

Although software is not expressly discussed in the FDCA, the FDA “has long considered software products to meet the definition of a device when [the software is] intended for use in diagnosing

98. Class II medical devices are subject to “general controls” and “special controls” that include: performance standards, post-market surveillance, patient registries, special labeling requirements, pre-market data requirements, and guidelines. *See Regulatory Controls*, *supra* note 94.

99. *See Merrill*, *supra* note 73, at 1815; *Classification of Medical Devices*, *supra* note 97.

100. *See Medical Devices*, *supra* note 69.

101. In 2012, the fees for pre-market notification were \$4,717, whereas the costs for submitting a device for pre-market approval “can reach \$1,000,000, plus user fees of an additional . . . \$256,384. . . .” 21 C.F.R. § 880, *available at* <http://www.gpo.gov/fdsys/pkg/FR-2008-02-08/html/E8-2325.htm>.

102. *See Merrill*, *supra* note 73, at 1809.

103. *See Medical Devices*, *supra* note 69.

104. *See Merrill*, *supra* note 73, at 1806; *see also* DEP’T OF HEALTH, EDUC. AND WELFARE, STUDY GROUP ON MEDICAL DEVICES, *MEDICAL DEVICES: A LEGISLATIVE PLAN* (1970); Cooper, *supra* note 87.

105. *See Merrill*, *supra* note 73, at 1809.

106. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 520(f)(1)(A), 90 Stat. 539, 567 (1976) (codified as amended at 21 U.S.C. § 360j(f)(1)(A) (1994)).

107. *Id.* § 516.

108. *Id.* § 518.

and treating diseases and other conditions.”¹⁰⁹ In 1989, the FDA first addressed its statutory authority over software.¹¹⁰ In its Draft Guidance for the Regulation of Computer Products, the Agency asserted: “To the extent that computer products used in medicine are intended to affect the diagnosis and treatment of patients and thus are medical devices, the [FDA] must provide reasonable assurance that these products are safe and effective.”¹¹¹ While the FDA affirmatively declared its general statutory authority over software, the Agency announced that it would exercise enforcement discretion over many types of low-risk software, such as software that merely provided “traditional library . . . functions.”¹¹² According to one commentator, Dale Cooke, Vice President and Group Director of Digitas Health, “When FDA asserts that it will exercise regulatory discretion [over software], it is stating that (it) has the legal authority to enforce regulations, but that it is choosing not to do so.”¹¹³ Thus, even if the FDA chooses not to actively regulate certain software, this does not detract from its broad authority to regulate software as medical devices.¹¹⁴

The FDA’s historical approach to regulating stand-alone software emphasizes the Agency’s view that a more nuanced, lighter regulatory touch is appropriate. The 1989 Draft Guidance set a reserved regulatory approach to software; those standards stated that the FDA likely would not apply the FDCA to computer products “that are intended to involve competent human intervention before any impact on human health occurs.”¹¹⁵ Under this policy, the FDA exercises its discretion to withhold enforcement of the FDCA on such software as:

109. Danzis & Pruitt, *supra* note 92, at 2.

110. U.S. FOOD & DRUG ADMIN., FDA POLICY FOR THE REGULATION OF COMPUTER PRODUCTS: 11/13/89 - DRAFT 1, (1989), *available at* <http://www.softwarecpr.com/Docs/FDAsoftwarepolicy1989draft.pdf>.

111. *Id.*

112. *Id.*

113. *FDA Mobile App Guidance Focuses on Risk, Calls for “Enforcement Discretion,”* COAL. FOR HEALTHCARE COMM’N (Sept. 30, 2013), <http://www.cohealthcom.org/2013/09/30/fda-mobile-app-guidance-focuses-on-risk-calls-for-%E2%80%9Cenforcement-discretion%E2%80%9D/>.

114. Certain software systems are statutorily exempted from the FDA’s device authority. *See* 21 C.F.R. § 807.65(c) (1993) (exempting general purpose software, like spreadsheet and word processing software); 21 C.F.R. § 807.65(d) (exempting software manufactured by medical practitioners solely for their own practices); 21 C.F.R. § 807.65(f) (exempting software intended solely for use in nonclinical research, teaching, and analysis).

115. U.S. FOOD & DRUG ADMIN., *supra* note 110.

- software intended only for use to perform traditional “library” functions, such as storage, retrieval, and dissemination of medical information;
- software intended only for use in general accounting or communication functions; and
- software intended for educational purposes rather than for diagnosis or treatment.¹¹⁶

Conversely, the FDA applied the FDCA to software like laboratory information systems (LIS), as well as picture archiving and communications systems (PACS).¹¹⁷

The FDA never codified or formalized the 1989 Draft Guidance.¹¹⁸ In fact, in 2005 the Agency withdrew the 1989 Draft Guidance, and reiterated its longstanding policy that because of the “history, complexity, and diversity of computer systems and controlling software, it would be impractical to adopt one ‘software’ or ‘computer’ policy to address all computer and software medical devices.”¹¹⁹ The Agency continues to apply its general three-tiered risk analysis to these devices, which classifies different software systems as Class I and II medical devices, yet never as Class III devices.¹²⁰ In summary, the regulatory question is not *if* the FDA has the statutory authority to regulate software, but rather *how* it can best utilize this authority to advance public health in relation to the rapidly evolving software of mobile health applications.

III. FDA REGULATION OF MOBILE APPLICATIONS

Since the first mobile health application reached the market in 1997, the FDA has regulated mobile applications as medical devices.¹²¹ Since 2008, when mobile applications became more

116. *Id.*; see also 70 Fed. Reg. 824, 890 (Jan. 5, 2005); 76 Fed. Reg. 8637, 8638 (Feb. 15, 2011); U.S. DEP’T OF HEALTH & HUMAN SERVS. ET AL., MOBILE MEDICAL APPLICATIONS: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2015), available at www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.

117. Danzis & Pruitt, *supra* note 92, at 2.

118. *Medical Devices*, *supra* note 69; Medical Device Data Systems, 76 Fed. Reg. 8637, 8638 (Feb. 15, 2011) (codified at 21 C.F.R. pt. 880).

119. *Id.*

120. See, e.g., 21 C.F.R. § 862.2100 (2015) (classifying laboratory information systems as Class I device); 21 C.F.R. § 892.2010–20 (2015) (classifying medical imaging management systems as Class I and II devices); 76 Fed. Reg. 8637, 8641 (classifying medical device data systems as Class I device).

121. See *Health Information Technologies: Administration Perspectives on Innovation and Regulation Before the H. Energy & Commerce Comm.*, 113th Cong. (testimony of Christy Foreman,

pervasive and complex, the FDA started to develop a more defined regulatory scheme for this technology. In September 2013, the FDA announced a revised scheme in its 2013 Final Guidance.¹²² This Part explores the FDA's historical approach to mobile applications and the Final Guidance, and identifies unanswered regulatory questions.

A. Early Enforcement of the FDCA for Mobile Applications

Early on, developers were uncertain about how the FDA would exercise its statutory authority to regulate mobile applications.¹²³ The story of MIM Software clearly reflects this uncertainty. In 2008, immediately after the App Store launched, MIM Software created and uploaded the first medical application to the App Store: MobileMIM.¹²⁴ MobileMIM allowed physicians to view CT, MRI, and PET scan images on an iPhone and thus to immediately “make diagnoses without having to be back at the workstation or wait for film.”¹²⁵ Shortly thereafter, MIM Software pulled MobileMIM from the App Store due to regulatory concerns.¹²⁶ According to Mark Cain, the Chief Technology Officer of MIM Software, the FDA's regulatory authority forced MIM Software to cease distribution of MobileMIM: “We put [the app] out on the [App Store] for free on Day [One]. We knew that the FDA governs commercial distribution of devices so we thought a free app would not need approval. But when they found the app in the App Store, they ordered us to take it down.”¹²⁷ Subsequently, in July 2008, MIM Software submitted

Director, Office of Device Evaluation, Center for Devices and Radiological Health), available at <http://energycommerce.house.gov/hearing/health-information-technologies-administration-perspectives-innovation-and-regulation>.

122. Press Release, U.S. Food & Drug Admin., FDA Issues Final Guidance on Mobile Medical Apps (Sept. 23, 2013), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369431.htm>.

123. Ken Block, *FDA Goes Mobile: Regulation of Medical Apps*, EUR. MED. DEVICE TECH. (Apr. 21, 2014), <http://www.emdt.co.uk/daily-buzz/fda-goes-mobile-regulation-medical-apps>.

124. Chris Gullo, *Mobile MIM Receives Second FDA Clearance*, MOBI HEALTH NEWS (Dec. 19, 2011), <http://mobihealthnews.com/15363/mobile-mim-receives-second-fda-clearance/>.

125. Press Release, U.S. Food & Drug Admin., FDA Clears First Diagnostic Radiology Application for Mobile Devices (Feb. 4, 2011), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm242295.htm>.

126. Chris Seper, *iPad Radiology App Wins FDA Approval in Breakthrough for Mobile Imaging*, MEDCITY (Feb. 4, 2011), <http://medcitynews.com/2011/02/iphone-ipad-radiology-app-wins-fda-approval/>.

127. Felasfa Wodajo, *How the iPad Radiology App MobileMIM Became the First to Get FDA Approval: Interview with CTO Mark Cain*, IMEDICALAPPS (Apr. 14, 2011), <http://www.imedicalapps.com/2011/04/how-the-ipad-radiology-app-mobilemim-became-the-first-to-get-fda-approval-interview-with-cto-mark-cain/>.

MobileMIM to the FDA for approval. According to Cain, “Within [one] week, there were a lot of questions and a lot of confusion. The FDA was confounded that [MIM developers] were not making hardware. The fact that it was a phone was confusing.”¹²⁸ Ultimately, in February 2011, after two years of dialogue between MIM Software and the FDA, the FDA approved MobileMIM.¹²⁹

B. The FDA’s Mobile Medical Application Guidance Documents

To clarify regulatory uncertainty, the FDA issues guidance documents to alert the medical field to the “FDA’s current [regulatory] thinking” as to how it intends to enforce its broad statutory authority.¹³⁰ The guidance documents “do not create or confer any rights for or on any person and do not operate to bind FDA or the public.”¹³¹ Rather, they signal the FDA’s current policy towards exercising enforcement discretion for various subsets of medical devices.¹³² Thus, guidance documents do not alter the FDA’s authority, which extends to the limits defined by the FDCA, and the FDA can at any point change its view on how to enforce the Act.¹³³ For mobile applications, the FDA issued its regulatory guidance in draft and final form: the 2011 Draft Guidance and the 2013 Final Guidance.

1. 2011 FDA Draft Guidance

In July 2011, the FDA released its Draft Guidance, setting forth a proposal to regulate mobile applications.¹³⁴ The FDA planned to regulate a subset of mobile applications that both (1) met the broad definition of a medical device and (2) served as an accessory to a “regulated medical device” or transformed a mobile platform into a “regulated medical device.”¹³⁵ The second requirement

128. *Id.*

129. *See The 1938 FDCA, supra* note 78.

130. *Regulatory Information: Search for FDA Guidance Documents*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/> (last visited May 10, 2015).

131. *Id.*

132. *See id.*

133. *See* Anthony Vale, *Can a State Impose Civil Penalties on a Drug or Device Company for Using a Federally-Approved Label?*, 11 BLOOMBERG PHARMACEUTICAL L. & INDUSTRY REP. NO. 40 (Oct. 30, 2013), available at http://www.pepperlaw.com/publications_article.aspx?ArticleKey=2780 (“Congress gave the FDA exclusive authority to enforce the FDCA.”).

134. *See* U.S. DEP’T OF HEALTH & HUMAN SERVS. ET AL., *supra* note 116.

135. *See id.*

would include apps that (a) act as an accessory to a regulated medical device (e.g., remotely displaying data from a bedside monitor); (b) transform a mobile platform into a traditionally regulated medical device (e.g., an iPhone app that can perform the functions of a stethoscope); or (c) generate a patient-specific result, through formulae or processing algorithms that respond to user entered, patient-specific information.¹³⁶ The FDA termed qualifying applications “mobile medical applications.”

The Agency received 130 responses when it released the Draft Guidance for public comment.¹³⁷ Although some commenters praised the FDA’s willingness to exercise discretion to refrain from enforcement against some applications, industry stakeholders criticized the Draft Guidance for its lack of clarity.¹³⁸ The Draft Guidance appeared to maintain the FDA’s active regulation of some apps that perform very basic clinical analysis, including merely automating simple and well-understood clinical calculations and algorithms. For example, an Apgar scoring application—used to quickly and summarily assess the health of a newborn child immediately after birth—would simply add together five variables that could range from 0–2, yet qualified for regulation under the Draft Guidance.¹³⁹ One critic claimed that “requiring an app of this sort to comply with the host of regulatory requirements applicable to medical devices [is] excessive.”¹⁴⁰ Likewise, part of the Draft Guidance tangled its own nomenclature. In one section, the Draft Guidance discussed mobile apps subject to enforcement discretion—or apps the FDA will not actively regulate—but then described those apps as “mobile medical apps,” which is the title the FDA gives to mobile apps it *would* actively regulate.¹⁴¹

Although the Draft Guidance recognized the unique characteristics of mobile applications¹⁴² and treaded lightly when enforcing the FDCA with respect to mobile medical apps, the Agency still retained oversight of health-related software. Rather than send a

136. *See id.*

137. *Examining Federal Regulation of Mobile Medical Apps and Other Health Software: Hearing Before the Subcomm. on Health, Comm. on Energy & Commerce, 113th Cong.* (2013) (statement of Jeffrey Shuren, Director, Center for Devices and Radiological Health) available at <http://www.fda.gov/NewsEvents/Testimony/ucm375462.htm>.

138. Danzis & Pruitt, *supra* note 92, at 3.

139. *Id.*

140. *Id.*

141. *See id.*

142. *See, e.g., Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm255978.htm> (last updated June 4, 2014) (recognizing the unique characteristics of different mobile platforms).

warning letter—the traditional FDA method of notifying a company that the Agency “considers one or more products . . . to be in violation of the [FDCA]”¹⁴³—the FDA proposed “exercis[ing] notable restraint by sending an ‘It Has Come to Our Attention Letter.’”¹⁴⁴ For example, in May 2013, the FDA informed Biosense Technologies that its urinalysis app, uChek, qualified as a medical device because it performed the same task as a traditional medical device—urinalysis test system—albeit without the urinalysis dipstick.¹⁴⁵ The app reads the user’s dipstick and tracks several parameters, such as glucose, pH, and protein levels, as seen in the user’s urine.¹⁴⁶ The FDA’s letter advised Biosense that “any company intending to promote their device for use in analyzing, reading, and/or interpreting these dipsticks needs to obtain clearance for the entire urinalysis test system (i.e., the strip reader and the test strips, as used together).”¹⁴⁷ However, the letter also indicated that the agency planned to approach enforcement in the area of medical applications in a measured fashion, taking a case-by-case approach.¹⁴⁸ The FDA thus fulfilled its stated mission of notifying companies of potential regulatory obligations while withholding definitive decisions.

Overall, the Draft Guidance received praise for opening a dialogue between regulators and industry to try to help the FDA better understand the ever-developing mobile applications market.

2. 2013 FDA Final Guidance

After two years of review, which included consideration of scores of comments from medical experts,¹⁴⁹ on September 25, 2013, the

143. See U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL: EXHIBIT 4-1 PROCEDURES FOR CLEARING FDA WARNING LETTERS AND UNTITLED LETTERS (2012), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM176965.pdf>.

144. Suzan Onel, *Where the “App” World and FDA Collide: Current Status of the FDA’s Regulation of Medical Device Software and Mobile Medical Apps*, in RECENT DEVELOPMENTS IN FOOD AND DRUG LAW 153–74 (2014 ed. 2013).

145. See Letter from FDA, to Biosense Technologies Private Limited, Concerning the uChek Urine Analyzer (May 21, 2013), available at www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm.

146. Pooja Jaeeel, *Smartphone App Enables Mobile Analysis of Urine for Disease Pathology*, IMEDICALAPPS (May 1, 2013), <http://www.imedicalapps.com/2013/05/smartphone-app-enables-mobile-analysis-urine-disease-pathology/>.

147. See Letter from FDA to Biosense Technologies, *supra* note 145.

148. See *id.*

149. See Press Release, FDA Issues Final Guidance on Mobile Medical Apps, *supra* note 122.

FDA released its Final Guidance for mobile medical applications.¹⁵⁰ The FDA preserved the Draft Guidance's basic approach of limiting active regulation to "mobile medical applications," those mobile apps that can be used "as an accessory to a medical device already regulated by the FDA"¹⁵¹ or that "transform a mobile device into a medical device already regulated by the FDA."¹⁵² The Final Guidance specified that the FDA would tailor regulatory mechanisms in accordance with the same categories used for other medical devices, namely as class I (general controls), class II (special controls in addition to general controls), or class III (pre-market approval).¹⁵³

To better define mobile medical applications, the Final Guidance included detailed appendices of three different categories of applications.¹⁵⁴ The Final Guidance included these reference guides to help companies determine whether their application is subject to active FDA regulation. The first category includes those applications that the FDA does not classify as medical devices.¹⁵⁵ As such, the FDA will not regulate these applications. These applications include those meant to serve as medical references for both physicians and patients (such as electronic medical dictionaries or textbooks), educational apps used by healthcare providers for medical training, or apps meant to facilitate medical office functions, such as scheduling doctor shifts or tracking insurance claim data.¹⁵⁶

The second category includes those applications that meet the definition of a medical device, but for which the FDA intends to refrain from regulating because the application poses a low risk to patient safety.¹⁵⁷ For example, applications that provide supplemental clinical care through coaching or prompting to help patients manage their health—such as a reminder to the patient to exercise¹⁵⁸—will not face active FDA regulation.

The last category includes those applications that the FDA considers medical devices and that the FDA believes pose a significant risk of patient harm if they were to function improperly.¹⁵⁹ These

150. See FINAL GUIDANCE, *supra* note 11.

151. *Id.*

152. *Id.*

153. *Id.* at 13.

154. *Id.* at 20–22.

155. *Id.*

156. *Id.*; see also David L. Rosen, *FDA Submits Final Guidance on Mobile Medical Apps*, FOLEY & LARDNER LLP (Oct. 4, 2013), <http://www.foley.com/fda-submits-final-guidance-on-mobile-medical-apps-10-04-2013/>.

157. FINAL GUIDANCE, *supra* note 11, at 18.

158. See Rosen, *supra* note 156.

159. FINAL GUIDANCE, *supra* note 11, at 15–16.

types of apps can either enable a mobile device to operate as a regulated medical device—e.g., use of sensors to measure certain bodily fluids¹⁶⁰—or enable a device to operate as a controller for a regulated medical device—e.g., a wireless remote for an X-ray machine.¹⁶¹ The FDA intends that apps in this category will be subject to the same risk-based approach used by the agency to assess and regulate traditional medical devices.

As with traditional medical devices, the FDA's approach to mobile applications is "focused on their functionality" or "intended use."¹⁶² In general, if a mobile app is intended to perform a medical device function,¹⁶³ it is a medical device, regardless of the platform on which it is run.¹⁶⁴ For example, several mobile applications run on smartphones to analyze and interpret EKG waveforms to detect heart function irregularities.¹⁶⁵ The FDA will treat these applications like analogous software running on a desktop computer, which falls under purview of 21 CFR § 870.2340 ("Electrocardiograph"). The FDA intends to apply its regulatory oversight to only those mobile apps that, "are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended."¹⁶⁶

Ultimately, the Final Guidance is a progressive regulatory scheme because of its reserved approach. That is, the FDA chose to exercise enforcement discretion—or non-enforcement—with respect to the vast majority of mobile applications, "focus[ing] its regulatory oversight on a subset of mobile medical [applications] that present a greater risk to patients if they do not work as intended."¹⁶⁷ Demonstrating this, between the February 2011 Draft Guidance and September 2013 Final Guidance,¹⁶⁸ FDA approved approximately

160. See Rosen, *supra* note 156.

161. *Id.*

162. FINAL GUIDANCE, *supra* note 11, at 8.

163. A mobile app performs a medical device function if it operates "for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease." *Id.*

164. The FDA's oversight is not determined by the platform. See *id.* ("Under this guidance, FDA would not regulate the sale or general/conventional consumer use of smartphones or tablets.")

165. *Id.*

166. *Id.* at 13.

167. See Press Release, FDA Issues Final Guidance on Mobile Medical Apps, *supra* note 122.

168. To reiterate, the law—the FDCA—never changed in this time period (or before, for that matter). Therefore, the deft touch with which the FDA enforced the FDCA with mobile health applications during this period is a strong predictor for FDA enforcement going forward.

40 mobile medical applications.¹⁶⁹ This number, compared to the over 40,000 mobile health applications made available to consumers,¹⁷⁰ shows FDA's hesitancy to strongly regulate mobile applications.

3. Ambiguity in the Risk-Based Regulatory Scheme

Although the 2013 Final Guidance has been lauded by many industry experts for its prudent regulatory approach,¹⁷¹ its risk-based regulatory scheme does not clearly define the apps that the FDA will actively regulate. The Final Guidance states that the FDA will actively regulate any app that "could pose a risk to a patient's safety" if the app failed, but it will not actively regulate apps that "pose a low risk to patients."¹⁷² However, the Final Guidance failed to address the distinction between a mobile medical app that poses a low risk (i.e., non-active FDA enforcement) and an app that poses a risk to the patient's safety (i.e., active FDA enforcement). Understanding this distinction is essential for app developers to determine whether an app in the idea-stage may come under future FDA regulation.

To clarify this distinction, Appendix B in the Final Guidance includes approximately twenty examples of applications that qualify as medical devices, but which the FDA does not intend to actively regulate.¹⁷³ For example, the FDA will not actively regulate "mobile apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks."¹⁷⁴ While helpful, the small quantity of examples offers limited help and will only be less helpful going forward, as apps constantly evolve.

The ultimate ability of the Final Guidance to properly balance innovation and safety will depend on the clarity of the distinction

169. Robert Lowes, *FDA to Regulate Only 'Small Subset' of Mobile Medical Apps*, MEDSCAPE (Sept. 23, 2013), <http://www.medscape.com/viewarticle/811519>.

170. Xavier E. Martinez, *7 Best FDA Approved Health Apps*, POWER YOUR PRACTICE, <http://www.poweryourpractice.com/medical-technology-trends/7-best-fda-approved-health-apps/> (last visited Apr. 11, 2015).

171. See, e.g., Eric Wicklund, *FDA Gets Thumbs Up on Mobile Apps Regs*, HEALTHCARE IT NEWS (Sept. 24, 2013), <http://www.healthcareitnews.com/category/city/washington-dc> ("mHealth advocates are giving good early reviews to the U.S. Food and Drug Administration's final guidance document on the regulation of mobile medical apps, with one expert calling it 'an expansive document that truly seeks to deregulate our nimble and innovative industry, while ensuring patient safety.'").

172. FINAL GUIDANCE, *supra* note 11, at 13, 16.

173. See *id.* at 23–25.

174. *Id.* at 23.

between an app that presents a *risk* and a *low risk*. Currently, this is a difficult proposition, as a single application can be used in a variety of ways. For example, as a commentator observed, “a scale that displays an individual’s weight has an extremely low inherent risk if the individual is merely using the data for personal wellness purposes, yet the same display of the same data may have a moderate or high inherent risk if the patient is required to notify a healthcare provider when their weight reaches a certain point.”¹⁷⁵ Ultimately, idea-stage innovators must be able to confidently predict the risk classification of an application in order to assess its economic feasibility.

IV. THE PROPOSED REFORM

At this stage, the risk-based regulatory scheme presents unavoidable ambiguities. The mobile health application market appeared and took-off almost overnight, and will continue to evolve at an unimaginable pace. Applications advanced significantly from those available just a few years ago: for example, compare the Doctor-Calc’s Medical Calculator, which provides users with hundreds of clinical equations such as Body Mass Index (BMI) and weight conversions,¹⁷⁶ with Philips’ COPD application, which transmits the user’s heart rhythm from a patch to their iPhone and then instantly uploads the data to a cloud-based healthcare data management hub for the user’s doctor.¹⁷⁷ In all likelihood, the capabilities of mobile medical apps today will pale in comparison to apps developed only a few years from now.

To catch and keep up with this rapidly evolving market, the FDA must engage with developers in the mobile application market. To do this, and to bolster its 2013 Final Guidance, the FDA should (1) transform the FDA’s little-used section 513(g) Request Program into a mandatory pre-market notification program for all mobile health applications and (2) use these pre-market notifications to create a public database for the FDA to post enforcement determinations. This database would then both serve as an expansive list of

175. BRADLEY MERRILL THOMPSON ET AL., MHEALTH REGULATORY COALITION, A CALL FOR CLARITY: OPEN QUESTIONS ON THE SCOPE OF FDA REGULATION OF MHEALTH 38 (2010), available at <http://mhealthregulatorycoalition.org/wp-content/uploads/2010/12/mrcwhitefinal122210.pdf>.

176. See *Medical Calculator*, iTUNES, <https://itunes.apple.com/app/medical-calculator/id288555653?mt=8> (last visited Oct. 13, 2014).

177. See David Kender, *Philips Gives COPD Patients a Lifeline with New Gadget*, USA TODAY (Oct. 13, 2014), <http://www.usatoday.com/story/tech/2014/10/13/philips-gives-copd-patients-a-lifeline-with-new-gadget/17171535/>.

examples for developers to identify apps the FDA has declined to actively regulate and allow doctors to publish feedback on mobile applications. This Part will outline the proposal and explain how such reform will allow the FDA to successfully implement its Final Guidance, and simultaneously avoid increased regulation.

A. First Prong: Pre-market Notification Program

The first prong of this reform—the requirement for all mobile health application developers to submit pre-market notification to the FDA—alters a seldom-used option available to mobile health app developers. Under section 513(g) of the FDCA,¹⁷⁸ medical device manufacturers can receive feedback from the FDA regarding the classification and regulatory requirements that may apply to their proposed medical device. That provision states:

Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this [Act], the Secretary shall provide such a person a written statement of the classification (if any) of such device and the requirements of this [Act] applicable to the device.¹⁷⁹

The pre-market notification program would transform this voluntary program into a mandatory pre-market notification program, but remove the requirement that the FDA respond to every submission. Before a developer markets any mobile medical application,¹⁸⁰ he would need to submit a section 513(g) request.¹⁸¹

The pre-market notification program is *not* the same as pre-market approval. Pre-market approval is a formal determination by the FDA of the safety and effectiveness of an application.¹⁸² This is a

178. See 21 U.S.C. § 360c(g) (2012).

179. *Id.*

180. The exact determination of when an application becomes a mobile health application versus mobile medical application is uncertain. The FDA can work with industry to determine where this dividing line should be.

181. The submission must include (a) a cover letter, (b) a description of the app, (c) a description of what the app is to be used for, and (d) any proposed labeling or promotional material for the app and, as applicable, any labeling or promotional material of a similar, legally marketed app, if available. See FDA AND INDUSTRY PROCEDURES FOR 513(G) REQUESTS FOR INFORMATION UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, U.S. FOOD & DRUG ADMIN. 8 (Apr. 6, 2012).

182. See *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN. (Aug. 19, 2014), <http://www.fda.gov/Medicaldevices/Deviceregulationandguidance/Howtomarketyourdevice/Pre-market-submissions/Pre-market-approval-pma/Default.htm>.

very expensive and slow process.¹⁸³ Rather, the pre-market notification program would provide the FDA with a quick, informal first look at mobile health applications before developers begin to market them.¹⁸⁴ Within sixty days, the FDA would provide two responses to the application innovator. First, the FDA would determine if the application qualifies as a medical device. Over time it would become more obvious which applications qualify as medical devices, and the overwhelming majority of responses would therefore be “yes.” Second, the FDA would determine whether it intends to actively regulate the specific application. If the Agency determines that it would decline to actively regulate the application, then the innovator would have fulfilled his FDA reporting obligations (as long as no alterations take place). If the Agency decides to actively regulate the application, then the FDA would help guide the innovator through the next step: classifying the app as a Class I, II, or III device.

The FDA will better protect patients from unsafe applications by transforming the voluntary pre-market notification program into a mandatory program for mobile applications. First, the pre-market notification will allow the FDA to effectively implement the risk-based enforcement discretion announced in the 2013 Final Guidance. The risk-based system intends to balance innovation and patient safety;¹⁸⁵ however, as discussed above, the FDA did not clearly define and distinguish app characteristics that present “a risk” or a “low risk.”¹⁸⁶ This lack of clarity makes applying the system extremely challenging, if not impossible, in an industry that “is constantly evolving and requires the FDA to continually balance interests of patient safety and technological innovation in its regulation of these devices.”¹⁸⁷ In the two years after the issuance of the Draft Guidance, the FDA attempted to clearly define this distinction, and in the Final Guidance the Agency only provided current examples as guideposts for future innovators. As this technology develops, these guideposts will become outdated and thus cease to be useful. The FDA must fully understand the entire mobile health application landscape to reset and evolve these guideposts. The pre-

183. *See id.*

184. For this proposal, the exact determination of when an application becomes a mobile health application (does not require pre-market notification) versus a mobile medical application (requires pre-market notification) is uncertain and would be a question for future research.

185. *See, e.g.,* Rosen, *supra* note 156 (“The FDA intends that Apps falling into this category will be subject to the same risk-based approach used by the agency to assess and regulate traditional medical devices.”).

186. *See supra* discussion at Part III.B.iii.

187. Onel, *supra* note 144, at *11.

market notification program would force the industry to educate the FDA on this new, ever-evolving market.

Second, the FDA would take an active role in assisting app developers as they navigate the FDCA requirements. The question facing the vast majority of app developers in the early stage is *not* whether their app will qualify as a medical device,¹⁸⁸ but rather whether the FDA will use enforcement discretion or classify the app as a Class I, II, or III device. This presents a challenging inquiry for developers, which becomes more complicated because most app developers are not repeat players in the FDA's regulatory world. Confronting Agency oversight, particularly in this context, promises a new and challenging experience.¹⁸⁹ First-time innovators may not even *think* that their application behooves direct FDA regulation, or they may find the process intimidating and opt to abandon development of a new app.¹⁹⁰ To help alleviate this confusion, the pre-market notification program would provide a process for the FDA to assist application developers determine which regulatory requirements apply to their applications.

Likewise, the pre-market notification program would support the FDA's preference to educate and work with app developers—many of whom have never worked with the FDA—rather than take punitive enforcement action against many applications.¹⁹¹ As discussed above, the FDA used a tempered approach with Biosense Technologies and its urinalysis app uCheck.¹⁹² Rather than send a warning letter—the traditional FDA response to notify a company that the agency “considers one or more products . . . to be in violation of the [FDCA]”¹⁹³—the FDA “exercised notable restraint by sending an ‘It Has Come to Our Attention Letter.’”¹⁹⁴ Subsequently, the FDA

188. See *supra* Part I.B. (explaining that the vast majority of mobile health applications qualify as medical devices subject to FDA regulatory enforcement).

189. See Chris Wiltz, *FDA's Regulation of Mobile Medical Apps Will Probably Confuse You*, MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY (May 30, 2013), <http://www.mddionline.com/blog/devicetalk/fdas-regulation-mobile-medical-apps-will-probably-confuse-you>.

190. See, e.g., Andrew Litt, *When is a Mobile App a Medical Device? The Future of Healthcare May Depend on the Answer*, COMPUTERWORLD (Mar. 26, 2014), <http://www.computerworld.com/article/2476087/healthcare-it/when-is-a-mobile-app-a-medical-device—the-future-of-healthcare-may-depend-on-the-answ.html> (“Others (including some members of Congress) see this gray area as just the kind of ambiguity and uncertainty that will discourage innovation.”).

191. *Mobile Medical Apps Guidance*, DUANE MORRIS LLP (Oct. 4, 2013), http://www.duane-morris.com/alerts/mobile_medical_apps_guidance_5037.html.

192. See *supra* note 145 and accompanying text.

193. See U.S. FOOD & DRUG ADMIN., *supra* note 143.

194. Onel, *supra* note 144.

opened a line of communication with Biosense to discuss the evolving regulatory status of uChek and other related applications.¹⁹⁵ The pre-market notification program would similarly open dialogue between the FDA and industry to the benefit of both sides.

The current FDA process for the approval of traditional medical devices sharply contrasts with the lack of information available for prospective mobile application developers. In the early stages of development, a prospective traditional device developer can use nine databases to quickly determine their device's classification, including a CDRH tool titled "Classify Your Medical Device."¹⁹⁶ For mobile app developers, these tools are virtually nonexistent.¹⁹⁷ Commentators have complained that the publicly available "510(k) summaries" for the apps that the Agency has approved provide "little information of practical use for developing a comprehensive data package to support clearance of a later [filing]."¹⁹⁸ Further, even if an app maker can determine with confidence what device classification covers its app, it will still face a significant challenge in determining what data it will need to submit to support a marketing filing.¹⁹⁹ The FDA maintains hundreds of device-specific guidelines to help traditional device developers determine the proper data development necessary to support their submissions.²⁰⁰ Conversely, beyond the Final Guidance, there are no device-specific guidelines for mobile apps.

Critics might claim that pre-market notification should remain voluntary, as it is currently constructed under section 513(g), because any increase in the FDA's involvement could stymie app development.²⁰¹ Regulatory hurdles—and potentially costly ones at that—may dissuade developers from pursuing new applications.²⁰² However, this result is unlikely. One of the major benefits of this program to developers, educating the FDA, *depends* on developers

195. Darius Tahir, *Biosense Modifies Urinalysis App To Comply With FDA*, "THE GRAY SHEET," Jul. 22, 2103, at 11.

196. See *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/default.htm> (last updated July 29, 2014).

197. *Mobile Medical Apps Guidance*, *supra* note 191.

198. *Id.*

199. *Id.* ("However, app makers should understand that the guidance does not provide any advice on the specific information and data that an app maker will need to develop and, in many cases, submit to [the] FDA.")

200. *Id.*; see generally REGULATORY INFORMATION, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> (last visited Mar. 20, 2015) (containing links to thousands of FDA guidances).

201. See Onel, *supra* note 144.

202. See *id.*

using the program, and would encourage rather than dampen innovation and entrepreneurialism. Currently, very few medical device developers opt to use the voluntary program, which costs the applicant \$2,900.²⁰³ For mobile application developers, only highly cautious, responsible parties with deep pockets will utilize this tool. Irresponsible developers—who are of the most concern to the FDA—are the *least* likely to opt into the voluntary section 513(g) program. This internal contradiction exposes the inadequacy of the current program; it merely sets the FDA’s mind at ease and does not actually protect the public from harm.

Furthermore, regulatory certainty serves as a critical condition for innovation.²⁰⁴ As one legal commentator noted: “Confusion around whether a particular app will be regulated is simply sand in the gears of commerce, keeping the software development machine from reaching its full potential.”²⁰⁵ In February 2014, at the direction of Congress, the FDA organized a working group to discuss the 2013 Final Guidance.²⁰⁶ The 29-person working group was geographically diverse and included patients, doctors, innovators, venture capital investors, and healthcare third-party payers.²⁰⁷ In its final analysis, the group’s suggested improvements called for the FDA “doing a better job of explaining the existing legal requirements.”²⁰⁸ As one commentator put it, “[t]he problem isn’t the [FDCA].”²⁰⁹ The group pointed to the FDA and to its enforcement decisions, as the most qualified actor to determine the nuances of the mobile application market.²¹⁰ As the same commentator noted: “The devil is in the details, and innovators need those details to be

203. GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF – USER FEES FOR 513(G) REQUESTS FOR INFORMATION, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/ucm209852.htm> (last visited Mar. 20, 2015). Determining the proper cost of this program is outside the scope of this article. However, the app manufacturers’ costs are not expected to be significant. By making the program mandatory, the overhead costs will be spread among many manufacturers. Additionally, the costs will likely be passed on to consumers, further diluting the manufacturer’s expense.

204. See Chris Pruitt, *Mobile Medical Apps: What Will Future FDA Regulation Look Like?* INSIDE MED. DEVICES (Nov. 14, 2012), <http://www.insidemedicaldevices.com/2012/11/14/fda-regulation-of-mobile-medical-apps-what-does-the-future-hold/> (“This uncertainty has caused many app developers to struggle with the questions of whether their apps are subject to regulation and, if so, what requirements would apply.”).

205. Bradley Merrill Thompson, *How the FDA Can Improve Regulation of Mobile Health, According to FDASIA Workgroup*, MOBI HEALTH NEWS (Mar. 3, 2014), <http://mobihealthnews.com/30501/how-the-fda-can-improve-regulation-of-mobile-health-according-to-fdasia-workgroup/>.

206. *Id.*

207. *Id.*

208. *Id.*

209. *Id.*

210. *Id.*

able to make business decisions. One of the biggest challenges that innovators have in this space is the presently opaque regulatory system.”²¹¹ As a result of the group’s conclusions, on March 19, 2014, a bipartisan group of senators sent a letter to the FDA, urging the FDA to further clarify its Final Guidance “to avoid stakeholder confusion over how a wider range of medical software might be appropriately regulated.”²¹² The pre-market notification program will seek to resolve this lack of clarity and certainty surrounding medical software regulation. Direct work with *all* developers, not only the responsible ones that opt into the current voluntary program, will allow the FDA to better understand mobile apps and clearly define its regulatory scheme.

In the absence of further clarification, Congress could push harder for a more extreme result—removing the FDA’s statutory authority to regulate mobile medical applications. In February 2014, Senator Marco Rubio introduced a bill titled The Preventing Regulatory Overreach to Enhance Care Technology (PROTECT) Act of 2014, which would amend section 201(h) of the FDCA to clarify that the term “medical device” does not include clinical software or health software such as mobile medical applications.²¹³ Instead of the FDA, the PROTECT Act would charge the National Institute of Standards and Technology (NIST) with oversight over digital health products. However, as one commentator noted, “[the] NIST is *not* a regulatory body with the power to investigate wrongdoing. It is a federal body that works with the industry to develop and apply technology, measurements, and standards.”²¹⁴

This “nuclear option” could have disastrous consequences for the industry and consumers alike. Developers may need to comply with new NIST standards.²¹⁵ According to the same commentator, “[i]n the past, [creating new standards] has entrenched the incumbents but hindered startups, as this certification process costs a lot

211. *Id.*

212. Press Release, Senate Comm. on Health, Educ., Labor & Pensions, Senators Urge Further Clarity and Transparency from FDA on Medical Mobile Apps, (Mar. 19, 2014), *available at* <http://www.help.senate.gov/newsroom/press/release/?id=2354f485-f387-40c4-80c9-158491f2fd1a>; *see also* Thompson, *supra* note 204 (“[The] FDA needs to do a better job at a very granular level of explaining what types of software the agency regulates and what types it doesn’t.”).

213. Nita Farahany, *Reining in FDA Regulation of Mobile Health Apps*, WASH. POST (Mar. 25, 2014), <http://www.washingtonpost.com/news/olokh-conspiracy/wp/2014/03/25/reining-in-fda-regulation-of-mobile-health-apps/>.

214. Farr, *supra* note 17.

215. *Id.*

of money.”²¹⁶ The strongest lobbyists, representing the largest developers, would push for incumbent-friendly regulations.²¹⁷ Bradley Merrill Thompson, a Washington, D.C.-based attorney who advises the FDA on this subject, calls the proposed bill a “meat cleaver” that would do a lot of damage to the regulation of mobile medical applications.²¹⁸ He asserts that the PROTECT Act “is a colossally bad idea, both for patients who would be put at risk, but also for [an] industry that would be dragged down by apps that don’t work and destroy the credibility for the industry.”²¹⁹ Thus, this nuclear option should be avoided at all costs. The pre-market notification system may sufficiently convince members of Congress that they do not need to enact such an extreme bill, as increased industry-agency dialogue would further cement the FDA’s legitimacy in regulating mobile medical applications.

B. Second Prong: Mobile Medical Application Database

The second prong of this reform—establishing a public database for the FDA to disclose its enforcement discretion determinations and for doctors to provide feedback on mobile applications—would be an important step to ensure post-market surveillance of mobile medical applications. The second prong does *not* provide a substitute for the first prong, but rather it depends on the first prong. The breadth and usefulness of the database would rely on an FDA mandate that requires all mobile health app developers to submit a pre-market notification. Additionally, the database would allow physicians and users to submit adverse events to the FDA. Importantly, this public database would increase physicians’—and subsequently patients’—trust in mobile medical applications as a safe and effective healthcare tool. A recent poll of 250 doctors found that forty-two percent will not prescribe mobile apps to patients because of the lack of regulatory oversight.²²⁰ The database could alleviate this unease.

Post-market surveillance would increase physician faith in mobile apps for two reasons: first, it would help ensure the FDA learns of

216. *Id.*

217. *Id.*; *How long it takes the FDA to “approve” a 510(k) submission*, EMERGO, <http://www.emergogroup.com/resources/research/fda-510k-review-times-research> (last visited Mar. 20, 2015).

218. Eric Wicklund, *Opponents say PROTECT Act Could Destroy mHealth, Endanger Patients*, MHEALTHNEWS (Feb. 17, 2014), <http://www.mhealthnews.com/news/opponents-protect-act-destroy-mhealth-endanger-patients-mobile-fda>.

219. *Id.*

220. *See* Thompson, *supra* note 204.

faulty apps, even if the risk only becomes apparent after market entry. The FDA observed this trend in reports about adverse events associated with pharmaceutical drugs: “unexpected and sometimes serious safety problems can emerge once a product goes to market and is used by millions of people.”²²¹ This concern may be exacerbated for mobile medical apps, where the FDA emphasizes a light pre-market regulatory touch, as compared to the heavy pre-market regulation of drugs.²²² Second, a risk-based regulatory scheme necessitates an adaptive risk analysis. Mobile technology and app development are constantly changing. “What stands today could change tomorrow.”²²³ The mobile medical apps available in 2008 look very different from the apps available in 2014. And the same will be true in 2020. As a result, for the FDA to maintain a risk-based regulatory scheme, it must receive user input to adjust its pre-market risk analysis as new technology develops. The FDA’s pre-market risk analysis is prospective, based on existing technology. Thus, user data—and the subsequent recalibration of mobile app risk analysis—are necessary if the FDA intends to conduct effective risk analysis and properly protect consumers from unsafe mobile apps.

Creating an FDA public database is not a novel idea. For post-marketing safety surveillance of all approved drug and therapeutic biologic products, the Center for Drug Evaluation and Research (CDER)²²⁴ maintains the FDA Adverse Event Reporting System (FAERS).²²⁵ This computerized information database allows physicians and consumers alike to voluntarily report any adverse events and medication errors that might occur with these marketed products.²²⁶ FAERS empowers the FDA to monitor new safety concerns related to a marketed product, evaluate a manufacturer’s compliance with reporting regulations, and respond to outside requests

221. *The Public’s Stake in Adverse Event Reporting*, U.S. FOOD & DRUG ADMIN (Aug. 20, 2009), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm179586.htm>.

222. *See Premarket Approval*, *supra* note 182 (describing the onerous pre-market approval process for pharmaceutical drugs).

223. Brian Dolan, *In Tense Hearing, Congressman Declares “Software is not a Medical Device,”* MOBI HEALTH NEWS (Nov. 21, 2013), <http://mobihealthnews.com/27563/in-tense-hearing-congressman-declares-software-is-not-a-medical-device/>.

224. CDER is a division of the FDA that monitors most drugs as defined in the FDCA. *See About the Center for Drug Evaluation and Research*, U.S. FOOD & DRUG ADMIN. (Dec. 9, 2014), <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/default.htm>.

225. *See FDA Adverse Event Reporting System (FAERS)*, U.S. FOOD & DRUG ADMIN. (Sept. 8, 2014), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

226. *Id.*

for information.²²⁷ The results of this infrastructure can be powerful: voluntary reports of severe and sometimes fatal conditions led to the market removal of the nonsteroidal anti-inflammatory drug Duract (bromfenac) in 1998 and the antibiotic Zyvox (linezolid) in 2000, both within months of the drugs' market approvals.²²⁸ As the FDA put it, "the bottom line: voluntary and mandatory reporting plays an important role in the FDA's postmarket safety monitoring."²²⁹

Moreover, this database would help early-stage innovators to quickly ascertain how their app may be classified before they submit a pre-market notification. As described above, currently there are no resources available for entrepreneurs to proactively educate themselves on potential regulatory requirements.²³⁰ As one entrepreneur put it, "[q]uite bluntly [the FDA] need[s] to be more entrepreneur friendly."²³¹ Sophisticated mobile medical app development requires investment. In a pitch to a venture capitalist, the innovator must be able to project whether or not the FDA will regulate the app, as this can dramatically affect the necessary investment and extend associated timelines.²³² The mobile medical app database would contain robust data on how the FDA has approached previous applications, thereby helping innovators anticipate potential regulatory obligations. A mobile medical app database would provide app developers with an equivalent tool to what the FDA already provides traditional medical device developers.

CONCLUSION

Creating and maintaining a regulatory scheme that protects the public from unsafe mobile medical applications and simultaneously promotes innovation is a significant undertaking. Although the FDA's 2013 Final Guidance is a positive first step towards regulating mobile medical applications, the FDA needs to do more. As the technology continues to develop, the FDA must continue to work directly with all actors—including innovators, doctors, and patients—to keep pace. To assist in this effort, the FDA should adopt a pre-market notification program and mobile medical application

227. *Id.*

228. *See The Public's Stake in Adverse Event Reporting, supra* note 221.

229. *Id.*

230. *See supra* notes 186–88 and accompanying text.

231. *See* Thompson, *supra* note 205.

232. *Id.*

database. This Note recommends two interrelated solutions to help the FDA keep its finger on the pulse of the mobile medical application market, while not stymieing growth and development. The FDA will, thus, ensure that this burgeoning market can reach its peak potential.