

# EFFECTIVENESS OF FEDERAL REGULATION OF MOBILE MEDICAL APPLICATIONS

## INTRODUCTION

Steve Jobs hated the design of the health-monitoring devices used to treat him during his final days.<sup>1</sup> In posthumous homage to its founder, Apple released the Health app, powered by the HealthKit developer framework, as part of its iOS 8 operating system update and its new iPhone 6 release in September of 2014.<sup>2</sup> HealthKit allows the Health app to access third party apps and wearable devices.<sup>3</sup> Although the Health app—as a mobile medical application (“app”)—could arguably fit the mold of a medical device subject to Food and Drug Administration (“FDA”) regulation, Apple managed to escape such regulation of its product. This Note discusses the reasons this occurred.<sup>4</sup>

A myriad of medical smartphone apps are available in the app market.<sup>5</sup> Apple’s foray into the market triggered a surge in apps that are compatible with the Health app.<sup>6</sup> As a result, mobile health applications are becoming more integrated into Americans’ everyday lives.

Samsung, a fierce competitor in the smartphone market, is also touting the health and wellness features of its Galaxy S5.<sup>7</sup> The Galaxy S5 is the

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1. Brian X. Chen, *Success of Apple’s iWatch May Rely on Health Care Partnerships*, N.Y. TIMES (Sept. 7, 2014), <http://www.nytimes.com/2014/09/08/technology/can-apple-build-a-cool-and-convenient-iwatch.html>.

2. HealthKit, now known as the Health app, was slightly delayed and was not released concurrently with iOS 8. Lauren Goode, *Bug Delays Launch of Apps Using Apple’s HealthKit in iOS 8*, RECODE (Sept. 17, 2014, 4:10 PM), <http://recode.net/2014/09/17/bug-delays-launch-of-apps-using-apples-healthkit-in-ios-8/>. “The health dashboard app is getting an update in iOS 9.3 that adds sliders to categories like weight, workout or sleep that provide suggestions for apps that may help you reach your goals in these areas. It also integrates your move, exercise and stand data from the Apple watch to simplify your health data tracking to one app.” Cammy Harbison, *iOS 9.3 Preview: Apple to Bring Multi-User iPad, Lock for Apps, Night Mode and More*, IDIGITALTIMES (Jan. 11, 2016, 2:32 PM), <http://www.idigitaltimes.com/ios-93-preview-apple-bring-multi-user-ipad-lock-apps-night-mode-and-more-503097>.

3. *HealthKit*, APPLE INC., <https://developer.apple.com/healthkit/> (last visited Apr. 8, 2016).

4. Brian Dolan, *FDA Makes Clear It Won’t Regulate Apps Like Apple’s HealthKit*, MOBIHEALTHNEWS.COM (June 16, 2014), <http://mobihealthnews.com/34173/fda-makes-clear-it-wont-regulate-apps-like-apples-healthkit/>.

5. “More than 100,000 health apps are available in the iTunes and Google Play stores . . . .” Joshua A. Krisch, *Questioning the Value of Health Apps*, N.Y. TIMES (Mar. 16, 2015, 3:27 PM), [http://well.blogs.nytimes.com/2015/03/16/health-apps-provide-pictures-if-not-proof-of-health/?\\_r=0](http://well.blogs.nytimes.com/2015/03/16/health-apps-provide-pictures-if-not-proof-of-health/?_r=0).

6. Aditi Pai, *23 Health and Wellness Apps That Connect to Apple’s HealthKit*, MOBIHEALTHNEWS.COM (Sept. 30, 2014), <http://mobihealthnews.com/36870/23-health-and-wellness-apps-that-connect-to-apples-healthkit/>.

7. *Samsung Galaxy S5: Features*, SAMSUNG, <http://www.samsung.com/global/microsite/galaxy5/features.html> (last visited Apr. 8, 2016).

first smartphone with a built-in heart rate monitor.<sup>8</sup> Samsung included SHealth software, similar to Apple's Health app, which is compatible with the Galaxy S5 pedometer.<sup>9</sup> The Galaxy S5 also connects to Samsung Gear Fit, a wristband that provides personalized real-time information on the progress and results of a workout using the device's optical heart rate sensor, similar to the Apple Watch.<sup>10</sup>

These are just two examples of how mobile health is expanding from basic pedometers and informative medical apps into more complex interactive programs and apps. It is understandable that governmental regulation has not been able to adequately keep pace with mobile medical technology.<sup>11</sup> The rapidly growing popularity of smartphones in the consumer market has triggered aggressive investment in mobile health, sometimes referred to as "mHealth."<sup>12</sup> Some of the mHealth investment money goes toward the development of medical apps.<sup>13</sup> Technology companies are rolling out sophisticated applications for computers and smartphones that can perform a wide variety of tasks; from basic monitoring of personal health statistics to complex medical testing and diagnosis, including a pregnancy test app that utilizes a smart phone's Bluetooth,<sup>14</sup> an app that monitors blood pressure,<sup>15</sup> and even an app that can conduct a urinary analysis.<sup>16</sup>

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8. Bahar Gholipour, *Galaxy S5: How the Heart-Rate Monitor Compares to Other Devices*, LIVE SCIENCE (May 8, 2014, 1:35 PM), <http://www.livescience.com/45458-galaxy-s5-heart-rate-comparison-experiment.html>. When compared to heart rate apps found in the Google Play store, the margin of error between Samsung and the apps was negligible, so it is not clear that the Galaxy S5 heart rate monitor is any more effective than the free and inexpensive apps found in the iTunes store or the Google Play store that are compatible with phones without a built in monitor. Daniel P., *Cool Gimmicks: Galaxy S5 Heart Rate Sensor vs a Pulse Measuring App*, PHONE ARENA (Apr. 11, 2014, 8:43 PM), [http://www.phonearena.com/news/Cool-gimmicks-Galaxy-S5-heart-rate-sensor-vs-a-pulse-measuring-app\\_id55037](http://www.phonearena.com/news/Cool-gimmicks-Galaxy-S5-heart-rate-sensor-vs-a-pulse-measuring-app_id55037).

9. See *Samsung Galaxy S5: Features*, *supra* note 7.

10. *Samsung Gear: Features*, SAMSUNG, [http://www.samsung.com/global/microsite/gear/gearfit\\_features.html](http://www.samsung.com/global/microsite/gear/gearfit_features.html) (last visited Apr. 8, 2016).

11. Mobile medical health is a fairly new area of regulatory law, as smartphones and apps for smartphones did not even exist before 2007. *The FDA May Want to Regulate Your mHealth App.—Updated*, OMNICA CORP. (Sept. 23, 2014), <http://www.omnica.com/the-fda-will-look-at-your-mhealth-app/>.

12. "Mobile health,' or 'mHealth,' is the use of mobile communications devices like smartphones and tablet computers for health or medical purposes, usually for diagnosis, treatment, or simply well-being and maintenance." Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1176 (2014).

13. "CompuGroup Medical AG (CGM), a leading provider for eHealth solutions worldwide, and Microsoft entered into strategic cooperation. In a mutual action plan, both Microsoft and CGM are investing in mobile services for better communication between doctors and patients based on CGM LIFE eSERVICES and Windows 8.1. Through this cooperation, CGM will strengthen its portfolio of mobile healthcare solutions for patients and doctors thus expanding its global technology leadership in the healthcare industry." Press Release, CompuGroup Medical AG, CompuGroup Medical AG and Microsoft Focus on Mobile Applications in Healthcare Together (Mar. 28, 2014).

14. Megan Friedman, *An iPhone App Can Now Tell You If You're Pregnant*, ELLE (Jan. 6, 2016), <http://www.elle.com/life-love/sex-relationships/news/a33051/first-response-bluetooth-pregnancy-test/>.

Due to the rapid growth and advancement of technology, uncertainty has emerged as to whether some of the medical apps on the market should be considered medical devices, which are subject to stringent regulation by the FDA.<sup>17</sup> The FDA issued final guidelines regarding the regulation of medical apps in September of 2013 and updated the guidance in February 2015, but it has not issued formal regulations.<sup>18</sup>

Mobile technology is an integral part of daily life in the United States; as of January 2014, 90% of adults in the United States owned a cell phone, and 64% of adults owned a smartphone.<sup>19</sup> Almost 20% of smartphone users in the United States have at least one application on their device that helps them track or manage their health and have used such an app in the past year.<sup>20</sup> By some estimates, 500 million users worldwide will use one or more of these apps within the year.<sup>21</sup> And by 2018, more than 50% of the 3.4 billion smartphone and tablet users worldwide will have downloaded a medical health app.<sup>22</sup>

Relevant to this Note, smartphones and medical apps are becoming increasingly popular among healthcare professionals. Nearly eighty percent of physicians use smartphones as part of their medical practice.<sup>23</sup>

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15. Maxwell Software, *Blood Pressure Companion*, iTUNES (May 9, 2016), <https://itunes.apple.com/us/app/blood-pressure-companion/id453210774?mt=8>.

16. Anna Edney, *iPhone Urinalysis Draws First FDA Inquiry of Medical Apps*, BLOOMBERG TECH. (May 23, 2013), <http://www.bloomberg.com/news/2013-05-23/iphone-urinalysis-draws-first-fda-inquiry-of-medical-apps.html>.

17. Stephanie Kreml, *FDA Creates Medical App Regulation Maze*, INFO. WK. (Mar. 3, 2014, 3:24 PM), <http://www.informationweek.com/healthcare/mobile-and-wireless/fda-creates-medical-app-regulation-maze/d/d-id/1114095> (“[T]he [2013 FDA] guidance also showed the agency’s uncertainty over how the world of medical apps is going to evolve.”).

18. FOOD AND DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2015), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>.

19. *Mobile Technology Fact Sheet*, PEW RESEARCH CTR., <http://www.pewinternet.org/fact-sheet/mobile-technology-fact-sheet/> (last visited Apr. 8, 2016).

20. *Health Fact Sheet*, PEW RESEARCH CTR., <http://www.pewinternet.org/fact-sheets/health-fact-sheet/> (last visited Apr. 8, 2016).

21. Honor Whiteman, *Health Apps: Do They Do More Harm Than Good?*, MED. NEWS TODAY (Sept. 26, 2014), <http://www.medicalnewstoday.com/articles/283117.php>. Due to the tremendous popularity of smartphones and apps, it is no surprise that the mobile app market is a booming industry. “[M]obile apps are projected to be a \$25 billion industry this year [2013] and are estimated to have already produced 500,000 jobs.” *Health Information Technologies: Harnessing Wireless Innovation, Memorandum of Hearing Before Subcomm. on Comm’n. and Tech.*, 113th Cong. 1 (2013).

22. RESEARCH2GUIDANCE, MOBILE HEALTH MARKET REPORT 2013–2017: THE COMMERCIALIZATION OF MHEALTH APPLICATIONS (VOL. 3) 7 (2013), available at <http://research2guidance.com/wp-content/uploads/2015/08/Mobile-Health-Market-Report-2013-2017-Preview.pdf>.

23. According to a 2013 survey, “[n]early 80 percent of the 300 practicing primary care, family and internal medicine physicians surveyed said they were using a smartphone in their day-to-day practice. Another 61% were using tablets.” Stephen Beck, *Mobile Health Is Enhancing Clinical Decisions at the Point of Care*, HIT CONSULTANT (June 9, 2014), <http://hitconsultant.net/2014/06/09/mobile-health-is-enhancing-clinical-decisions-at-the-point-of-care/>.

And eighty-five percent of physicians use medical applications as part of their practice.<sup>24</sup>

This Note proceeds as follows. Part I examines the development of mobile medical health applications and regulation in countries with comparable mobile-app use, and then explores the evolution of the FDA's position regarding the regulation of such apps. Part II analyzes and critiques current and conceivable regulatory strategies by the federal government, as well as private regulatory organizations such as the United States Pharmacopeial Convention and the Health on the Net Foundation. Part III argues that current FDA regulations are insufficient and suggests a peer reviewer or other organization may be better suited to assess the usability of apps and offer usage guidelines for consumers. Part III also discusses three proposed models for regulation of mobile medical apps. This Note argues that a regulatory approach that includes a peer review system and a non-profit organization that specializes in mobile medical technology will be more efficient and useful to monitor mobile medical apps than the current FDA guidelines.

## I. HISTORY

### A. *Medical Apps*

Health and medical apps first emerged in the late 2000s by offering tools such as calorie counters and simple wearable devices like pedometers that were integrated with cell phone apps.<sup>25</sup> Medical apps have consistently grown in popularity, and large technology companies continue to invest in mobile health.<sup>26</sup>

Mobile medical apps often utilize a smartphone's built-in features, like touch screens, cameras, lights, sounds, and wireless access, as well as software to process the data collected.<sup>27</sup> The information gathered can be presented to the user in an informative or even in a diagnosis-like format. Increasingly accessible and more affordable technology has allowed more people to access such applications but has also raised questions and concerns regarding safety and regulation.

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24. "In addition, 86 percent of all clinicians—doctors, nurses and nurse practitioners—now use smartphones in their practice areas every day, up from 78 percent in 2012." *Id.* As doctors have superior medical knowledge and experience to determine if an app is reliable enough to use in their practice and treatment of patients, this Note focuses on consumer use of medical apps. However, doctors could also benefit from a greater level of peer review and more information on the efficacy and safety of mobile medical health apps.

25. HEALTHAFFAIRS & ROBERT WOOD JOHNSON FOUND., HEALTH POLICY BRIEF: MHEALTH AND FDA GUIDANCE, at 2 (2013).

26. Press Release, CompuGroup Medical AG, *supra* note 13.

27. Cortez, *supra* note 12, at 1177.

Some companies have developed devices that work in tandem with smartphones but do not require a mobile phone to operate.<sup>28</sup> For example, Scanadu, a Silicon Valley-based company that makes medical technology devices for consumers, created a device that can monitor and log the data of pulse, respiratory rate, blood pressure, temperature, and other vitals.<sup>29</sup> Because it is a standalone device, the FDA required Scanadu to seek further approval before the device goes onto the market.<sup>30</sup>

Like standalone health devices, mobile phones can be used to engage in complex medical procedures through applications that work in conjunction with smartphone features and external tools and devices that plug into smartphones. Such features and programs on mobile phones may also be subject to the same discretionary review and regulation by the FDA as standalone devices. External devices that attach to the phone are particularly easy to peg for further review and approval, particularly if the application gives diagnostic-like data readings.

One such app that offers the user a diagnosis is the Instant Heart Rate app.<sup>31</sup> The application can take the user's heart rate by allowing the user to place his or her finger over the camera for ten seconds.<sup>32</sup> Another app that utilizes a smartphone's built in features is BiliCam, which allows parents to check if their newborn has jaundice by taking a picture of a calibration card against their baby's skin.<sup>33</sup>

Due to time and monetary constraints, mobile app developers do not want their apps to be subject to FDA and regulatory scrutiny. Whether a mobile app is a medical device is not as clear-cut as it is for a stand-alone medical device that is clearly designed for the purpose of diagnosis or treatment. Policy and regulation have yet to catch up with this evolving technology, creating a gray area encompassing such mobile health apps.

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28. See, e.g., SCANADU, <http://www.scanadu.com> (last visited Apr. 8, 2016).

29. Stacey Higginbotham, *The Scanadu Scout's Big Breakthrough May Actually Be in Clinical Trials*, GIGAOM (May 24, 2013, 10:49 AM), <https://gigaom.com/2013/05/24/the-scanadu-scouts-big-breakthrough-may-actually-be-in-in-clinical-trials/>.

30. Cortez, *supra* note 12, at 1176.

31. Azumio Inc., *Instant Heart Rate—Heart Rate Monitor & Fitness Buddy Training Tracker Programs*, iTUNES, <https://itunes.apple.com/us/app/instant-heart-rate-heart-rate/id395042892?mt=8> (last visited July 8, 2016).

32. Alex Krouse, *iPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 731, 743 (2012).

33. Catharine Paddock, *Smartphone App to Screen for Jaundice in Newborns*, MED. NEWS TODAY (Aug. 29, 2014), <http://www.medicalnewstoday.com/articles/281701.php>.

### *B. History of FDA Involvement in Mobile Medical Apps*

The FDA is a federal agency that exists under the purview of the US Department of Health and Human Services.<sup>34</sup> The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, over-the-counter and prescription drugs, dietary supplements, and other food and medical products and devices available to consumers.<sup>35</sup> Pertinent to this Note, the FDA is empowered by Congress to enforce the Federal Food, Drug and Cosmetic Act, among other laws.<sup>36</sup> Notably, the FDA enforces section 361 of the Public Health Service Act and associated regulations, from which it derives its authority to regulate medical devices.<sup>37</sup> More specific statutory authority is exerted “over those mobile apps that meet the definition of ‘device’ in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).”<sup>38</sup>

The FDA issued its first guidance regarding mobile medical applications in July of 2011, after soliciting public and stakeholder comments and opinions.<sup>39</sup> Those that responded “overwhelmingly supported a narrowly tailored, risk-based approach.”<sup>40</sup> Industry stakeholders were eager for guidance from the FDA so they could proceed with research and development.<sup>41</sup> The FDA released this guidance in its report, *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, in the Federal Register in September of 2013.<sup>42</sup>

In the 2013 Guidance, the FDA attempted to define what factors make a mobile app a medical device, stating:

*Mobile apps that transform a mobile platform into a regulated medical device and therefore are mobile medical apps: These*

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34. U.S. FOOD & DRUG ADMIN., <http://www.fda.gov> (last visited Apr. 8, 2016).

35. *FDA Organization*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/default.htm> (last visited Apr. 8, 2016).

36. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (2014).

37. Public Health Service Act, 42 U.S.C. § 361 (2014).

38. *Examining Federal Regulation of Mobile Medical Apps and Other Health Software: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 113th Cong. (2013) (statement of Jeffrey Shuren, Dir., Ctr. for Devices & Radiological Health, Food & Drug Admin.), available at <http://www.fda.gov/NewsEvents/Testimony/ucm375462.htm> [hereinafter *Hearing on Mobile Medical Apps*]; see also Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h).

39. Press Release, U.S. Food & Drug Admin., FDA Outlines Oversight of Mobile Medical Applications (July 19, 2011).

40. *Hearing on Mobile Medical Apps*, *supra* note 38; see also *Public Workshop - Mobile Medical Applications Draft Guidance, September 12-13, 2011*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm> (last visited Apr. 8, 2016).

41. See *Public Workshop—Mobile Medical Applications Draft Guidance*, *supra* note 4.

42. *Hearing on Mobile Medical Apps*, *supra* note 38; see also *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, Availability, 78 Fed. Reg. 59,038 (Sept. 25, 2013).

mobile apps use a mobile platform's built-in features such as light, vibrations, camera, or other similar sources to perform medical device functions (e.g., mobile medical apps that are used by a licensed practitioner to diagnose or treat a disease).<sup>43</sup>

The FDA distinguished some types of apps they will regulate from some they will not. However, the Guidance leaves a considerable amount of discretion to the FDA.<sup>44</sup> FDA director Jeffery Shuren explained the FDA's stance on medical app regulation in a hearing before the Subcommittee on Health of the House Committee on Energy and Commerce, stating:

Our mobile medical app policy is based on risk and functionality. For example, an electrocardiography device—an ECG machine—that measures heart rhythms to help doctors diagnose patients is still an ECG machine, regardless of whether it is the size of a bread box or the size of a credit card. The risks it poses to patients and the importance of ensuring for practitioners and patients that it is safe and effective are essentially the same. Our guidance makes clear that if a mobile app transforms a mobile platform into a medical device, like an ECG machine, or is an accessory to a medical device, such as an app that acts as a remote control for a CT scanner, and it is the kind of functionality we already regulate—that is, we have approved, cleared, or classified such a device—we would continue to regulate that kind of technology, if it is on a mobile platform.<sup>45</sup>

The FDA considers a mobile health app to be a medical device if the app meets the definition of a medical device, is an accessory to a regulated medical device, or transforms a mobile platform into a regulated medical device.<sup>46</sup> The FDA determines whether an app is a device by evaluating

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43. *Examples of MMAs the FDA Regulates*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/digitalhealth/mobilemedicalapplications/ucm368743.htm> (last visited Apr. 8, 2016).

44. *See Examples of Pre-Market Submissions That Include MMAs Cleared or Approved by FDA*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368784.htm> (last visited Apr. 8, 2016); *see also Examples of MMAs That Are NOT Medical Devices*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm388746.htm> (last visited Apr. 8, 2016); *Examples of Mobile Apps for Which the FDA Will Exercise Enforcement Discretion*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm> (last visited Apr. 8, 2016).

45. *Hearing on Mobile Medical Apps*, *supra* note 38.

46. FOOD AND DRUG ADMIN., *supra* note 18. The definition of a medical device under the Federal Food, Drug, and Cosmetic Act is:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure,

the marketing claims of the apps.<sup>47</sup> Through this guidance, the FDA sought “to strike the right balance by providing a risk-based, focused approach to the oversight of a small subset of mobile apps that present risks to patients if they do not work as intended.”<sup>48</sup>

Although it seems that the FDA established guidelines, a closer examination reveals ambiguities in the FDA guidelines, contributing to uncertainty among app developers and technology companies. One industry concern is the scope of the regulation and the level of scrutiny their apps will be subject to if they fall within the FDA’s discretion.<sup>49</sup> In August of 2014, the FDA released draft guidance that made many low-risk medical devices exempt from premarket 510(k) review, which was updated in February of 2015.<sup>50</sup> A 510(k) is submitted to the FDA before a manufacturer proposes to market a medical device.<sup>51</sup> If the FDA finds the new device is substantially equivalent to a legally marketed device, the manufacturer may market it immediately.<sup>52</sup> The 510(k) exemption includes certain mobile applications that can convert a cell phone into a medical device.<sup>53</sup> This exemption “may smooth the path to market for many medical mobile apps the FDA’s 2013 guidance suggested would be subject to premarket approval requirements.”<sup>54</sup>

If the FDA finds an app it believes should be characterized as a medical device, they will alert the company through an “it has come to our attention” letter.<sup>55</sup> There are several user fees associated with certain

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mitigation, treatment, or prevention of disease, in man or other animals; or, intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h) (2014).

47. See *Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm> (last visited Apr. 8, 2016).

48. *Hearing on Mobile Medical Apps*, *supra* note 38.

49. Erin Gilmer, *Developing Mobile Apps as Medical Devices: Understanding U.S. Government Regulations*, IBM DEVELOPERWORKS (Apr. 16, 2013), <http://www.ibm.com/developerworks/library/mo-fda-med-devices/mo-fda-med-devices-pdf.pdf>.

50. FOOD AND DRUG ADMIN., *supra* note 18, at 16.

51. FOOD AND DRUG ADMIN., U.S. DEP’T OF HEALTH AND HUMAN SERVS., THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS [510(K)], at 3 (2014), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf>.

52. This is only true for similar devices that do not require pre-market notification. *Id.*

53. Erica J. Kraus & Kristi V. Kung, *New FDA Rules Are Boon to Medical Mobile App Developers*, LAW360 (Aug. 7, 2014, 3:51 PM), <http://www.law360.com/articles/564719/new-fda-rules-are-boon-to-medical-mobile-app-developers>, archived at <https://perma.cc/FUC9-TTQH>.

54. *Id.*

55. See, e.g., Letter from James L. Woods, Deputy Dir., Patient Safety & Prod. Quality, Office of In Vitro Diagnostics & Radiological Health, to Myshkin Ingawale, Biosense Technologies Private Ltd. (June 24, 2014).



medical device applications.<sup>56</sup> The collection of fees from the medical industry to fund reviews of innovative drugs, medical devices, generic drugs, and biologics is authorized under Title II of the Food and Drug Administration Safety and Innovation Act (“FDASIA”).<sup>57</sup> These fees can add up, particularly for small companies and start-ups, making it more difficult for some medical apps to enter the market.<sup>58</sup>

### C. *The Draft Guidance*

Finding value in many mobile health applications, the FDA must balance innovation and risk. Therefore, the FDA has chosen to focus the majority of regulation on apps that could present the greatest risk to consumers when they malfunction.<sup>59</sup> As such, the FDA will not regulate apps that “are not marketed, promoted or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or do not otherwise meet the definition of medical device.”<sup>60</sup>

However, “[w]hen [apps] are marketed, promoted, or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or otherwise meet the definition of medical device,” the FDA may enforce the regulations with respect to those apps at its discretion.<sup>61</sup> The FDA’s discretion in this regard is where the line blurs between exempt apps and apps that require FDA approval. FDA discretion is expanded under 21 CFR § 801.4, which allows products to be labeled as devices if they are labeled using language in the claim reserved for devices, even if the product does not seem to be a medical device.<sup>62</sup>

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56. “For [fiscal year] 2013, the registration fee for each establishment is \$2,575 US Dollars. There are no waivers or fee reductions for small businesses. Starting in [fiscal year] 2013, all establishments must pay registration fees, regardless of establishment type or activities conducted.” FOOD AND DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., IMPORTANT INFORMATION ON THE MEDICAL DEVICE USER FEE RATES FOR FY 2013 (OCT 1, 2012 THROUGH SEPT. 30, 2013) 1 (2012), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAlII/UCM315989.pdf> [hereinafter MEDICAL DEVICE USER FEE RATES].

57. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 201 (2012) (medical device user fee amendments of 2012).

58. See MEDICAL DEVICE USER FEE RATES, *supra* note 56.

59. *Hearing on Mobile Medical Apps*, *supra* note 38.

60. *Id.* at n.9.

61. *Id.*

62. 21 C.F.R. § 801.4 (2016).

#### *D. Role of Other Government Agencies in Medical Mobile Health Regulation*

Section 618 of FDASIA, enacted on July 9, 2012, required the Secretary of HHS to prepare a report containing “a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.”<sup>63</sup> As a result, the FDA, the ONC, and the FCC established an “FDASIA Workgroup” under ONC’s Health Information Technology Policy Committee.<sup>64</sup> The workgroup emphasized the importance of “treating functionality the same across platforms and recommended that FDA expedite guidance on mobile medical apps because of the critical importance of providing clarity as soon as possible.”<sup>65</sup>

#### *E. Medical Mobile Health in Peer Nations*

Although the United States does not have a concrete policy regarding mobile medical apps, other countries have instituted such policies, such as the United Kingdom (“UK”). The Medicines and Healthcare products Regulatory Agency (“MHRA”) is an executive agency of the Department of Health in the UK.<sup>66</sup> In March 2014, the MHRA published guidance on medical device stand-alone software, including mobile medical apps.<sup>67</sup> According to the MHRA, software that has a medical purpose could be considered a medical device.<sup>68</sup> The UK requires medical apps that have a “medical purpose” to contain a CE Mark.<sup>69</sup> A CE Mark signifies that the

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63. *Hearing on Mobile Medical Apps*, *supra* note 38 (quoting Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 201 (2012)).

64. *Id.* The workgroup gave its final recommendations in early September 2013, which the Committee adopted. *Id.*

65. *Id.*

66. MEDS. & HEALTHCARE PRODS. REGULATORY AGENCY, <http://www.mhra.gov.uk> (last visited Apr. 8, 2016).

67. *Medical Device Stand-Alone Software (Including Apps)*, MEDS. & HEALTHCARE PRODS. REGULATORY AGENCY, <http://www.mhra.gov.uk/Howweregulate/Devices/Devicesregulatorynews/CON395239> (last visited Apr. 8, 2016).

68. A “medical device” is defined in the Medical Device Directive (“MDD”) as: “software intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception.” *Guidance: Medical Device Stand-Alone Software Including Apps*, MEDS. & HEALTHCARE PRODS. REGULATORY AGENCY, <https://www.gov.uk/government/publications/medical-devices-software-applications-apps/medical-device-stand-alone-software-including-apps> (last visited Apr. 9, 2016) [hereinafter *Guidance on Medical Device Software*].

69. Fiona Graham, *Health Tech: When Does an App Need Regulating?*, BBC (Oct. 13, 2014), <http://www.bbc.com/news/business-29605951>. The types of apps that are most likely to fall into the

developer has met the requirements of a conformance assessment.<sup>70</sup> The requirements of the conformity assessment depend upon the classification of the device.<sup>71</sup> Most mobile medical apps fall into Class I, meaning that manufacturers must self-declare their devices and register with the MHRA.<sup>72</sup> Devices intended for diagnosis are generally Class IIa, which require the use of a notified body to assess compliance.<sup>73</sup> The fees associated with MHRA applications and audits are comparable to FDA fees in the United States.<sup>74</sup>

Additionally, the European Commission (“EC”) published a set of guidelines for the classification of medical software in January of 2012.<sup>75</sup> The guidelines are not legally binding, but it is expected that the guidelines will be used by Member States to create uniformity among directives for medical apps, software, and devices going forward.<sup>76</sup>

#### *F. History of Non-Profit Organizational Regulations*

Non-profit organizations can be an effective means to provide regulation and guidance. In this Subpart, I examine how the United States Pharmacopeia’s (“USP”) voluntary verification mechanism may provide a good structure for creating a similar verification program for mobile medical applications. I then consider how the structure of Health on the Net (“HON”), an international organization, may provide further guidance for the creation of a regulatory guidance system for mobile medical apps in the United States.

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category of medical devices are “[d]ecision support or decision making software that applies some form of automated reasoning, such as a simple calculation, a decision support algorithm or a more complex series of calculations, e.g. dose calculations, symptom tracking, clinicians guides.” *Guidance on Medical Device Software*, *supra* note 68.

70. *Medical Devices: Conformity Assessment and the CE Mark*, MEDS. & HEALTHCARE PRODS. REGULATORY AGENCY, <https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ce-mark> (last visited Apr. 8, 2016).

71. *Id.*

72. *Guidance on Medical Device Software*, *supra* note 68.

73. *Id.* “A notified body is an organisation that has been designated by an EU member state (the designating authority) to assess whether manufacturers and their medical devices meet the requirements set out in legislation.” *Guidance: Notified Bodies for Medical Devices*, MEDS. & HEALTHCARE PRODS. REGULATORY AGENCY, <https://www.gov.uk/government/publications/notified-bodies-for-medical-devices/notified-bodies-for-medical-devices> (last visited Apr. 8, 2016) [hereinafter *Notified Bodies*].

74. *Notified Bodies*, *supra* note 73.

75. *Guidance on Medical Device Software*, *supra* note 68.

76. DIRECTORATE B, UNIT B2 “HEALTH TECHNOLOGY AND COSMETICS,” EUROPEAN COMM’N, GUIDELINES ON THE QUALIFICATION AND CLASSIFICATION OF STAND ALONE SOFTWARE USED IN HEALTHCARE WITHIN THE REGULATORY FRAMEWORK OF MEDICAL DEVICES (2012).

### 1. *United States Pharmacopeia*

USP was founded in 1820, and USP standards were officially recognized through the Federal Food and Drug Act of 1906.<sup>77</sup> USP develops and publishes standards for drug substances, drug products, excipients, and dietary supplements in the United States Pharmacopeia–National Formulary.<sup>78</sup> The FDA enforces any breach of USP standards or provisions, as USP does not have its own enforcement component.<sup>79</sup>

USP also has a voluntary verification program.<sup>80</sup> It awards a mark to ingredients and products that pass its verification requirements and meet good manufacturing practices to help ensure the quality of products for consumers.<sup>81</sup> This program could be used as a model to build capacity for a verification program for mobile medical apps.

### 2. *Health on the Net*

In 1995, leaders in telemedicine came together to address growing concerns regarding the unequal quality of online health information and created the Health on the Net Foundation. HON is a non-profit, non-governmental organization that has been granted consultative status to the Economic and Social Council of the United Nations.<sup>82</sup> HON's mission "is to guide the growing community of healthcare consumers and providers on the World Wide Web to sound, reliable medical information and expertise."<sup>83</sup>

The uncertain quality of medical advice provided on web sites and the lack of scientific evidence behind treatment claims concerned the founders of HON.<sup>84</sup> Accordingly, HON created a code of conduct, the HONcode.<sup>85</sup> The HONcode was the first of its kind to address health and medical

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77. U.S. PHARMACOPEIAL CONVENTION, <http://www.usp.org> (last visited Apr. 8, 2016); *see also USP Milestones—A Timeline*, U.S. PHARMACOPEIAL CONVENTION, <http://www.usp.org/about-usp/our-history/usp-milestones-timeline> (last visited Apr. 8, 2016).

78. *USP in U.S. Law*, U.S. PHARMACOPEIAL CONVENTION, <http://www.usp.org/about-usp/legal-recognition/usp-us-law> (last visited Apr. 8, 2016).

79. *Id.*

80. *Working with U.S. FDA*, U.S. PHARMACOPEIAL CONVENTION, <http://www.usp.org/about-usp/legal-recognition/working-us-fda#> (last visited Apr. 8, 2016).

81. *USP Verification Services*, U.S. PHARMACOPEIAL CONVENTION, [www.usp.org/USPVerified](http://www.usp.org/USPVerified) (last visited Apr. 8, 2016).

82. *New NGO Status for HON*, HEALTH ON THE NET FOUND., <http://www.hon.ch/Global/NGO.html> (last visited Apr. 8, 2016).

83. *Mission & Users*, HEALTH ON THE NET FOUND., [http://www.hon.ch/Global/HON\\_mission.html](http://www.hon.ch/Global/HON_mission.html) (last visited Apr. 8, 2016).

84. *Quality Issue on the Web and HON*, HEALTH ON THE NET FOUND., [http://www.hon.ch/MediaCorner/FAQs\\_HONcode.html](http://www.hon.ch/MediaCorner/FAQs_HONcode.html) (last visited Apr. 8, 2016).

85. *Id.*

websites.<sup>86</sup> HONcode is a self-regulatory, voluntary certification system.<sup>87</sup> At the request of a healthcare website, the HONcode team “addresses, among other things, the authority of the information provided, data confidentiality and privacy, proper attribution of sources, transparency of financial sponsorship and the importance of clearly separating advertising from editorial content.”<sup>88</sup> The HONcode has been adopted by over 3000 websites.<sup>89</sup> The foundation is able to operate with a small staff. It depends, however, on its Advisory Board and Council and people from around the world in the healthcare industry to attain its goals and objectives.<sup>90</sup> HON is inspected by independent organizations to ensure objectivity and accuracy.<sup>91</sup>

Although HON does not have any regulatory or enforcement power, its guidelines may be used by governmental regulatory agencies. For example, the French government has mandated that all health websites must be certified by HON.<sup>92</sup> This is similar to the way USP regulations have been adapted by the FDA to become mandatory and enforceable regulations in the United States.

Private organizations work well for niche or technical issues, because larger, more broadly mandated government agencies may lack the time, capacity, and expertise to deal with narrow but complex issues. The remainder of this Note explores how mobile medical apps continue to operate in and adapt to the current regulatory environment, including

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86. *New NGO Status for HON*, *supra* note 82; see also *The HON Code of Conduct for Medical and Health Web Sites (HONcode)*, HEALTH ON THE NET FOUND., <http://www.hon.ch/HONcode/Conduct.html> (last visited Apr. 8, 2016). The principles of the HONcode are:

1. Authority—information and advice given only by medical professionals with credentials of author/s, or a clear statement if this is not the case;
2. Complementarity—information and help are to support, not replace, patient-healthcare professional relationships which is the desired means of contact;
3. Confidentiality—how the site treats personal and non-personal information of readers;
4. Attribution—references to source of information (URL if available) and when it was last updated;
5. Justifiability—any treatment, product or service must be supported by balanced, well-referenced scientific information;
6. Transparency of authorship—contact information, preferably including email addresses, of authors should be available;
7. Transparency of sponsorship—sources of funding for the site;
8. Honesty in advertising and editorial policy—details about advertising on the site and clear distinction between advertised and editorial material.

*The HON Code of Conduct for Medical and Health Web Sites (HONcode)*, *supra*.

87. *Quality Issue on the Web and HON*, *supra* note 84.

88. *Id.*

89. *New NGO Status for HON*, *supra* note 82.

90. *Questions About the Health on the Net Foundation*, HEALTH ON THE NET FOUND., [http://www.hon.ch/MediaCorner/FAQs\\_HON.html#HON3](http://www.hon.ch/MediaCorner/FAQs_HON.html#HON3) (last visited Apr. 8, 2016).

91. Press Release, Health on the Net Found., HON Quality Management System (Oct. 2007).

92. *Id.*

possible ways to make the process more efficient than the FDA's current method of regulation.

## II. ANALYSIS

Although several technology companies have tried to enter into the mobile medical app and health data market, including Samsung, Google, Verizon, and Qualcomm, Apple's marketing and branding gurus may give mobile medical apps and mobile health data collection the final push towards mainstream use.<sup>93</sup> Regulators must act appropriately and swiftly to decide how to handle and regulate the new technology, including the health data components of mobile medical applications.

### A. Areas of Potential Public Concern

Reliability and accuracy are two of the main components of mobile medical apps that concern consumers, healthcare providers, and government regulators the most. Technology apps do not always specify their target audience, such as if the app is specifically intended for healthcare professionals or for the general public. This means that consumers can access and utilize apps that may be better suited for use by a physician.<sup>94</sup> A physician using a mobile medical app may receive more reliable results than the average user, who may not accurately input or understand medical data. Inaccurate or unreliable readings from an app may lead to undue worry by a user, or may provide a false sense of healthiness.

Reliability is important because doctors and consumers need to know which apps are safe for medical purposes and which apps are just for fun or gimmicks. A study revealed inconsistencies from one app to another, with varying degrees of reliability.<sup>95</sup> Reliable apps will give consistent, accurate results. Accountability will also have to be taken into account when considering the reliability of an app, since app developers are quick

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93. See Darius Tahir, *Why Are Hospitals Using Apple's HealthKit? It's Simple*, MOD. HEALTHCARE (Feb. 5, 2015), [http://www.modernhealthcare.com/article/20150205/NEWS/302059938?utm\\_source=twitterfeed&utm\\_medium=linkedin+company+page](http://www.modernhealthcare.com/article/20150205/NEWS/302059938?utm_source=twitterfeed&utm_medium=linkedin+company+page). Apple is already beginning to dominate the technology market in top hospitals. See, e.g., Christina Farr, *Exclusive: Apple's Health Tech Takes Early Lead Among Top Hospitals*, REUTERS (Feb. 5, 2015, 5:10 PM), <http://www.reuters.com/article/2015/02/05/us-apple-hospitals-exclusive-idUSKBN0L90G920150205>.

94. Cortez, *supra* note 12, at 1777. Notably, only 28% of physicians who use smartphones and 18% of physicians who use tablets are "very satisfied" with the quality of apps for their profession. Thomas Stringham, *Survey of Physicians Suggests Tablets More Useful Than Smartphones*, AM. EHR (June 12, 2013), [http://www.americanehr.com/about/learn\\_more/news/13-06-12/Survey-of-Physicians-Suggests-Tablets-More-Useful-Than-Smartphones.aspx](http://www.americanehr.com/about/learn_more/news/13-06-12/Survey-of-Physicians-Suggests-Tablets-More-Useful-Than-Smartphones.aspx).

95. Faye Haffey et al., *A Comparison of the Reliability of Smartphone Apps for Opioid Conversion*, 36 DRUG SAFETY 111 (2013).

to find ways to distance themselves from any results reached by their apps through legal disclaimers. Similarly, healthcare providers may be unwilling to take on liability for patient action taken as a result of information provided by an app. In that situation, a healthcare provider would likely argue that patients are not actively involved in treatment with the healthcare institution through an app, even if the data may be accessed by the healthcare provider.

Reliability is not always an easy metric to collect, but accuracy is something that can be more easily calculated through a non-profit peer review verification program. A verification of reliability is necessary because some apps offer patients a diagnosis and suggest a course of treatment before they even see a physician. In situations like this, accuracy is paramount. The reading on the app may lead to self-diagnosis and a false sense of security for users. The user may even resist other courses of treatment suggested by a treating physician that knows the patient's history and conducted an in-person examination. For example, a risk stratification app was created by the American College of Cardiology and the American Heart Association to help providers estimate ten-year and lifetime risks for atherosclerotic cardiovascular disease ("ASCVD").<sup>96</sup> Although this app was crafted with physicians in mind, it is freely available on iTunes and also includes resources for patients.<sup>97</sup>

Although the ASCVD Risk Estimator is not a medical device, it offers a prognosis and course of action based on personalized health metrics gathered by and recorded in the app. The FDA will not be able to regulate an app like this, because they do not have regulatory authority, as the app will not likely qualify as a device. Instead, the FDA may find that the app markets diagnostic capabilities and want to regulate it for safety and accuracy. The FDA will find it difficult to do so, as they lack the legal authority and technical know-how to correctly assess the safety and accuracy of the app. For these reasons, a peer reviewer or organization is better suited than the FDA to assess usability and offer usage guidelines for consumers. This approach will better ensure accuracy and provide proper precautions for consumers.

### *B. Expansion of Mobile Health Technology*

Technology companies are beginning to work in coordination with healthcare organizations to create apps that are useful for consumers and healthcare providers. For example, in a deviation from its consumer-based

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96. American College of Cardiology, *ASCVD Risk Estimator*, iTUNES, <https://itunes.apple.com/us/app/ascvd-risk-estimator/id808875968?mt=8> (last visited Apr. 8, 2016).

97. *Id.*

sales model, Apple partnered with the Mayo Clinic and electronic health records vendor Epic Systems to ensure that the Health app and HealthKit properly connect with organizational electronic health records, allowing institutions to quickly intervene with patients whose Health app readings deviate from the normal range.<sup>98</sup>

The Mayo Clinic and the Cleveland Clinic are actively exploring ways to use the data collected through mobile medical apps to treat patients with chronic medical conditions, including high blood pressure and diabetes.<sup>99</sup> The Mayo Clinic is testing a service to monitor patient information from apps and devices in order to follow up with treatment recommendations.<sup>100</sup>

Apple engaged with Mount Sinai, the Cleveland Clinic, Johns Hopkins, and electronic health records provider Allscripts to discuss how Apple's Health app service will work with those healthcare providers.<sup>101</sup> Due to the Health Information Technology for Economic and Clinical Health Act ("Hitech Act"), many healthcare organizations and institutions are prepared to integrate additional technology into their systems, such as mobile access for patients and providers.<sup>102</sup> The Hitech Act, part of the 2009 stimulus package, directed healthcare providers to start using electronic health records.<sup>103</sup> Due to the increased sharing of personal health information, privacy will be a key area of concern going forward for app developers and healthcare providers, systems, and institutions.<sup>104</sup>

Partnering with hospitals and health systems is both helpful and problematic. On the one hand, apps that are created with the help of hospitals, doctors, and other medical personnel could mean improved reliability and functionality. On the other, marketing the apps will be complicated because hospitals benefit financially from patients coming into the hospital, and doctors may feel as though they are losing some control over patient care.

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98. Neil Versel, *Apple's HealthKit Connects with Mayo and Epic, But Don't Call It Revolutionary*, FORBES (June 3, 2014, 1:28 PM), <http://www.forbes.com/sites/neilversel/2014/06/03/apples-healthkit-connects-with-mayo-and-epic-but-dont-call-it-revolutionary/>.

99. Goode, *supra* note 2.

100. *Apple Prepares Healthkit Rollout Amid Tangled Regulatory Web*, CNBC (Aug. 12, 2014, 8:44 AM), <http://www.cnbc.com/id/101913396#>.

101. Allscripts will likely make a move quickly, as "[d]ozens of major health systems that use Epic's software will soon be able to integrate health and fitness data from the Health app into Epic's personal health record, called MyChart, according to a person briefed by Apple." *Id.*

102. Aaron E. Carroll, *The Trouble with Apple's Health App*, N.Y. TIMES (June 16, 2014), [http://www.nytimes.com/2014/06/17/upshot/apples-healthkit-probably-wont-bring-a-new-age.html?\\_r=0](http://www.nytimes.com/2014/06/17/upshot/apples-healthkit-probably-wont-bring-a-new-age.html?_r=0).

103. *Id.*

104. Cyber security will be of particular concern after the massive personal information breach at Anthem Blue Cross Blue Shield. Reed Abelson & Matthew Goldstein, *Anthem Hacking Points to Security Vulnerability of Health Care Industry*, N.Y. TIMES (Feb. 5, 2015), <http://www.nytimes.com/2015/02/06/business/experts-suspect-lax-security-left-anthem-vulnerable-to-hackers.html>.



### C. FDA Concerns

Privacy issues are one reason that a governmental agency may need to regulate an app. Many mobile health apps require users to enter private personal and health information.<sup>105</sup> Accordingly, the privacy components of medical apps are an area of concern for the FDA and other governmental agencies, such as the Department of Health and Human Services (“HHS”).<sup>106</sup> HHS is working on ascertaining the effects of the Health Insurance Portability and Accountability Act (“HIPAA”), which is primarily used to shield and control the sharing of protected health information on medical apps.<sup>107</sup> For example, Apple set up its Health app so that providers, not Apple, are responsible for following privacy requirements.<sup>108</sup> This is a strategy other application developers could use to skirt existing federal regulations, at least as they relate to privacy concerns and HIPAA guidelines. If the FDA does regulate mobile medical apps, developers will likely search for loopholes and adjust their applications to dodge regulation.

In addition to concerns such as privacy, the FDA often decides whether they will regulate a mobile medical health app by evaluating how the app is marketed and held out to the public.<sup>109</sup> For example, in the meeting between the FDA and Apple, the FDA said that the agency will choose whether to regulate based on the intended use of a device.<sup>110</sup> During the meeting, the FDA addressed Apple’s glucometer example: “[T]he glucometer may be unregulated if the intent is for a user to follow their blood sugar for the purposes of better nutrition. If the glucometer is marketed for diabetics, however, it would more likely be regulated as a medical device.”<sup>111</sup>

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105. *Fact Sheet 39: Mobile Health and Fitness Apps: What Are the Privacy Risks?*, PRIVACY RIGHTS CLEARINGHOUSE, <https://www.privacyrights.org/mobile-health-and-fitness-apps-what-are-privacy-risks> (last visited Apr. 8, 2016).

106. Anne Marie Helm & Daniel Georgatos, *Privacy and mHealth: How Mobile Health “Apps” Fit into a Privacy Framework Not Limited to HIPAA*, 64 SYRACUSE L. REV. 131 (2014).

107. “HIPAA protects personally-identifiable health information . . . stored or transmitted by a ‘covered entity,’ like a care provider or health plan. Patient-generated information from a mobile app, for instance, has to be protected once the data is given to a covered entity or its agent.” *Apple Prepares Healthkit Rollout Amid Tangled Regulatory Web*, *supra* note 100.

108. *Id.* When the iPhone is locked with a passcode, all health and fitness data in the Health app is encrypted, and Apps that access HealthKit are required to have a privacy policy. *Health*, APPLE INC., <http://www.apple.com/ios/health/> (last visited Apr. 8, 2016).

109. Serhat Kurt, *Apple and the FDA Have Discussed FDA Regulations Regarding Possible New Mobile Products, Sensors and a Glucometer*, APPLE TOOLBOX (June 9, 2014), <http://appletoolbox.com/2014/06/apple-fda-discussed-fda-regulations-regarding-possible-new-mobile-products-sensors-glucometer/>.

110. *Id.*

111. *Id.*

Additionally, many app developers have started to include disclaimers such as “not intended for use as a medical device,” hidden in the fine print, to avoid legal and regulatory liability.<sup>112</sup> It is unclear how phrases like that will protect app developers if the FDA determines the app is marketed as a medical tool that will aid in a user’s diagnosis or treatment.

#### *D. The FDA’s Regulatory Approach*

Health technology experts and scholars have argued for greater FDA involvement and regulation in the mobile medical health industry.<sup>113</sup> However, the FDA claims to have developed the Agency’s mobile medical apps policy to protect public health and promote innovation and does not plan on becoming more involved.<sup>114</sup>

The concern of industry experts and insiders surrounding FDA regulation of mobile medical apps is understandable because the FDA has not always been the most responsive to changes in medical technology. For instance, the FDA was less than responsive when medical devices software emerged in the 1980s.<sup>115</sup> This raised concerns as to why the US public should trust the FDA to properly handle the regulation of medical health apps.<sup>116</sup> The extremely fast pace of app development and the tendency for an app to become obsolete within a matter of months has already been a unique challenge to the FDA.<sup>117</sup> Bakul Patel, a senior

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112. Siemens AG, *UA Guide*, iTunes, <https://itunes.apple.com/us/app/ua-guide/id918506363?mt=8> (last visited Apr. 8, 2016). For instance, the UA Guide app, which is designed for healthcare professionals when conducting urinalysis, includes the follow disclaimer:

The UA Guide is not intended for use as a Medical Device Application, as an accessory to regulated medical devices, or for use in clinical practice or to assist in making clinical decisions. The UA Guide is intended for educational purposes only and is not commercially marketed for a specific medical indication.

*Id.*

113. See, e.g., Cortez, *supra* note 12 (arguing for stricter FDA oversight); see also Samuel J. Dayton, *Rethinking Health App Regulation: The Case for Centralized FDA Voluntary Certification of Unregulated Non-Device Mobile Health Apps*, 11 IND. HEALTH L. REV. 713 (2014) (suggesting that the regulation framework should be created solely by the federal government); Vincent J. Roth, *The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation Is Required?*, 15 N.C. J.L. & TECH. 359 (2014) (exploring the different regulatory approaches the FDA could take, and arguing for a more stringent approach).

114. *Hearing on Mobile Medical Apps*, *supra* note 38.

115. Cortez, *supra* note 12, at 1200–17.

116. “We’ve got an agency, which was created long before these technologies even existed, proposing to shoehorn health IT into its existing framework . . . . It’s like pushing a square peg into a round hole[.]” stated Dan Haley, Athena’s Vice President of Government and Regulatory Affairs. Christina Farr, *Congress Wants to Kick the FDA Out of Digital Health with This New Bill*, VENTUREBEAT (Feb. 26, 2014, 8:00 AM), <http://venturebeat.com/2014/02/26/new-digital-health-bill-proposes-to-undermine-the-fda-draws-mixed-reactions/>.

117. Joshua Barajas, *FDA Regulation Can’t Keep Pace with New Mobile Health Apps*, PBS (July 7, 2014), <http://www.pbs.org/newshour/rundown/fda-regulation-unable-keep-pace-new-mobile-health-apps/>.

policy adviser for the FDA's Center for Devices and Radiological Health, discussed this problem, stating that "[t]he whole mobile app world has its own ecosystem where things live, die and sort of recycle again, and it's mostly consumer driven."<sup>118</sup> Because of the fast "life cycles" of apps and unpredictability of consumer desires, the FDA must either develop a way to handle the massive volume and time constraints surrounding medical app review, propose a new solution, or yield control to another agency or organization.

For now, the FDA's focus is on the oversight of mobile medical apps intended to supplement a regulated medical device.<sup>119</sup> For example, an application that allows a medical professional to make a diagnosis by viewing a medical image such as an ultrasound, MRI, mammogram, or PET scan from a picture taken on and transmitted from a smartphone or tablet is subject to regulation.<sup>120</sup> The FDA also intends to focus on medical apps that transform a mobile platform into a regulated medical device like an ECG.<sup>121</sup>

Of significant advantage to companies that sell mobile apps, like Apple, Google, and Samsung, is that the FDA will not regulate companies that sell mobile apps through online marketplaces as manufacturers.<sup>122</sup> However, once the FDA finds that an app is a medical device, the app will be held to the same stringent standards as any other medical device. The gray area encompassing those apps that are neither clearly regulated medical devices nor simply apps is problematic for developers, consumers, and doctors.

Regarding the regulation of companies that sell mobile devices that use apps, the FDA recently released (under a Freedom of Information Act request) a memorandum that described its meeting with Apple executives in December of 2013.<sup>123</sup> Apple was primarily concerned about the FDA's approach to regulation of medical apps, as the release date neared for its Health app and Apple Watch.<sup>124</sup> FDA officials said that the FDA "would be more likely to regulate the software that puts [a medical] sensor to use, if use of the software alters the device's use to be a medical device."<sup>125</sup> The officials also told Apple that "apps that actively measure something"

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118. *Id.*

119. *The FDA May Want to Regulate Your mHealth App.—Updated*, OMNICA CORP., <http://www.omnica.com/the-fda-will-look-at-your-mhealth-app/> (last visited Apr. 8, 2016).

120. *Id.*

121. *Id.*

122. Ki Mae Heussner, *Urine-Analysis App Turns to Indiegogo to Help It Win FDA Clearance*, GIGAOM (July 30, 2013, 4:30 AM), <https://gigaom.com/2013/07/30/urine-analysis-app-turns-to-indiegogo-to-help-it-win-fda-clearance/>.

123. Kurt, *supra* note 109.

124. The Apple iWatch may include health sensors, such as a glucometer. *Id.*

125. *Id.*

are “diagnostic” and are, therefore, more likely to make the entire tool, a mobile phone in this case, subject to regulation.<sup>126</sup>

Ultimately, the FDA’s guidance leaves it with a substantial amount of discretion. This discretion and lack of clarity may result in inconsistent FDA action with respect to many health apps, which in turn leads to uncertainty for app developers, as the following examples demonstrate.

### *E. Instances of FDA Action*

The FDA becomes involved with medical apps when it believes an app crosses the line into medical device territory. For instance, in the spring of 2013, the FDA flagged Biosense’s uChek.<sup>127</sup> The app is blocked from the market until it receives FDA approval.<sup>128</sup> A letter from the FDA to Biosense stated that the app was blocked because, “though the types of urinalysis dipsticks [Biosense] reference[s] for use with [its] application are cleared, they are only cleared when interpreted by direct visual reading. Since [Biosense’s] app allows a mobile phone to analyze the dipsticks, the phone and device as a whole functions as an automated strip reader.”<sup>129</sup>

Biosense launched a crowdsourcing campaign through Indiegogo to help raise money and collect user data for its uChek app to help gain FDA clearance.<sup>130</sup> Biosense will likely need to seek 510(k) approval, which does not usually require clinical testing.<sup>131</sup> The application requires that the company prove its device is similar to one already on the market.<sup>132</sup>

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126. Scott Gottlieb & Coleen Klasmeier, *Why Your Phone Isn’t as Smart as It Could Be*, WALL ST. J. (Aug. 7, 2014, 8:16 PM), <http://www.wsj.com/articles/scott-gottlieb-and-coleen-klasmeier-why-your-phone-isnt-as-smart-as-it-could-be-1407369163>.

127. Edney, *supra* note 16.

128. *Id.*

129. Letter from James L. Woods, *supra* note 55.

130. Heussner, *supra* note 122.

131. *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/> (last visited Apr. 9, 2016) (“A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to [Premarket Approval].”).

132. Edney, *supra* note 16.

### F. Instances of FDA Inaction

The Apple Health app fits into a category of apps that the FDA said it will not regulate.<sup>133</sup> The FDA will not regulate apps that allow “a user to collect, log, track and trend data such as blood glucose, blood pressure, heart rate, weight or other data from a device to eventually share with a health care provider, or upload it to an online (cloud) database, personal or electronic health record,” things the Health app intends to do.<sup>134</sup> However, just because the FDA declines to regulate an app does not mean a developer is safe from other governmental regulation. In 2011, the Federal Trade Commission (“FTC”) made its first health claims in the mobile app marketplace against two acne apps that purported to be able to treat acne with colored lights emitted from smartphones or mobile devices.<sup>135</sup> The FTC alleged that the acne treatment claims made for both apps were unsubstantiated. Inaction by the FDA may reveal a willingness on behalf of the FDA to not become involved in the free flow of information sent directly to healthcare providers from app users.

### G. Ongoing Legislation

Congressional legislation on mobile medical health apps is currently nonexistent.<sup>136</sup> Congress may take action on the issue of mobile medical apps in the future, which will help guide the FDA. The proposed legislation includes three acts: The MEDTECH Act,<sup>137</sup> the SOFTWARE Act,<sup>138</sup> and the PROTECT Act.<sup>139</sup>

The Medical Electronic Data Technology Enhancement for Consumers’ Health Act, or the MEDTECH Act, proposes that electronic health records and “other technologies that only store and communicate information [be] exempt from FDA regulation.”<sup>140</sup> An exemption that exists only through FDA guidance and is not law.<sup>141</sup> This shields apps that allow users to store their medical records in an app or communicate health

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133. Dolan, *supra* note 4.

134. *Examples of Mobile Apps for Which the FDA Will Exercise Enforcement Discretion*, *supra* note 44.

135. Both claims were settled. Press Release, Fed. Trade Comm’n, “Acne Cure” Mobile App Marketers Will Drop Baseless Claims Under FTC Settlements (Sept. 8, 2011).

136. “Neither will it be involved in regulating sales or general use of smartphones, tablets, or other mobile devices.” HEALTHAFFAIRS & ROBERT WOOD JOHNSON FOUND., *supra* note 25, at 3.

137. MEDTECH Act, S. 1101, 114th Cong. (2015).

138. SOFTWARE Act, H.R. 2396, 114th Cong. (2015).

139. PROTECT Act of 2014, S. 2007, 113th Cong. (2014).

140. John R. Graham, *Regulating Mobile Health Apps Under a 38-Year-Old Law: It’s Time for Congress to Act*, NAT’L CTR. FOR POL’Y ANALYSIS (Dec. 17, 2014), <http://healthblog.ncpa.org/regulating-mobile-health-apps-under-a-38-year-old-law-its-time-for-congress-to-act/>.

141. *Id.*

statistics to their healthcare providers. A new provision of the MEDTECH Act gives the FDA the authority to “regulate any medical software ‘reasonably likely to have serious adverse health consequences.’”<sup>142</sup> However, the new provisions impose limits on the FDA’s power to regulate software by requiring the FDA to publish a notice in the Federal Register justifying its rationale for regulating the software and allowing thirty days for public comment.<sup>143</sup> The Senate Health, Education, Labor and Pensions Committee approved the last version of the MEDTECH Act on March 9, 2016.<sup>144</sup>

The Sensible Oversight for Technology which Advances Regulatory Efficiency Act, or the SOFTWARE Act, first introduced in October of 2013 and re-introduced in January of 2015, “divides health IT into only two categories: medical software to be regulated by the U.S. Food and Drug Administration and health software that won’t be regulated.”<sup>145</sup> If the bill passes, the FDA must develop a new regulatory program to regulate the first category of medical software.<sup>146</sup> According to the Act, medical software “is intended to analyze patient-specific information and other information to recommend to healthcare professionals a single treatment or course of action . . . without the need for such professionals to perform additional interpretation of, or to independently confirm the means for, such recommendation.”<sup>147</sup> The language implies the Act will pertain to software used by healthcare professionals in healthcare settings, rather than technology found in mobile medical apps. Congress has not taken further action since the Act was reintroduced in January 2015.

If passed, the Preventing Regulatory Overreach to Enhance Care Technology (“PROTECT”) Act of 2014 would strip authority from the regulators who currently oversee health technology, particularly the FDA.<sup>148</sup> The bill is intended to relieve the FDA of regulatory burdens, and “its sponsors say the bill would prioritize the FDA’s attention to technologies that pose the greatest health risk, rather than giving the agency broad authority over ‘low-risk health IT’ and thus hindering

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142. David Pittman, *MEDTECH Act Revision Boosts FDA’s Power*, POLITICO (Mar. 8, 2016, 10:00 AM), <http://www.politico.com/tipsheets/morning-ehealth/2016/03/medtech-act-revision-boosts-fdas-power-213094#ixzz44sVlgGVd>.

143. *Id.*

144. Jeannie Baumann, *Senate Panel Approves Zika Measure, Other Innovation Bills*, BLOOMBERG (Mar. 10, 2016), <http://www.bna.com/senate-panel-approves-n57982068382/>.

145. Dan Bowman, *SOFTWARE Act Revision ‘Simplifies’ Health IT Regulation*, FIERCEHEALTHCARE (Jan. 26, 2015, 11:40 AM), <http://www.fiercehealthit.com/story/software-act-revision-simplifies-health-it-regulation/2015-01-26>.

146. *Id.*

147. *Id.* (internal quotation marks omitted).

148. Farr, *supra* note 116.

innovation.”<sup>149</sup> Some believe that this bill goes too far and will put consumers at risk if the medical apps do not function as advertised.<sup>150</sup> As with most legislation, it is unclear when and to what extent this legislation will pass, but there has not been any action taken since 2014, when it was referred to the Committee on Health, Education, Labor and Pensions.<sup>151</sup>

The current absence of regulation leaves the mobile health industry uncertain. Dan Haley, Vice President of Government and Regulatory Affairs at Athena, is unsatisfied that the FDA gave the industry little more than a set of “non-binding recommendations” that may be changed at the FDA’s whim.<sup>152</sup> Such uncertainty may discourage innovation in the medical app market. Developers have expressed concern that the FDA’s unclear guidelines and enforcement policies have scared them away from designing more mobile medical apps.<sup>153</sup> Additionally, classification as a medical device could subject medical mobile health apps to the 2.3% medical device tax from the Patient Protection and Affordable Care Act (“ACA”).<sup>154</sup> “Overbroad application of this classification could stall the innovation, investment, and job creation that wireless smartphones and apps are bringing to healthcare, as well as ultimately impact the larger wireless ecosystem.”<sup>155</sup>

As Google co-founder Sergey Brin put it during a speech to CEOs of technology companies in Silicon Valley, “[h]ealth is just so heavily regulated . . . it’s just a painful business to be in.”<sup>156</sup> An advantage of smartphone apps is that they are constantly improved through updates, “yet under the FDA’s existing rules, once a medical app comes under the agency’s premarket scheme, each iteration can require formal submissions

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

150. A coalition of patient advocacy organizations, including the American Medical Women’s Association, the Jacobs Institute of Women’s Health, National Consumers League, National Physicians Alliance, National Research Center for Women & Families, and the National Women’s Health Network, voiced such a concern in a letter sent to Senator Tom Harkin (D-Iowa), Chairman of the Senate Committee on Health, Education, Labor and Pensions (HELP) on February 14, 2014. Greg Slabodkin, *Industry Group Voices ‘Extreme’ Concern with PROTECT Act*, FIERCEHEALTHCARE (Feb. 19, 2014, 4:20 PM), <http://www.fiercemobilehealthcare.com/story/industry-group-voices-extreme-concern-protect-act/2014-02-19>.

151. PROTECT Act of 2014, S. 2007, 113th Cong. (2014).

152. Farr, *supra* note 116.

153. Christina Farr, *Entrepreneurs Say the FDA is Killing Medical Innovation*, VENTUREBEAT (Apr. 30, 2013, 7:00 AM), <http://venturebeat.com/2013/04/30/stifled-by-regulation-entrepreneurs-take-life-saving-devices-overseas/>.

154. “Depending on how the law is interpreted, this tax potentially could apply to mobile health applications as well as smartphones and tablets.” *Health Information Technologies*, *supra* note 21, at 2.

155. *Id.*

156. Gottlieb & Klasmeier, *supra* note 126.

and in some cases review by the agency before it can be offered to consumers,” which is prohibitively costly for developers in terms of time and money.<sup>157</sup> Stringent regulation could slow or halt future development and improvements of apps and make developers less likely to create such apps in the first place, out of fear of excessive regulation. To allow tech companies to develop new and useful apps and encourage innovation in this important field, the process must be made less “painful.”

### III. PROPOSAL

Despite the confusing and changing regulatory climate, technology companies continue to explore possibilities in the healthcare industry. Government regulators and agencies must either keep up with advancements in technology or refrain from the regulation of mobile medical apps. The current gray area creates confusion for developers, consumers, and the healthcare industry. There are three possibilities for the regulation of mobile medical apps: (1) FDA regulation, (2) regulation by non-profits that are given standing and enforcement power through legislation, or (3) regulation by non-profits without legislative standing or governmental oversight.

#### A. *Government Regulation and Certification*

The first option is government regulation, likely by the FDA. As discussed in Part I, if the FDA continues to attempt to regulate mobile medical apps, it needs to address challenges like the fast pace of development, as the sheer volume of app production could overwhelm the FDA’s limited resources.

As part of a regulatory scheme for mobile medical apps, the FDA may find a way to streamline a verification program, similar to CE verification in the United Kingdom, that would allow consumers and healthcare professionals to know if an app is safe. Copying the UK approach may not be popular in the United States because of the strict definition of a medical app in the United Kingdom.<sup>158</sup> Accordingly, the threshold for FDA regulation should not be too stringent, as a backlog will quickly form if the process is too lengthy, and beneficial mobile medical apps will take too long to get to the market. Additionally, the FDA should allow for updates and minor changes to be made without requiring new certification to deal with the rapidly changing nature of mobile medical apps.

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157. *Id.*

158. *Guidance on Medical Device Software*, *supra* note 68.



A certification system would provide a greater amount of preventative care, conforming with one of the ACA's key initiatives.<sup>159</sup> If a certification system exists, doctors can give better recommendations regarding which apps patients can use to monitor their vital statistics, chronic conditions, and minor illnesses. Increased collaboration between app makers, like Apple, and electronic health record systems, like Epic and AllScripts, will aid and streamline data sharing between apps and healthcare facilities.

The use of apps for monitoring and preventive care will lower healthcare costs for providers and consumers. Apps that are medical devices and, therefore, regulated by the FDA, may lower healthcare costs because they will provide millions of doctors and patients with easy access to medical advice. Unlike a simple online search, mobile medical apps have the potential to personalize a diagnosis because apps are interactive and able to utilize the features of smartphones to get accurate data and health history and trends instantly. Patients no longer have to go into a doctor's office to get an accurate reading and interpretation of their heart rate, blood pressure, or blood sugar. Doctors can receive the data through the apps and interpret the metrics, monitor, and give advice to their patients in lieu of frequent, and costly, face-to-face appointments.

Rising healthcare costs make mobile medical app solutions more attractive to consumers, which increases the importance of making sure apps on the market are safe and effective. Additionally, many Americans do not seek preventative care because they do not have easy access to healthcare providers or do not think it is necessary to go to the doctor for preventative care.<sup>160</sup> If preventative care and monitoring becomes more accessible through mobile phone apps, people may be more likely to monitor their health and know when to seek care if a problem arises. This is especially true when people use mobile health apps that are integrated with hospitals and health systems. More efficient and cost effective preventative care and monitoring is likely what Apple has in mind as it builds relationships with hospitals and corporations like the Mayo Clinic and Epic Systems.<sup>161</sup>

The slow progression of legislation and bureaucracy is one of the key reasons that a non-governmental solution may bring more expedient

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159. Insurers are required to cover preventative services for children, seniors, women, and adults, including blood pressure screenings, cholesterol screenings, mammograms, colonoscopies, and osteoporosis screenings. See *Coverage to Care*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/healthcare/prevention/index.html> (last visited Apr. 8, 2016).

160. Eryn Brown, *Many Didn't Benefit from Preventive Care Before 2010, CDC Says*, L.A. TIMES (June 14, 2012), <http://articles.latimes.com/2012/jun/14/news/la-heb-cdc-prevention-report-healthcare-reform-20120614>.

161. Chen, *supra* note 1.

results. Expediency is fundamental to keep pace with an industry developing as rapidly as mobile medical care.

### *B. Non-Profit Peer Review with Government Partnership*

The second option is regulation by a non-profit organization comprised of experts in the field. This non-profit organization can be given an enforcement arm adopted through legislation. Similar to prescription drug guidance and standards set forth by the USP, this approach would provide a uniform set of guidelines for developers, regulators, and consumers.

The FDA, like many governmental agencies, is often overburdened and underfunded.<sup>162</sup> Therefore, allowing a private organization with specialized expertise in mobile medical health applications to regulate the industry may be more efficient and effective.<sup>163</sup> The public-private relationship between the FDA and USP is a perfect example of how a non-profit organization that specializes in a certain area can help the government regulate an important but very complex field. The development of guidelines or a certification system for mobile health apps by a non-profit and/or peer review may lead to safer apps on the market and advance public health initiatives. A set of guidelines or “stamp of approval” will allow consumers to make better decisions when choosing which mobile medical apps to use for things like preventative care.

However, this option may take a long period of time to achieve because the organization must gain peer and political approval before their recommendations would be given serious legislative consideration and be given agency recognition status. Creating an organization to provide guidance is the first step towards achieving this goal and may provide consumers with useful information until formal guidance and regulation is published.

### *C. Non-Profit Guidance and Certification*

The third option is regulation by a non-profit organization without legislative standing, akin to how HON operates. HON was created in response to an enormous and growing amount of medical information available on the Internet.<sup>164</sup> The increasing use of smartphones and

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162. SUBCOMM. ON SCI. AND TECH., FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY (2007), available at [http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_01\\_FDA%20Report%20on%20Science%20and%20Technology.pdf](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf).

163. See Dayton, *supra* note 113.

164. *The Services Offered by HON*, HEALTH ON THE NET FOUND., <http://www.hon.ch/home1.html> (last visited Apr. 8, 2016).

growing availability of medical apps is similar to the rapid growth of medical websites that triggered the establishment of HON. Similar concerns about mobile medical apps may facilitate the formation of a peer organization to assist in the verification of mobile apps for efficacy and safety. Ideally, as in a legislatively recognized non-profit, the government will eventually adopt regulations proposed by the non-profit organization, akin to what some European countries have done for HON certification.

HON recognized that increasing numbers of the general public sought healthcare information online, but oversight of such information—and misinformation—was lacking.<sup>165</sup> This problem, however, could be improved through the certification of many mobile medical apps. A voluntary certification process for mobile medical apps could be extremely beneficial for lay consumers as well as mobile health app developers and health professionals.

Due to the problems faced by the FDA regarding the regulation of mobile medical apps, a non-profit alternative may be more effective.<sup>166</sup> This approach will better ensure accuracy and provide proper precautions for consumers. It will also have the capability to operate on an expedited timeframe.

A system similar to Health on the Net would be most conducive for the review and certification of mobile health and medical applications that do not fall within the purview of FDA guidelines or regulations. Applications that do not fall within either category are apps that contain medical information but in no way analyze or use patient metrics to create a diagnosis or treatment suggestions. Although such apps are not as likely to cause harm, a peer review and certification system could provide much needed guidance. This will help to reassure consumers that they are using an app that provides safe and reliable medical information.

A non-profit verification program would be completely voluntary for app developers and would not have any enforcement powers for non-compliance. The only exception would be in taking away certification if the app developer voluntarily applied for certification and later changed its application without seeking further approval. If a government wants the guidelines to be enforceable, the legislature may adopt a non-profit's guidelines as law, similar to what France did by enforcing the guidance promulgated by Health on the Net.

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165. In fact, “[o]ne in ten sites about cancer treatment and mental diseases have wrong information.” *Quality Issue on the Web and HON*, *supra* note 84.

166. *See* Roth, *supra* note 113.

If a group interested in the safety and efficacy of mobile medical apps could find a platform to present its ideas, it could have an accelerated path to recognition and credibility. A non-profit organization will have to build credibility within academic and medical communities. Health on the Net did this by partnering with governments and the United Nations.<sup>167</sup> Affiliating with an existing nongovernmental organization or non-profit may help an organization build credibility and recognition more expediently. Health on the Net came about after a summit regarding the rapid spread of information and misinformation on the Internet and flourished through its affiliation with the United Nations.<sup>168</sup> Because of the growing number of people in the world with access to smartphones, the international community may want to partner with an organization focused on the verification of safe and reliable mobile medical apps.

#### CONCLUSION

Part III discussed three potential regulators of health apps: (1) the FDA; (2) a non-profit organization that will organize a voluntary verification program; or (3) a non-profit organization that will develop guidelines that a governmental agency, likely the FDA, will adopt and enforce. A peer review system combined with a non-profit organization that specializes in mobile medical technology will be more efficient and useful for mobile medical apps than the current FDA guidelines (or lack thereof). This Note shows that the ideal level of formality is a sensible approach to regulation, somewhere in between the verification methods of USP and Health on the Net.

Too much government regulation may decrease investment in mobile medical technology because regulation is costly and time consuming. Decreased investment will hamper research and development for mobile medical apps that could help monitor people's health and wellbeing. A peer review and nonprofit option is less expensive and more efficient. However, those options lack regulatory enforcement power. The FDA can eventually adopt some of the private guidelines once they have proven to be effective and beneficial. Current FDA guidance may be preventing useful apps from coming onto the market, while allowing mere gimmicks to enter and remain on the health app market. Developers of useful apps are wary of becoming entangled in a complex and vague regulatory web and the costs associated with it. The case-by-case review being utilized by the FDA is not an effective way of keeping up with the growing volume

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167. *New NGO Status for HON*, *supra* note 82.

168. *Id.*

and demand for mobile medical apps. By giving app developers a quicker and cheaper alternative route to getting safe, reliable, and accurate mobile medical health apps to consumers, the mobile health field will continue to grow and produce high quality medical apps.

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