MOBILE MEDICAL APP REGULATION: PREVENTING A PANDEMIC OF "MOBILECHONDRIACS"

I. INTRODUCTION

Good news for number crunchers, bad news for hypochondriacs: the human body has been digitized. Advancements in biotechnology and human genome sequencing,[1] paralleled by the exponential saturation of wireless communication networks over the last decade,[2] have opened the door for software programmers to turn wireless devices like smartphones, tablet computers, and personal digital assistants (PDAs) into mobile medical devices.[3] This confluence of medicine and telecommunications ignites a new healthcare paradigm[4] in which the human body becomes a mine filled with golden patient data, the smartphone becomes a pickaxe, and doctors become statistical prospectors who can now diagnose, treat, and soon *prevent* illness anywhere, in real time. And while some who have already joined the gold rush find themselves sifting through mountains of new medical data, both patient and doctor must tread lightly in transitioning to hyper-informed consent and preventative care models[5] until the application software (app) industry and the federal government begin to work together

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1. Francis S. Collins et al., *A Vision for the Future of Genomics Research*, 422 NATURE 835, 835 (2003), *available at* http://www.nature.com/nature/journal/v422/n6934/pdf/nature01626.pdf. The National Human Genome Research Institute announced the complete sequencing of the entire human genome on April 24, 2003. *See About NHGRI: A Brief History and Timeline,* NATIONAL HUMAN GENOME RESEARCH INSTITUTE, http://www.genome.gov/10001763 (last visited Nov. 17, 2013) (providing a timeline of the institute's past and recent efforts).

2. ERIC TOPOL, THE CREATIVE DESTRUCTION OF MEDICINE 3-5 (2012).

3. *See* Joshua Brustein, *Coming Next: Using an App as Prescribed,* N.Y. TIMES, Aug. 20, 2012, at B1, *available at* http://www.nytimes.com/2012/08/20/technology/coming-next-doctors-prescribing-apps-to-patients.html; Peter Wayner, *Monitoring Your Health with Mobile Devices*, N.Y. TIMES, Feb. 23, 2013, at B7, *available at* http://www.nytimes.com/2012/02/23/technology/personaltech/monitoring-your-health-with-mobile-devices.html.

4. TOPOL, *supra* note 2, at 5. *See also* Charles M. Davids & Michael J. Santorelli, *Seizing the Mobile Moment: Spectrum Allocation Policy for the Wireless Broadband Century*, 19 COMMLAW CONSPECTUS 1, 19 (2010) ("Broadband [internet access] is . . . enabling a universe of telemedicine services that provide a number of life-enhancing, and potentially lifesaving benefits.").

5. *See* Wayner, *supra* note 3 (suggesting that "[t]here are some really progressive doctors who are recognizing the opportunities here for better care and prevention, but most are resistant to change").

to ensure that the biodata collected by real live patients is not simply fool's gold.[6]

Smartphones are inexpensive, multi-use, portable computing platforms whose apps can be installed, updated, and accessed with the simple tap of a finger, instantaneously transforming the functionality of the device to satisfy every whim of the beholder. As Dr. Eric Topol aptly analogized, these adaptable pocket supercomputers are like "pluripotent stem cells, capable of acting as our calculator, alarm clock, photo album, watch, camera, video and voice recorders, flashlight, and more."[7] Amidst the vast sea of high-cost, limited-function medical devices currently occupying care facilities nationwide, a physician can consolidate much of her office and laboratory into a messenger bag containing only a hand-held smartphone or tablet and an array of small attachable accessories.[8] In fact, mobile medical apps and accessories capable of collecting, translating, and analyzing myriad signals from a patient's body are already on the market.[9] Apps can already detect low glucose levels,[10] regulate high blood pressure,[11] prevent impending heart attacks,[12] and "smell" a patient's breath for organic compounds found in cancerous cells[13] — all in real time, all for the sake of preventive care. To return to the mining metaphor, the smartphone not only serves as a pickaxe for mining data, but also acts as a canary in the coal mine,[14] alerting patients to the presence of hidden dangers.

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6.   *Id.* ("Some of the attempts to turn the iPhone into a medical device are little more than toys."). *See also* Jenny Gold, *Medical Apps Bump up against Regulators*, USA TODAY, July 3, 2012, at 5D.

7.   TOPOL, *supra* note 2, at 62. *See also* Ian Murnaghan, *Pluripotent Stem Cells*, EXPLORE STEM CELLS, http://www.explorestemcells.co.uk/pluripotentstemcells.html (last visited Feb. 17, 2013) (finding that in cellular biology, a pluripotent stem cell has the potential to "differentiate into almost any cell in the body" prior to its embryonic stage).

8.   Abraham Verghese, M.D., *The Things We Carried, Then and Now*, N.Y. TIMES, Oct. 9, 2012, at D2 ("As technology advances and gets more portable, I see [doctors] bringing more tools to the bedside . . . instead of sending [patients] hither and thither to diagnostic suites.").

9.   Brian Dolan, *Analysis: 75 FDA-cleared Mobile Medical Apps*, MOBI HEALTH NEWS, (Dec. 12, 2012), http://mobihealthnews.com/19638/analysis-75-fda-cleared-mobile-medi cal-apps/.

10.   *See, e.g.*, Brian Dolan, *FDA Clears AgaMatrix's iPhone Glucose Meter*, MOBI HEALTH NEWS (Dec. 7, 2011), http://mobihealthnews.com/15137/fda-clears-agamatrixs-iphone-glu cose-meter/.

11.   TOPOL, *supra* note 2, at 69.

12.   *Id.* at 68.

13.   *Id.* at 164-65; Katherine Bourzac, *Cancer Breath Test Enters Clinical Trials*, MIT TECH. REVIEW (Feb. 14, 2012), http://www.technologyreview.com/news/426894/cancer-breath-test-enters-clinical-trials/.

14.   Long ago, miners brought canary birds or mice into coal mines to detect deadly gases. Essentially, if the caged canary died in the mine, the level of carbon monoxide or other gas was too high, signaling the need for emergency evacuation of all miners. *See* Walter H. Page &

The influx of mobile medical apps and devices on the horizon could likely cause a shift from reaction-based care to prevention-based care. For example, a physician treating a patient at risk of diabetes could prescribe an app to monitor a patient's glucose levels[15] and another to encourage healthy eating and exercise choices.[16] Doctors and patients can then employ more individualized data to derive a treatment plan that is potentially more effective than conventional population-based prescription methods.[17] Treatments beneficial to a number of clinical trial participants often prove harmful to a specific subset of patients whose attenuated circumstances, comorbidity factors, or genetic aversions to certain drugs complicate effective prescribing.[18] Wireless monitoring via smartphone could help shift the practice of medicine away from a one-size-fits-most[19] approach and toward a model based on a walking one-person medical trial. Such individualized and highly-informed decision-making can improve the overall quality of patient care[20] and drastically reduce the likelihood of unnecessary or ineffective treatments and tests,[21] which can result in the additional benefit of saving the patient and provider money. All this rests on the presumption, however, that these new mobile medical apps and devices actually work as intended.

Ensuring the safety and efficacy of mobile medical apps requires regulation that balances consumer safety and freedom to innovate. The potential benefits for patients and health care providers are limitless, but so

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Arthur W. Page, *Resuscitation Cage for Mine Canaries,* 28 THE WORLD'S WORK: REDRAWING THE RAILROAD MAP OF THE WORLD 474, 474 (1914).

15. *See, e.g.*, *About iBGStar*, iBGSTAR.US, http://www.ibgstar.us/what-is-ibgstar.aspx (last visited Jan. 23, 2013).

16. *See, e.g.*, *Diabetes Nutrition & Diet Tracker by Fooducate*, ITUNES APP STORE, https://itunes.apple.com/us/app/diabetes-nutrition-diet-tracker/id545282286?mt=8 (last visited Feb. 18, 2013).

17. *See* TOPOL, *supra* note 2, at 210-15 (arguing that constant wireless monitoring illuminates nuances in different patients with the same illnesses, which means "massive trials of population-based medicine would no longer be needed; instead we could design trials of a few hundred patients at most").

18. *See id.* at 210.

19. *See id.* at 21-22 (describing "large-scale randomized, double-blind, placebo-controlled clinical trial[s]" as "population medicine, the antithesis of medicine directed at and for an individual").

20. *See* Paul J. Fortier et al., *Improved Patient Outcomes through Collaborative Monitoring and Management of Subtle Behavioral and Physiological Health Changes*, 44 HAW. INT'L CONF. SYSTEM SCIS. PROC. 1 (2011), *available at* http://www.hicss.hawaii.edu/hicss_44/bp44/CL12.pdf.

21. Edmond M. Cronin et al., *Remote Monitoring of Cardiovascular Devices: A Time and Activity Analysis*, 9 HEART RHYTHM 1947, 1947-48 (2012).

too may be the potential pitfalls.[22] A consumer monitoring his own medical data may become acutely and intimately aware of confusing or worrisome data to the harmful extent that the technology could cause more false alarms than anticipated.[23] Factors contributing to the end result of an undesirable user response could be as foreseeable as design defects and software glitches. However, on a more ethereal level, even the way in which health data is displayed to the user within the app itself must be carefully considered and executed, as even an app's aesthetics could interfere with its effectiveness.[24] Further, not all apps are created equal; some health apps simply provide information, others may collect and transmit patient-specific data, and then others may actually synthesize that patient data through the use of algorithms to make automated recommendations for diagnosis and treatment.[25] Thus, mobile medical apps that interpret patient data for the purpose of making critical medical decisions must be finely calibrated and monitored closely.[26] Otherwise, as health apps continue to multiply, they will inadvertently create a new population of *mobilechondriacs*: consumers whose detrimental preoccupation with self-monitoring via mobile medical devices and applications leads them to seek excessive and unnecessary medical treatment.[27]

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22. In addition to medical dangers to consumers, transmitting health data over wireless networks and via mobile apps presents data privacy concerns under HIPAA. *See* Kimberly Rhodes & Brian Kunis, *Walking the Wire in the Wireless World: Legal and Policy Implications of Mobile Computing*, 16 J. TECH. L. & POL'Y 25, 38 (2011).

23. *See infra* Part II; TIFFANY O'CALLAGHAN, *Internet-savvy Patient or "Cyberchondriac"?*, TIME, Feb. 25, 2010, *available at* http://healthland.time.com/2010/02/25/internet-savvy-patient-or-cyberchondriac/print/.

24. For example, one study found that the body undergoes physiological changes in blood pressure, body temperature, and intraocular pressure when exposed to certain hues of color, and that these responses vary based on the preference of an individual. *See* Hye-Ryeon Jin, et al., *Study on Physiological Responses to Color Stimulation: Focused on User Centered Design Sensibility Engineering Design of Color*, INT'L ASS'N SOCIETIES DESIGN RESEARCH 1 (2009).

25. *See* FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: MOBILE MEDICAL APPLICATIONS 10-11 (2011) [hereinafter DRAFT GUIDANCE] (defining the scope of mobile medical apps to be regulated); U.S. DEPT. OF HEALTH & HUMAN SERVS., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 12 (2013) [hereinafter FINAL GUIDANCE], *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM2633 66.pdf. *See also infra* Part IV.A.

26. The FDA has long established Quality Systems requirements with respect to device calibration, including automated features. *See* Food, Drug, & Cosmetics Act, 21 C.F.R. § 820.72 (2004). "Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capabale of producing valid results." *Id.*

27. I created this portmanteau to identify the subset of consumers who are most-likely to be at an elevated risk of harm (i.e., misdiagnosis followed by seeking unnecessary medical

Part II considers this very real possibility and justifies the need for mobile medical app and device developers to mitigate unintended consequences for consumers. To be sure, the onus rests largely on the app manufacturer to implement quality systems that ensure accurate data measurement and interpretation where that data ultimately informs important medical decisions.[28] The app user must ultimately be empowered to understand the implications of collecting individualized biological data on a regular (or constant) basis.

While the United States Food and Drug Administration (FDA) regulates medical software and devices based on intended use, the foreseeable risks here differ in kind depending on the app's intended *user*. Thus, this discussion necessitates a distinction between apps intended to be used by patient-consumers and those to be used by doctors.[29] Part II.A enumerates the benefits to patients and consumers using mobile medical apps for self-quantification and identifies the negative consequences of selling mobile medical apps directly to consumers — who may or may not actually *need* them — through the current open-access "app store" marketplaces.[30] On the other hand, healthcare providers using mobile medical apps face a conundrum with respect to "prescribing" software downloads or mobile gadgets either as a substitute for traditional medical devices[31] or as an analytical tool to process patient-reported data.[32] Part II.B thus offers a short list of foreseeable considerations for healthcare providers in implementing mobile medical devices and apps in daily practice.[33] Ultimately, as both patients and providers expectedly face a considerable learning curve in transitioning to the mobile medical paradigm, the question of liability is complicated.

Medical devices of all types, mobile or otherwise, have the potential to cause harm due to malfunction, interference, or defective design; this applies to both physical and software components of a device. This affirms

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treatment) caused by mobile medical apps. In general, the term "cyberchondriac" is used to describe "person[s] who fear the worst after using the internet to diagnose [their] ailment[s]." Gertrude Block, *Language Tips*, 82 N.Y. St. B.A. J. 3, 60 (May 2010). Therefore, a "mobilechondriac" is a cyberchondriac whose smartphone enables not only constant internet connectivity, but actual health monitoring and diagnosis ability.

28. *See infra* Part II.

29. *See* DRAFT GUIDANCE, *supra* note 25, at 5 ("Some of these new mobile apps are specifically targeted to assisting individuals in their own health and wellness management. Other mobile apps are targeted to healthcare providers as tools to improve and facilitate the delivery of patient care.").

30. *See infra* Part II.A.

31. *See infra* Part II.B.

32. *See infra* Part II.B.

33. *See infra* Part II.B.

the need for FDA oversight for the sake of protecting consumers, and for other checks on app manufacturers, such as a tort action that might adequately apportion liability between the doctor, app developer, and smartphone manufacturer when a patient relying on an app is harmed by a malfunction.

Prior to issuing its Final Guidance on Mobile Medical Applications, the FDA approved a number of apps that it deemed substantially equivalent to existing medical devices or software that it had already approved under existing regulations and guidance.[34] However, for many mobile medical apps and accessories in development, the set of foreseeable harms looks different than other medical devices operating on independent platforms, and until September 2013, the FDA punted the issue for too long.[35] Moreover, many new mobile medical applications and accessories perform novel functions when operating on their own or when combined with other devices to the extent that the FDA's substantial equivalence test may be inapplicable.[36] This makes the faster premarket approval process inaccessible to many app developers, forcing them into a cost-prohibitive new device application process. Part III summarizes the regulatory scheme governing the marketing and manufacture of medical devices prior to the Final Guidance and identifies the inadequacies of said rules as applied to mobile medical applications and devices.[37]

On July 21, 2011 — four years after the first Apple iPhone was released — the FDA issued Draft Guidance for Industry and Food and Drug Administration Staff on Mobile Medical Applications (Draft Guidance).[38] The Draft Guidance proposed definitions for mobile platforms, apps, *medical* apps, regulated devices, and mobile medical app manufacturers,[39] limiting the scope of regulation to apps that either are "used as an accessory to a regulated medical device" or "transform a mobile platform into a regulated

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34.   *See infra* Part III.

35.   *See* Michele McNickle, *mHealth Regulations: Overdue or Overblown?,* MHEALTHNEWS (June 26, 2012), http://www.mhealthnews.com/news/mhealth-regulations-overdue-or-over blown ("It's easy to see how health IT has lapped the regulatory framework when thinking about the amount of IT introduced since the Draft Guidance was released."). *See also* Mark Crawford, *Mobile Medical Applications are a Challenge for the FDA*, PILGRIM SOFTWARE BLOG (Nov. 11, 2011), http://blog.pilgrimsoftware.com/mobile-medical-applications-are-a-chal lenge-for-the-fda/.

36.   Eric Gilmer, *Developing Mobile Apps as Medical Devices: Understanding U.S. Government Regulations*, IBM.COM (Apr. 16, 2013), http://www.ibm.com/developerworks/ mobile/library/mo-fda-med-devices/.

37.   *See infra* Part III.

38.   *See* DRAFT GUIDANCE, *supra* note 25.

39.   *Id.* at 7-9. *See infra* Part IV.

medical device."[40] Further, acknowledging "the extensive variety of actual and potential functions of mobile apps, the rapid pace of innovation in mobile apps, and potential benefits and risks to public health," the FDA narrowly tailored its purview to a subset of mobile medical apps that bear the traditional functionality of medical devices or those that "impact performance or functionality of currently-related devices."[41] In doing so, the FDA hoped to regulate mobile medical apps that pose the same types of risks to the public as do similar, currently approved medical devices.[42]

Following the Draft Guidance came a public notice and comment period during which the FDA received over 130 comments from app developers, medical device companies, interest groups, doctors, lawyers, and government agencies all weighed in before the close of the comment period, most of which urged limiting regulation for the sake of innovation.[43] The FDA then delayed issuing the Final Guidance several times much to the chagrin of the fast-moving and impatient health technology sector.[44] Though any guidance from an administrative agency is technically non-binding, mobile medical app manufacturers wishing to avoid unexpected and expensive federal scrutiny can finally breathe a sigh of relief and move forward.

Part IV introduces the new Final Guidance for mobile medical apps.[45] Therein, Part IV.A outlines the goals, definitions, classifications, and scope of the Final Guidance, and provides examples of apps and devices that fall within the scope of the new mobile medical app subset, and those that are simply mobile *health* apps.[46] Then, Part IV.B argues that because the FDA does not want to stifle innovation, and also because it currently lacks the

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40. *See* DRAFT GUIDANCE, *supra* note 25.

41. *Id.* at 4.

42. Press Release, Food & Drug Admin., FDA Outlines Oversight of Mobile Medical Applications (July 19, 2011), *available at* http://www.fda.gov/newsevents/newsroom/pressan nouncements/ucm263340.htm; DRAFT GUIDANCE, *supra* note 25, at 4.

43. *Mobile Medical Apps: FDA Issues Final Guidance*, MED. NEWS TODAY (Sept. 24, 2013, 3:00 AM), http://www.medicalnewstoday.com/articles/266479.php. *See also* DRAFT GUIDANCE, *supra* note 25. *See also* Letter from Clara Evans, Director, Catholic Healthcare West, to Margaret Hamburg, Comm'r, Food and Drug Admin. (Oct. 19, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0530-0091. This letter represents a majority of the public commenters' concerns on the FDA's Draft Guidance. *See also* Comment from Robert Andrew Fabich, Public Citizen, REGULATIONS.GOV (Sept. 27, 2011) http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0530-0032 (statement represents a majority of the public commenters' concerns on the FDA's Draft Guidance).

44. Sara Jackson, *FDA Mobile Medical App Guidance Faces Delay to 2013*, FIERCE MOBILE HEALTHCARE (May 28, 2013), http://www.fiercemobilehealthcare.com/story/fda-mo bile-medical-app-guidance-faces-delay-2013/2012-05-24.

45. *See infra* Part IV.

46. *See infra* Part IV.A.

resources and foresight to otherwise impose strict regulations, the new guidance ultimately places the onus on mobile medical app manufacturers to self-regulate while the FDA keeps watch at arm's length.[47]

For these manufacturers and mobile software developers, the Final Guidance leaves many questions unanswered. Part V identifies several foreseeable problems the Final Guidance still fails to explicitly address and offers practical solutions for manufacturers — especially those software companies who find themselves under FDA jurisdiction for the first time — seeking to create and market mobile medical apps under the new parameters.[48] While taking cues from existing regulations might avoid disparate standards for evaluating mobile medical apps and devices versus traditional medical software and devices, the Final Guidance foreshadows adverse procedural and practical consequences that may arise for both app manufacturers and for the FDA office tasked with policing compliance, approving applications and reporting and tracking adverse events. Specifically, Part V argues that the Final Guidance comes with problems related to terminology and scope, and fails to approach neither patient-specific analysis software nor accessories to medical devices and apps. Thus, the FDA must overcome significant political and legal hurdles to provide efficient, expedient, and dynamic oversight of the coming wave of mobile health products, which it may be able to achieve by creating a new FDA office in conjunction with the Federal Communications Commission specifically for medical software and devices that utilize wireless or broadband connectivity.[49]

The FDA's input, though late, is still better than never, considering the substantial long-term growth in the mobile health industry. The Final Guidance focuses on patient risk awareness and on curbing the potential mobilechondriac pandemic. Part VI concludes that the FDA's new guidance is a necessary step toward protecting the consumer from apps that either fail to enhance or maintain the consumer's ability to make informed health decisions.[50] However, that step alone is not sufficient. Where the FDA's capacity to regulate meets its ultimate lack of resources, it is forced to cast a small regulatory net, capturing only a narrow subset of apps that transform mobile devices into mobile *medical* devices, leaving untouched a sea of mobile apps that all may have real and possibly serious health consequences for users. With increased funding and the passage of key

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47. *See infra* Part IV.B.

48. *See infra* Part V.

49. *See* Jenny Gold, *Lawmaker Pitches New FDA Office of Mobile Health*, KAISER HEALTH NEWS (Sept. 26, 2012), http://www.kaiserhealthnews.org/stories/2012/september/27/fda-mo bile-apps.aspx. *See infra* Part V.

50. *See infra* Part VI.

legislation, the FDA could position itself — namely, by creating a new office for mobile medical technologies — to not only educate mobile app consumers (i.e., patients *and* healthcare providers) to use caution and discretion when relying on this emerging technology, but also to impose labeling and disclaimer restrictions upon mobile app manufacturers whose products directly or indirectly aid in the diagnosis, treatment, and management of health conditions.[51] If nothing else, since consumers of mobile medical apps are about to head into a mine of personal biological data, the FDA should require mobile medical app manufacturers to plainly and expressly disclose the sources of any medical information and calculations inside the app, including practical limitations every app consumer should know before relying upon the app for medical purposes.

II. "MOBILECHONDRIACS" AND THE MOBILE MEDICAL LEARNING CURVE

A.   *Self-quantifying from the Patient's Perspective*

As access to mobile medical apps becomes easier and easier over time through numerous outlets, many patients[52] will increasingly utilize and even rely upon apps and devices to make decisions about their lifestyle, diet, and medical care. The total number of smartphones in use worldwide exceeded one billion by the end of the third business quarter in 2012.[53] This number represents one seventh of the global human population,[54] and is expected to double by 2015.[55] The FDA estimates that in 2015, 500 million smartphone users will be using at least one healthcare app.[56] It is worth noting that these figures even exclude internet-enabled tablets.[57]

Healthcare apps can range from simple informational programs to body mass index calculators, pedometers, pulse monitors, pill-minders, and beyond. Some pose more risk to public health than others. By summer 2013, over 40,000 health-related mobile apps were available for iPhone and Android phones.[58] Of those, the FDA had granted approval (via its premarket approval process) of only 75 new mobile medical apps whose intended use was substantially equivalent to a similar approved app or

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51.   *See infra* Part VI.

52.   I use "patients" interchangeably with "consumers" and "users" here.

53.   Jun Yang, *Smartphones in Use Surpass 1 Billion, Will Double by 2015*, BLOOMBERG (Oct. 17, 2012, 4:00 AM), http://www.bloomberg.com/news/2012-10-17/smartphones-in-use-surpass-1-billion-will-double-by-2015.html.

54.   *Id.*

55.   *Id.*

56.   *See* Press Release, Food & Drug Admin., *supra* note 42.

57.   *Id.*

58.   Gold, *supra* note 6, at 5D.

device.[59] These numbers reflect both the recognition by mobile software developers of an opportunity to enter the Health Information Technology (HIT) market, and the reluctance of the FDA to regulate an ever-broadening spectrum of health-related apps with its limited resources for increased regulation and enforcement.[60] They also reveal that the FDA assumes many of the health-related apps on the market pose little to no risk to consumers. What remains to be fathomed is the extent to which many apps that are seemingly harmless standing alone, may produce harmful results when used in combination with other apps to inform their medical decision-making process. After all, smartphones and mobile devices are designed to allow many apps to be installed and run simultaneously, so a person who downloads one of 40,000 health apps is likely to download another: the demand expands as quickly as technological innovation.[61]

The technological boom not only propelled a new facet of the health industry, but it also sparked a "socialized" health movement[62] of people obsessed with self-measurement for the sake of human optimization. The collaborative movement is called "Quantified Self" (QS) and its members are dedicated to using (and sometimes making) tools to better understand themselves.[63] Self-tracking is nothing new, yet thanks to smartphones, tablets, and other mobile devices with plenty of built-in and attachable sensors (e.g., cameras, accelerometers, gyroscopes, microphones) participants can rely on their pocket supercomputers to record, chart, and analyze their diet, exercise, mood,[64] productivity, sleep — *anything*.[65] Scores

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59. *See* Dolan, *supra* note 9. *See also* Gilmer, *supra* note 36 (explaining apps with 501k clearances are "substantially equivalent to other devices on the market").

60. *See* David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981 (2008) ("The FDA is chronically underfunded, overworked, incapable of effectively tackling the massive job Congress assigned it, and bereft of the leadership needed to defend itself in the court of public opinion."); *Id.* at 983. *See also* DRAFT GUIDANCE, *supra* note 25, at 10-11 (citing examples of health-related apps that the FDA does not currently seek to regulate).

61. *See How Smartphones are on the Verge of Taking over the World*, N.Y. DAILY NEWS, Mar. 22, 2013, http://www.nydailynews.com/life-style/smartphones-world-article-1.1295927.

62. Not to be confused with the hot-button catch phrase "socialized medicine" frequently used to attack the Patient Protection and Affordable Care Act, or "Obamacare." *See, e.g.*, David Greenberg, *Who's Afraid of Socialized Medicine? Two Dangerous Words that Kill Health Care Reform*, SLATE (Oct. 8, 2007, 1:20 PM), http://www.slate.com/articles/news_and_politics/history_lesson/2007/10/whos_afraid_of_socialized_medicine.html.

63. *About the Quantified Self*, QUANTIFIEDSELF.COM, http://quantifiedself.com/about/ (last visited Jan. 25, 2013).

64. *See, e.g.*, Ernesto Ramirez, *Toolmaker Talk: Jonathan Cohen (Expereal)*, QUANTIFIEDSELF.COM (Oct. 16, 2012), http://quantifiedself.com/2012/10/toolmaker-talk-jonathan-cohen-expereal/.

of these mobile device supplements are marketed as "health and fitness" apps in the iTunes App Store,[66] and many are available for free for all Apple mobile device users. The data collected by each individual app can illuminate patterns in personal health and habit with real, medical decision-making implications.

The self-tracking coin has two sides, though. Because there are not currently restrictions barring consumers from purchasing unneeded mobile medical apps,[67] the market is open to anyone with a smartphone or tablet with internet access. For example, the iTunes App Store features a specific "medical" app category in its online catalogue. Therein, shoppers can select from several categories a button labeled "Apps for Healthcare Professionals."[68] Next appears a list of several categories with over 70 apps for iPhone and iPad.[69] The store demands no verification of medical credentials or license, and some of the apps are available for free. Others are much more expensive, and their cost alone may be a barrier to exclude many non-medical professionals from using the more sophisticated apps. Ultimately, since not all technology users are super-savvy (this author included), and since there are no access barriers between apps for medical professionals and those for everyday consumers,[70] a curious smartphone user could download a confusing app that might lead them to make misinformed health care decisions. With instant access to apps clearly designed to perform medical functions, new medical app users may learn too much information about themselves without knowing how to process it all.

Alternatively, health apps intended for use by the general population are much more widely available than those marketed specifically for medical use or for use by medical professionals. While the principle of *caveat*

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65. The group has a searchable online guide with almost 600 apps and gadgets for self-quantification. *See Quantified Self Guide*, QUANTIFIEDSELF.COM, http://quantifiedself.com/guide/ (last visited Jan. 25, 2013).

66. *iTunes App Store*, APPLE.COM, https://itunes.apple.com/us/genre/ios-health-fitness/id 6013?mt=8 (last visited Jan. 25, 2013).

67. Benjamin A. Rosser & Christopher Eccleston, *Smartphone Applications for Pain Management*, 17 J. TELEMEDICINE & TELECARE 308, 312 (2011).

68. *iTunes App Store*, APPLE.COM, https://itunes.apple.com/us/genre/ios-medical/id60 20?mt=8 (last visited Feb. 18, 2013).

69. Categories include EMR & Patient Monitoring, Imaging, Medical Education, Nursing, Patient Education, Personal Care, and Reference apps. *iTunes App Store*, *supra* note 68.

70. Compared to Apple iTunes, the "Google Play" app marketplace does not even distinguish between apps intended for medical professionals and those intended for everyday users. *See Medical Apps*, GOOGLE PLAY, https://play.google.com/store/search?q=medical&c =apps (last visited Feb. 19, 2013).

emptor[71] is certainly applicable to consumers relying on mobile apps for medical decisions, the app markets (like most internet-based marketplaces) do have a built-in protection in the form of scaled app rating systems (iTunes uses a five-star rating scale, for example) and user reviews — a kind of crowdsourced filter that elevates the products that work and buries those that do not. This infrastructure serves as an informal adverse event reporting system that could prove to be quite advantageous to the FDA as it begins to monitor the safety of mobile medical apps.

Increasing patient participation in health decisions can improve outcomes.[72] This participation depends on patient access to relevant and reliable health information. According to a 2011 study, "[e]ight in ten internet users looked online for health information in 2002 and the same proportion [did] so [in 2007] . . . . What has changed is who has access to the internet."[73] The troubling statistic, however, is that 75% of those seeking medical and health information online fail to look for "quality indicators such as the validity of the source" or whether the information created and posted is timely and still valid.[74]

Problems with information validity are found in the mobile health app market as well. In a study of pain management apps in 2011, Benjamin Rosser and Christopher Eccleston from the University of Bath Centre for Pain Research in the United Kingdom found that "of the [111] apps reviewed, 86% reported no health-care professional involvement, either directly as the app creator or indirectly as a source of information or evaluation of app content" and only 12% were reportedly authored by a physician.[75] Rosser and Eccleston urged that the deficiency of health professionals involved in creating pain management and other medical apps raised two main concerns: that "self-management should be considered a collaboration between patient and health-care professional. . ." and that "of the existing apps, there are few reports of the origin of content and validity."[76] Access to information certainly empowers patients, especially those who have not

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71. "Let the buyer beware" in Latin. *Caveat Emptor Definition*, MERRIAMWEBSTER.COM, http://www.merriam-webster.com/dictionary/caveat%20emptor (last visited Feb. 18, 2013).

72. *See, e.g.*, Robert J. Adams, *Improving Health Outcomes with Better Patient Understanding and Education*, RISK MGMT. & HEALTHCARE POL'Y, Oct. 2010, at 61, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3270921/pdf/rmhp-3-061.pdf.

73. SUSANNAH FOX, PEW INTERNET & AMERICAN LIFE PROJECT, HEALTH TOPICS: 80% OF INTERNET USERS LOOK FOR HEALTH INFORMATION ONLINE 9 (2011), *available at* http://www.pewinternet.org/~/media//Files/Reports/2011/PIP_Health_Topics.pdf.

74. RYEN WHITE & ERIC HORVITZ, MICROSOFT RESEARCH, CYBERCHONDRIA: STUDIES OF ESCALATION OF MEDICAL CONCERNS IN WEB SEARCH 2 (2008), *available at* http://research.microsoft.com/pubs/76529/TR-2008-178.pdf.

75. Rosser & Eccleston, *supra* note 67, at 311.

76. *Id.* at 312.

established a rapport with a doctor, and also those who do not have a primary care physician whatsoever. For those who have established relationships with health care providers, the relationships are not of "deference of information or responsibility, but transference of expertise and useful skills."[77] Though the study found that "[i]n general, there is little evidence to support the use of pain apps," it uncovered a great need for more involvement from knowledgeable health care professionals in the app development process to ultimately benefit and protect the app consumer.[78] But when the internet is the ultimate disseminator of typically unverified medical information — misleading or not — it is tempting to self-diagnose and easy to get it wrong.

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. Similarly, just like a search engine uses algorithms to produce the seemingly most-relevant results, even a sophisticated mobile medical app must be programmed to anticipate an endless, dynamic list of medical possibilities in order to perform effectively. Otherwise, the app meant to improve the user's quality of health could effectually turn the user into a mobilechondriac. For example, suppose a person experienced frequent throbbing pain in his forehead region. Frustrated, he decided to diagnose his symptoms using a "symptom checker" app[79] he downloaded for free. After indicating his symptoms, a list of 63 possible ailments appeared, ranked in order from most-likely to least-likely. The first five results were all expected: acute sinusitis, tension headache, cluster headache, migraine headache, and chronic sinusitis. But the rest of the list bore some terrifying, albeit probably remote, possibilities. "High blood pressure" was number six on the list. "Brain aneurysm" was number seven. Down the list: diabetes type I, lupus, multiple sclerosis, brain infection, cyanide poisoning, plague, bird flu, radiation sickness, and West Nile virus, to name a handful. Because the app is designed to display all *possible* results given the user-defined symptoms, the symptom checker app does not rule out any potential cause, whereas a physician is able to examine and gather more information to make a much narrower diagnosis.

Also buried in the results of possible ailments is "caffeine withdrawal," which might be common for many coffee-drinking adults. This is something a physician might have been able to ask in person. Perhaps the app developer could have included dietary habits in the initial symptom

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77. *Id.*

78. *Id.* at 311.

79. *WebMD SymptomChecker*, WEBMD, http://symptoms.webmd.com/#./symptomsView (last visited Feb. 19, 2013). The online version utilizes the same symptom database as the phone app.

questionnaire. But what about caffeine-free users? Not knowing whether a headache is just a sinus problem or a brain tumor, the user might feel compelled to seek immediate medical care in the emergency room.[80] Also consider the inverse, where the user actually has a serious illness like a brain tumor but dismisses it as sinusitis based on the mobile app results.

Even when a health app expressly disclaims its reliability or accuracy, the average app consumer is still disadvantaged. This is called "informational asymmetry" between patient and doctor.[81] While the patient may feel empowered by the availability of medical information on his smartphone or tablet, the doctor has the experience and formal education to exact meaningful diagnosis and treatment decisions. The doctor also hopefully has the sense *not* to recite a list of every possible affliction to a worried patient. But when mobile medical apps do more than simply dump information into the user's palm — like an app that gathers individualized data and then manipulates the data in some unique way to make an automated medical recommendation or drug dosage calculation — the danger is much more real. Overall, the benefits to most outweigh the extra cost to the select few, but safeguards should be in place to mitigate the risk to app consumers who become inadvertent mobilechondriacs.

B.   Download This Mobile Medical App and Text Me in the Morning

Without breaching the discussion of traditionalism versus ageism, mobile technology obviates a generational divide among older doctors and those fresh out of medical school.[82] The older generation of medical students learned that the physician was the "unambiguous source of medical knowledge;"[83] today, young doctors carry smartphones and tablets packed with digital references and dosage calculators on their grand rounds.[84] The sea change in medical education from the doctor's point of view has logically changed the *practice* of medicine;[85] whether that is a positive thing or not is for another paper. Though there are many who resist going digital, "[o]lder doctors admire, even envy, their young colleagues' ease with new

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80. *See* Zachary Meisel & Jesse Pines, *The Allure of the One-Stop Shop: The Real Reasons Why People Go to the E.R. when they Shouldn't*, SLATE (Sept. 12, 2008, 7:06 A.M.), http://www.slate.com/articles/health_and_science/medical_examiner/2008/09/the_allure_of_the_onestop_shop.single.html.

81. *Id.*

82. Katie Hafner, *Redefining Medicine with Apps and iPads*, N.Y. TIMES, Oct. 9, 2012, http://www.nytimes.com/2012/10/09/science/redefining-medicine-with-apps-and-ipads-the-digital-doctor.html?pagewanted=all&_r=0.

83. *Id.*

84. *Id.*

85. *Id.*

technology."[86] That said, there is a definite learning curve not only for patients,[87] but also for doctors as well.[88] As one doctor noted, "Just adding an app won't necessarily make people better doctors or more caring clinicians . . . . What we need to learn is how to use technology to be better, more humane professionals."[89] Using apps to improve doctor-patient relationships can improve quality of care, which in turn can reduce a doctor's civil liability for malpractice claims from aggrieved patients.[90]

But doctors who adopt new mobile medical app technology in their practice should be quite selective in choosing apps that actually work as intended. Otherwise, relying on or "prescribing" apps to patients that turn out to be harmful could be considered a significant departure from the reasonable standard of care, putting the doctor in a position of malpractice liability. In tort law, a regular person can be held liable for damages under a negligence claim when he had a duty (also called a "standard of care"), breached that duty, and his breach was the proximate cause (in most cases) of harm (damages) to someone else.[91] Each element is necessary to a complete negligence claim, but once a duty is established, the question of breach is typically measured by an objective standard of what a reasonably prudent person would do. That is, of course, unless the parties have some other special relationship, as do doctor and patient.[92]

Doctors, unlike their reasonably prudent patients,[93] are in a slightly different situation with respect to incorporating medical apps into their own practice because they are held to a higher standard of reasonableness.[94] Breaching that duty can sometimes mean using unorthodox techniques, medications, or devices; there, the departure would be considered a

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86. *Id.*

87. *See supra* Part II.A.

88. *See* Hafner, *supra* note 82.

89. *Id.* (quoting Palo Alto Medical Foundation's chief innovation and technology officer Paul C. Tang).

90. *See* Laura Blue, *Better Bedside Manners*, TIME, Sep. 05, 2007, *available at* http://www.time.com/time/health/article/0,8599,1659065,00.html (describing a study of physician-patient interaction which found that doctors with poor bedside manners received a disproportionate number of complaints than those with better communication skills).

91. The case *Blyth v. Birmingham Waterworks Co.* is the classic case defining negligence: "Negligence is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do." (1856) 11 Exch. 781, 784.

92. *See* Doherty v. Hellman, 547 N.E.2d 931, 933 (Mass. 1989); Flynn v. Bausch, 469 N.W.2d 125, 128 (Neb. 1991).

93. *See* Vaughn v. Menlove, (1837) 132 Eng. Rep. 490. The reasonably prudent person "acts sensibly, does things without serious delay, and takes proper but not excessive precautions." BLACK'S LAW DICTIONARY 1380 (9th ed. 2009).

94. *See* Hall v. Hilbun, 466 So.2d 856, 873 (Miss. 1985).

medical judgment that is less than minimally adequate.[95] *Hall v. Hilbun* established a national standard for determining a physician's "non-delegable duty of care," as follows:

> [G]iven the circumstances of each patient, each physician has a duty to use his or her knowledge and therewith treat through maximum reasonable medical recovery, each patient, with such reasonable diligence, skill, competence, and prudence as are practiced by minimally competent physicians in the same specialty or general field of practice throughout the United States, who have available to them the same general facilities, services, equipment and options.[96]

Though this standard of care does not seem particularly groundbreaking 30-plus years later, it is worth noting that in the same holding, the 1985 Mississippi Supreme Court clairvoyantly observed that "[p]hysicians are far more *mobile* than they once were. . ." with "ready access to professional and scientific journals . . . for continuing medical education from across the country."[97]

Equally important to this discussion of mobile medical technology is that the *Hall* court carved out an exception for the "old locality rule," which serves as a caveat to the nationwide standard.[98] Essentially, the court acknowledged that given the disparate quality and availability of medical tools between rural and metropolitan hospitals, a physician is only as good as his tools.[99] Thus, a doctor is required to understand the limitations of his equipment, facility, and skills, and must "exercise minimally adequate medical judgment" consistent with the medical judgment that informs similarly-situated physicians across the United States.[100]

Applying the *Hall* standard of care today, a rural doctor with wireless internet access on her mobile device could become better able to affordably acquire, understand, and implement practices used by other similarly-situated doctors in larger cities.[101] Essentially, mobile-based medical solutions may someday be the floor, not the ceiling, of modernized private physician practice. The advantages to incorporating mobile medical apps and devices into patient care in this context extend well beyond a significant reduction in overhead cost.

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95. *Id.* at 871.

96. *Id.*

97. *Id.* at 870.

98. *Id.* at 872 (emphasis added).

99. Hall v. Hilbun, 466 So.2d at 872.

100. *Id.*

101. To view multiple maps depicting 3G wireless coverage in the United States by service provider, see *3G Network Comparison: AT&T, Cricket, Metro PCS, Sprint, T-Mobile, US Cellular & Verizon*, CELLULARMAPS.COM, http://www.cellularmaps.com/3g_compare.shtml (last visited Jan. 25, 2013) [hereinafter *3G Network Comparison*].

Even more, if that doctor prescribes mobile medical apps to several patients (i.e. those who have smartphones), then she could collect their data wirelessly for on-demand analysis or even real-time alerts for medical emergencies.[102] The resultant data could be used to make both individualized and practice-wide observations and diagnoses about the health of a doctor's community with the larger goal of improving quality and access. Some "patients are even working together with physicians and scientists to conduct experiments, pooling their data for analysis that may shed light on the cause or best treatment for their [common] disease."[103] Empowering doctors and patients to conduct their own studies within a practice or a community at relatively low costs could simultaneously foster community-wide health improvement and could serve the dual purpose of a small post-market study for the actual medical apps used.[104]

Moreover, some physicians even test the new technology on themselves first, assuming the risk on an individual basis.[105] But a doctor who injures a *patient* by misdiagnosis due to errant medical app data or app malfunction is a much greater concern both for the FDA and for injured persons seeking common law remedies.[106] For informational apps, developers will likely seek to absolve themselves from liability to those "mobilechondriacs" with a disclaimer reading something to the effect of, "*this app is meant for informational use only and is not intended to aid in the diagnosis, treatment, or prevention of disease*" that either appears when the app is engaged, or in the very least is pasted into the terms and conditions the user must accept before using their newly-downloaded app. In fact, they may encounter something similar to the disclaimer utilized by WebMD, one popular medical information internet site, which reads:

> The contents of the WebMD Site, such as text, graphics, images, and other material contained on the WebMD Site ("Content") are for informational purposes only. The Content is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical condition. Never disregard professional

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102. *See* Matt Richtel, *Apps that Can Alert the Doctor when Trouble Looms*, N.Y. TIMES, Oct. 9, 2012, at D3.
103. Jeffrey Norris, *Self-Tracking May become Key Element of Personalized Medicine*, UNIV. CAL. SAN FRANCISCO (Oct. 5, 2012), http://www.ucsf.edu/news/2012/10/12913/self-tracking-may-become-key-element-personalized-medicine.
104. *Id.*
105. *Id.*
106. *Id.*

> medical advice or delay in seeking it because of something you have read on the WebMD Site![107]

There, the words "for informational purposes only" and "not intended to be a substitute" (for a physician's advice) may be satisfactory for a website that simply displays an aggregate of medical information. The disclaimer above not only attempts to educate the WebMD visitor that a medical problem warrants inspection by a medical professional, but also seeks to absolve WebMD from claims of fraudulent misrepresentation or even medical malpractice, which can be brought in situations where a patient-physician relationship has been established (even between a website and an internet user).[108]

Alone, even a keenly-worded disclaimer is insufficient for mobile apps providing information *plus* a unique function, especially since the legal effect of a disclaimer on the internet is still a disputed issue.[109] Disclaimer or not, an app not advertised as "medical" can prove to be medically significant to a patient who, as a result of using the app as directed, lowers his cholesterol or even remembers to take his medication on time. Non-medical apps help consumers remember to take medication,[110] make health dietary choices,[111] exercise,[112] or quit smoking.[113] After all, is not the primary reason for using *any* health-related app to prevent the onset of obesity, diabetes, heart disease, and other maladies tied to diet and overall health habits? The questions of liability and remedy remain for patients who

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107. *Additional Information*, WEBMD, http://www.webmd.com/about-webmd-policies/add itional-info?ss=ftr (last visited Feb. 18, 2013). The following paragraph in the disclaimer reads: "If you think you may have a medical emergency, call your doctor or 911 immediately. WebMD does not recommend or endorse any specific tests, physicians, products, procedures, opinions, or other information that may be mentioned on the Site. Reliance on any information provided by WebMD, WebMD employees, others appearing on the Site at the invitation of WebMD, or other visitors to the Site is solely at your own risk." *Id.*

108. *See* Philip M. Kober, *Regulating Medicine on the Internet*, WIS. LAWYER, Feb. 2010, at 10. *See also infra* Part II.B.

109. Kober, *supra* note 108, at 12. "Clearly stated, prominent disclaimers should be used to prevent over-reliance on such Web sites. However, self-help and other Web sites that simply provide information are not a substitute for seeking the advice of one's own physician, and the legal enforceability of such disclaimers remains unclear." *Id.*

110. *iTunes App Store*, APPLE.COM, https://itunes.apple.com/us/app/medcoach-medica tion-reminder/id443065594?mt=8 (last visited Jan. 25, 2013).

111. Raechel Conover, *4 Best Diet Apps to Help You Lose Weight*, CHEAPISM (Jan. 21, 2013, 11:12 AM), http://www.cheapism.com/blog/2367/diet-apps.

112. Lisa Freedman, *Best Fitness and Nutrition Apps for iPhone*, MENS FITNESS (Jan. 2013), *available at* http://www.mensfitness.com/training/best-fitness-and-nutrition-apps-for-iphone.

113. Kimberly Holland, *The 11 Best Quit Smoking iPhone and Android Apps of 2013*, HEALTHLINE (Aug. 9, 2013), http://www.healthline.com/health-slideshow/top-iphone-android-apps-quit-smoking.

suffer injury or death resulting from an app developer's digital negligence; the injured patient may not have a medical malpractice remedy if it cannot establish a patient-doctor relationship with the digital doctor.[114]

While a tort claim might be one option for the patient, a doctor relying on a defective mobile medical app may be able to bring a fraudulent misrepresentation claim under contract law against the app developer who marketed the app with specific claims for its intended medical use. However, this typically requires proving that the developer knew or should have known its claims were false.[115] Yet even these claims may not work where the developer has issued a disclaimer with respect to the physician's claim at issue.[116]

Further, who is liable for an injury to a patient resulting from some malfunction outside the app itself? Since smartphones are designed as multi-function computers with the capability to not only make telephone calls but also to host dozens if not hundreds of different apps, depending on them for constant monitoring or accurate information transmission carries a new set of dangers. For example, a patient utilizing a smartphone app that transmits information to his doctor may receive a phone call that interrupts or interferes with the collection or transmission of data. The possibility for other apps to interfere with each other is also present, as many can send "push notifications" which interrupt any app currently in use with a message that must be dismissed before resuming intended app use. There are also general connectivity issues for people in rural areas or coverage dead zones, who may not be able to send and receive critical information from their apps due to broadband limitations or lack of access to a cellular data network.[117]

Finally, the sensors embedded in the phone itself (or even the operating system) may malfunction, and then apps that depend on those sensors will follow suit. When this happens as a result of a defect in the phone, is the phone manufacturer now liable in the same way a manufacturer of a

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114. Kober, *supra* note 108.

115. The elements of a misrepresentation claim are outlined in the software case *Step-Saver Data Systems v. Wyse Technology*, which has become a staple in contract law casebooks. 939 F.2d 91 (3d Cir. 1991). They are: "(1) a material misrepresentation; (2) an intention to deceive; (3) an intention to induce reliance; (4) justifiable reliance by the recipient upon the representation; and (5) damage to the recipient proximately caused by the misrepresentation." *Id.* at 106.

116. *See, e.g.*, i2 Technologies, Inc. v. DARC Corp., No. 02-CV-0327-H, 2003 WL 22205091 (N.D. Tex. Sept. 23, 2003) (holding that where claims of fraudulent misrepresentations are made about a software's capabilities, those claims are precluded by a disclaimer to the same effect, and that the disclaimer defeats the reliance element of such an inducement claim).

117. *See 3G Network Comparison*, *supra* note 101.

pacemaker would be if it became defective and caused a heart attack? While the FDA may not be able to regulate the marketing and manufacture of the smartphones themselves, mobile medical app and accessory manufacturers should mitigate the risks of relying wholly on a platform created by someone else by building in safeguards to prevent interference and software incompatibility. One way to do this is by contractually requiring component and platform manufacturers to comply with Quality Systems regulations, discussed further in Part IV.B.[118] In short, obtaining more health information is important for the patient and doctor alike, but the information must be accurate, relevant, and verified, or it will lead to errant self-diagnoses by consumers and misdiagnoses (or missed-diagnoses) by doctors, the result of which could be harmless or quite serious, depending on the app itself and its intended use.

III. REGULATING NEW TECHNOLOGY WITH OLD RULES: PREMARKET NOTIFICATION, APPROVAL, AND THE CURRENT SPECTRUM OF AVAILABLE MOBILE MEDICAL APPS

The iPhone was first introduced in 2007[119] and the first mobile medical app was submitted for premarket approval in February 2011.[120] Since then, over 40,000 health-related apps have been made available for download.[121] During this period of time, the FDA either declined to regulate mobile medical apps that did not pose an immediate risk,[122] or alternatively granted premarket approval using existing regulations and guidance for medical software and already-approved medical devices.[123] As innovation

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118. *See* BRADLEY M. THOMPSON, FDA REGULATION OF MOBILE HEALTH 8-9 (2010), *available at* http://mobihealthnews.com/wp-content/pdf/FDA_Regulation_of_Mobile_Health.pdf ("In the medical device world, component suppliers are exempt from [Quality Systems and Design Control] requirements (though sometimes they are contractually required. . . . [This] means that the finished device manufacturer has the regulatory burden of assuring the quality of the components it uses."). *See also infra* Part IV.B.

119. Apple, *iPhone*, APPLE-HISTORY, http://apple-history.com/iphone (last updated Aug. 26, 2012).

120. "Mobile MIM" for iPhone was the first mobile medical app approved by the FDA. *See* Mike Luttrell, *Medical iPhone App is FDA Approved*, TGDAILY.COM, (Feb. 7, 2011), http://www.tgdaily.com/mobility-brief/53973-medical-iphone-app-is-fda-approved. The app, which is "used for the viewing, registration, fusion, and/or display for diagnosis of medical images" is now available in the Apple iTunes App Store for free at https://itunes.apple.com/us/app/mobile-mim/id281922769?mt=8.

121. Jenny Gold, FDA Regulators Face Daunting Task as Health Apps Multiply, USA TODAY (June 27, 2012), *available at* http://usatoday30.usatoday.com/news/health/story/2012-06-22/health-apps-regulation/55766260/1.

122. *See* Press Release, Food & Drug Admin., *supra* note 42.

123. The FDA based its guidance on existing regulations for medical device data systems, medical software, quality systems, and its classification system under the FD&C Act. *See* DRAFT GUIDANCE, *supra* note 25, at 12 & n.16; FINAL GUIDANCE, *supra* note 25, at 13 & n.21.

quickly outpaced government action, contentions naturally festered between eager mobile medical app developers and the hesitant FDA. Initially, the apps that received premarket approval under the existing regulations were relatively safe bets for FDA preapproval because they represented the substantial equivalent function of already-approved medical devices and software.[124]

The existing premarket notification regulations for medical devices found in section 510(k) of the Food and Drug Administration Modernization Act of 1997 (FDAMA)[125] already allowed device manufacturers to speed up the approval process before marketing a new medical device if the new device was substantially equivalent to a previously-approved device.[126] Device manufacturers (or distributors) must file a premarket notification with the FDA no fewer than 90 days before the device is released and distributed.[127] From this notification, the FDA "may issue an order of substantial equivalence only upon making a determination that the device . . . is as safe and effective as a legally marketed device."[128] Since not all devices pose the same risk to the general public, however, the evaluation criteria for determining substantial equivalence are divided into three classes.[129] Devices that pose a low risk to the health and safety of the general public fall under Class I, and the FDA will grant a determination of substantial equivalence "based primarily on descriptive information and a labeling review" for most devices in this category.[130] In fact, because of the low risk involved, many generic Class I devices are now exempt from the premarket notification process altogether, "unless the device is intended for a use that is of substantial importance in preventing impairment to human health or presents a potential unreasonable risk of illness or injury."[131] Some Class II generic devices have also been deemed exempt from premarket

124. Dolan, *supra* note 10. *See also* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FOOD & DRUG ADMIN., THE NEW 510(K) PARADIGM: ALTERNATE APPROACHES TO DEMONSTRATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS 2 (1998) [hereinafter 510(K) PARADIGM], *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationand Guidance/GuidanceDocuments/ucm080189.pdf (outlining final guidance for the premarket notification exemption process for Class I devices, except those devices that are "intended for a use that is of substantial importance in preventing impairment to human health" or those that "present[] a potential unreasonable risk of illness or injury").

125. Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified at 21 U.S.C. § 301 et seq.).

126. 510(K) PARADIGM, *supra* note 124, at 1.

127. *Id.* The premarket notification content requirements can be found at 21 C.F.R. 807.87. Premarket Notification Procedures, 21 C.F.R. § 807.87 (2001).

128. 510(K) PARADIGM, *supra* note 124, at 1.

129. *Id.* at 1-2.

130. *Id.* at 1.

131. *Id.* at 2.

notification.[132] These pose a greater risk than Class I exempt devices, but can still be approved as substantial equivalents to existing medical devices. Class III devices include those "for which general controls and special controls are insufficient to provide reasonable assurance of the safety and effectiveness of a device . . . ."[133] These Class III devices typically "intended to be used in supporting or sustaining human life or preventing impairment of human health, or that may present a potential unreasonable risk of illness or injury . . . ."[134] All Class I devices are subject to General Control requirements;[135] Class II devices are subject to additional Special Controls;[136] and Class III devices must undergo full "scientific review" through the premarket approval (PMA) process before being marketed.[137]

The time it takes to process a premarket notification correlates to the risk involved. To submit a premarket notification for a no-risk-to-low-risk device that will fall under Class I (an "exempt" version of an already-approved device), the app developer can register the device with the FDA,[138] pay a fee,[139] and expect clearance within five to seven business days, and no

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132. *Id. See also* Medical Devices; Exemptions From Premarket Notifications; Class II Devices, 63 Fed. Reg. 3, 142 (Jan. 21, 1998).

133. *Medical Devices: Regulatory Controls*, FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ (last updated Apr. 11, 2013) [hereinafter *Regulatory Controls*]. *See also* 510(K) PARADIGM, *supra* note 124, at 2.

134. *Regulatory Controls*, *supra* note 133.

135. *Id.*

136. *Id.*

137. *Id.; Medical Devices: Premarket Approval (PMA)*, FOOD & DRUG ADMIN., http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/ (last updated Jan. 24, 2012).

138. The FDA has an online system for this process. *FDA Industry Systems*, FOOD & DRUG ADMIN., https://www.access.fda.gov/oaa/logonFlow.htm;jsessionid=vSMTRsPSh3TZ8dv56htQJjQvF8H0DzL4Jrk8ZTdfs6STTLPG1GZj!-1716739001?execution=e1s1 (last visited Feb. 26, 2013).

139. Device manufacturers and others involved in the marketing of devices must pay "user fees" to the FDA to fund the approval process. The current annual user fee (effective October 1, 2012 to October 1, 2017) is $2,575. David Gartner, *Medical Device Establishment Registration and Listing – Notice of Changes for FY 2013*, FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm314844.htm (last updated Aug. 10, 2012). For a table of who must pay the annual user fees to be involved in the manufacturing and marketing of medical devices, see *id.* The Medical Device User Fee Amendments 2012 (MDUFA III) authorized the FDA to collect these fees, which amounts to nearly $600 Million over five years. *See Medical Device User Fee Amendments 2012 (MDUFA III)*, FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/default.htm (last updated Oct. 16, 2013).

formal 510(k) premarket approval application is needed.[140] An example of an exempt Class I device that could be duplicated as a mobile medical app is a gustometer used by ear, nose, and throat specialists to stimulate the taste buds by touching two electrodes to the tongue,[141] which could easily be reproduced as combination app and smartphone or tablet attachment. For Class II devices that have the same function and intended use as devices already on the market, like the recently released ultrasound app and attachment,[142] the processing time can last between four and ten months.[143] Finally, Class III devices — those with a novel or innovative intended use or combination of uses — require the longest amount of processing time, since they must be subjected to full premarket approval (PMA) including possible clinical trials, a process that takes anywhere from 180 days to 36 months.[144] A smartphone app wirelessly controlling an injectable nano-transmitter that delivers a drug on demand or at certain intervals would likely be categorized as Class III, since the risk associated with this technology is unknown.

Regardless of risk classification, all device manufacturers must implement Quality Systems protocol, though what that actually looks like in practice must be individually tailored to the particular development and manufacturing process based on the overall risk associated with the device's intended use.[145] For purposes of mobile medical apps, the Quality Systems regulations require "Design Controls" for "[d]evices automated with computer software."[146] Essentially, this means that a mobile medical app developer must create documentation and review procedures from the initial planning stages and implement them actively throughout the production process. The ultimate result is a well-documented procedure manual demonstrating that every detail was considered with the intended use and the risks to the patient end user in mind.[147] Presumably, app developers working primarily with computers can easily implement electronic

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140. Elisa Maldonado Holmertz, *Developing a Mobile App? How to Determine if it is a Medical Device and get it Cleared by the US FDA*, SLIDESHARE, at slides 25-26, *available at* http://www.slideshare.net/emergogroup/the-us-regulatory-approach-to-mobile-medical-apps.

141. 21 C.F.R. § 874.1500 (2013).

142. *See* Luke Timmerman, *Mobisante Wins FDA Approval for "Ultrasound on a Smartphone" Technology*, XCONOMY (Feb. 3, 2011), http://www.xconomy.com/seattle/2011/02/03/mobisante-wins-fda-approval-for-ultrasound-on-a-smartphone-technology/?single_page=true.

143. Holmertz, *supra* note 140, at slide 26.

144. *Id.*

145. Quality Systems, 21 C.F.R. § 820.5 (2012).

146. 21 C.F.R. § 820.30(a)(2)(i) (2012).

147. The Quality Systems regulations require several other controls, including Document Controls, Production and Process Controls, Purchasing Controls, Labeling and Packaging Controls, and more. *See* 21 C.F.R. §§ 820 et seq. (2012).

documentation systems to comply with these requirements and other documentation controls.

For better or worse, the FDA provisionally relied on its existing premarket notification and approval process to evaluate medical devices of all types, including mobile medical apps.[148] The most substantial practical concern that arises when using the existing regulations, however, is the disparity between the timeline for getting software or a device approved and the speed at which smartphone and tablet technology advances. The late Apple CEO Steve Jobs said it best in January 2008 (just one year after his groundbreaking new smartphone was introduced): "iPhone doesn't stand still — we're making it better and better all the time."[149] In fact, a new iPhone has been released every year since 2007.[150] Even more, within the lifespan of each new generation of the Apple smartphone, several updates to the iPhone operating system (iOS) occur, and older iPhone models are phased out of compatibility with each new iOS. This same process occurs with apps designed for the Android operating systems and for the Windows Mobile operating systems. Thus, each operating system update means a new app update, and eventually some older model phones will disallow new apps to be installed because the phones are unable to run the latest operating system versions.[151] In short, app developers seeking long-term participation in the mobile market, health-related or otherwise, must anticipate the dynamic changes in the mobile platform market to remain viable and competitive. So app developers marketing their software or accessory with an intended medical use must constantly test, redesign, and reimagine medical apps to maintain integrity, functionality, and efficacy in order to survive the constant mobile platform updates.

The 510(k) premarket notification timetable problem becomes even more apparent in the context of an FDA regulation that requires device manufacturers to seek approval for changes it makes to its device and software design, including labeling and marketing changes.[152] Given that

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148. Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified at 21 U.S.C. § 301 et seq.).

149. Press Release, Apple, Apple Enhances New Revolutionary iPhone with Software Update (Jan. 15, 2008), http://www.apple.com/pr/library/2008/01/15Apple-Enhances-Revo lutionary-iPhone-with-Software-Update.html.

150. The first generation iPhone was introduced in June 2007; iPhone 3G in June 2008; iPhone 3GS in June 2009; iPhone 4 in June 2010; iPhone 4S in October 2011; and the iPhone 5 hit the market in September 2012. *See Compare Models*, APPLEHISTORY.COM (2013), http://apple-history.com/compare/iphone_3g/iphone_3gs/iphone_4/iphone_4s.

151. Peter Cohen, *Here's Why You Shouldn't Upgrade to iOS 7. . .Yet*, IMORE.COM (Sept. 17, 2013, 2:38 PM), http://www.imore.com/heres-why-you-shouldnt-upgrade-ios-7-yet.

152. *See* 21 C.F.R. § 807.81(a)(3) (2013); FOOD & DRUG ADMIN., DECIDING WHEN TO SUBMIT A 510(K) FOR A CHANGE TO AN EXISTING DEVICE 1 (1997) [hereinafter DECIDING WHEN],

apps are updated frequently, the mobile medical app or device manufacturer will routinely face the possibility of having to submit a new 510(k) application for each update it makes. The 510(k) provision at issue states that the company marketing a device must submit a new premarket notification when the device "is about to be *significantly changed* or modified in design, components, method of manufacture, or intended use."[153] A "significant change" is one that "could significantly affect the safety or effectiveness of the device" or "a major change or modification in the intended use of the device."[154] Practically speaking, not every change to a device is "substantial," so the documentation and protocol requirements found in the Good Manufacturing Practices and Quality Systems regulations equip the manufacturer, and thereby the FDA on the front end, with the information to determine whether the change is substantial.[155] The manufacturer's protocol for determining substantial change should consider changes to: labeling; technology, engineering, and performance; and materials.[156]

For mobile medical app developers, where updating the software necessitates changing the computer algorithms the app uses for calculating medical information, the change could be considered substantial under the engineering, performance, and labeling categories.[157] Another example of a substantial change particularly relevant for mobile medical app updates is a change to the control mechanism of the device;[158] the mobile platform is a control mechanism (including the touchscreen interface and sensors), so when an existing app must be updated to work on a new smartphone, it may be subject to the substantial change 510(k) filing requirement. This process is not free; the standard filing fee for fiscal year 2014 for each 510(k) application is $5,170 (or $2,585 for small businesses with less than or equal to $100 Million in gross receipts or sales per year).[159] Add in the cost of writing the code for the new updates and testing them for validation as required by the Quality Systems standards, and the expenses for small developers seem relatively large.

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available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/ GuidanceDocuments/ucm080243.pdf.

   153.   21 C.F.R. § 807.81(a)(3) (emphasis added).

   154.   *Id.*

   155.   *See* DECIDING WHEN, *supra* note 152, at 3.

   156.   *Id.* at 7-22.

   157.   *Id.*

   158.   *Id.*

   159.   *Premarket Notification [510(k)] Review Fees*, FOOD & DRUG ADMIN., http://www.fda. gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSub missions/PremarketNotification510k/ucm134566.htm (last updated Dec. 13, 2013).

Because the time to process each 510(k) change application under current regulations is quite lengthy relative to the shelf-life of a given mobile platform or mobile medical app, and because mobile medical apps are meant to be easily updated and ever-improving, the 510(k) scheme for premarket notification existing prior to the FDA's Final Guidance will not continue to work for many mobile medical apps, especially those with attachments that will generally fall into Class II.[160] Though the FDA does already have a mechanism called "Special 510(k)" that remedies the problem for frequently-updated devices to a certain extent,[161] a more streamlined process should be created to account for mobile medical apps that necessitate frequent updates across multiple mobile platforms. Unfortunately, the Final Guidance provides little hope of a fast track for mobile apps except for the promise of additional future guidance.

IV. FDA FINAL GUIDANCE ON MOBILE MEDICAL APPLICATIONS: PROBLEMS AND SOLUTIONS

A.   *Final Guidance in a Nutshell: Definitions, Scope, and Classifications*

Drafting effective regulation begins in defining the terminology. The FDA Final Guidance provides new definitions for the mobile category of health care applications with practical examples for each definition.[162] The foundational definition is, appropriately, the "mobile platform." The Final Guidance defines mobile platforms as "commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature."[163] Devices like the iPhone, Android, and other "mobile computers" like tablets or portable computers are sufficient examples of platforms with the capability of supporting multiple apps.[164] Next, a "mobile application" (mobile app) is a "software application that can be executed (run) on a mobile platform, . . . or [one that] is tailored to a mobile platform but is executed on a server."[165]

But the question on every mobile health app developer's mind is presumably: what makes a mobile application a "mobile *medical* application" and not a mobile health application? The Final Guidance

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160. *See* 510(K) PARADIGM, *supra* note 124.

161. This process essentially allows the manufacturer to submit a 510(k) premarket notification for a substantial change without having to verify internal data to back it up. *See How to Prepare a Special 510(k),* FOOD & DRUG ADMIN. (Dec. 7, 2009), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134573.htm.

162. FINAL GUIDANCE, *supra* note 25, at 7-11.

163. *Id.* at 7.

164. *Id.*

165. *Id.*

offers that a mobile medical app is "a mobile app that meets the definition of *device* in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and either is intended: to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated device."[166] For seasoned medical device manufacturers, this might be satisfactory, but to the slew of green-horned app developers seeking possible entry into the mobile medical market, the definition requires further expedition into the FD&C Act. The definition requires that the mobile app suffice as a "device" under section 201(h) of the FD&C Act,[167] which defines a "device" as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals . . . .[168]

Just as the intended use of an accessory determines whether an apparatus is ultimately deemed a "device,"[169] the FDA further suggests that a mobile app's intended use dictates whether it *transforms* the mobile platform into a "device."[170] Manufacturers can demonstrate intended use "by labeling claims, advertising materials, or oral or written statements . . . ."[171] Mobile apps meeting these requirements are considered devices, and those that are considered "similar to software designed to run on a desktop computer" are regulated under 21 C.F.R. 862.1345.[172]

Boiled down, if a mobile app or device is marketed for an intended use for medical care, it transforms the mobile platform into a mobile medical device subject to FDA regulation. Fortunately, the FDA does not plan to regulate all mobile platforms that are *capable* of supporting mobile medical applications and devices, but rather only those mobile platforms that are commercially marketed with an *intended use* of acting as a medical device.[173] The Final Guidance exempts many app creators: mobile platform manufacturers who do not market their products with specific intended medical uses, third party marketers of mobile apps and devices, internet

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166. *Id.* (emphasis added).
167. *Id.*
168. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h) (2006).
169. *Id.*
170. DRAFT GUIDANCE, *supra* note 25, at 7-8; FINAL GUIDANCE, *supra* note 25, at 7.
171. FINAL GUIDANCE, *supra* note 25, at 8.
172. *Id.* at 7.
173. *Id.* at 10.

providers, doctors developing apps for private professional practice, and developers making apps for use in research or teaching.[174]

So, an Apple or a Samsung will not be directly subject to FDA Good Manufacturing Practices requirements nor will they be forced to pay annual device user fees[175] and submit 510(k) premarket notifications for new versions of their smartphones or tablets generally, but if either company began marketing it to medical professionals as a platform to improve patient outcomes or to aid in the diagnosis, treatment, etc. of a medical condition, then the line may be blurred. As such, it is not clear whether mobile platform manufacturers may attempt to market their device directly to physicians and medical care providers and make any medical claims at all. Mobile medical *app* manufacturers face a similar dilemma: given the learning curve for utilizing new apps and devices on a mobile platform, will app developers hire "app reps," much like the pharmaceutical industry, to demonstrate the product to health professionals? If so, these "app reps" will presumably be subject to the same restrictions on marketing as are pharmaceutical and traditional medical device sales representatives.[176] While the Final Guidance excludes the app stores from the definition of manufacturer, it does not answer any of these questions related to marketing the mobile platform to health care professionals. Thus, the burden falls on the mobile medical industry to find its own answers.[177]

B.   The Mobile Medical Industry Bears the Burden (and Benefit) of Self-regulation

Because manufacturers and developers have a finger on the rapid pulse of mobile medical innovation, and because the FDA will only require premarket approval for a narrow scope of mobile medical apps,[178] the mobile medical industry is in the best position to regulate itself effectively. Moreover, the choice of the FDA to issue guidance (at least for now), rather than strict and distinct regulations for mobile medical devices, inherently places the onus on the industry to implement general controls and to adhere to the existing medical device regulations wherever applicable. Given the

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174. *See id.* at 10-11.

175. *See id.* at 10.

176. One example of the FDA's regulation over drug reps is an adverse-event-reporting-type system for physicians to report dubious marketing practices by drug companies and drug reps, called the "Bad Ad Program." *See* Robert Lowes, *FDA Urges Physicians to Report Misleading Drug Promotions*, MEDSCAPE NEWS TODAY (May 11, 2010), http://www.medscape.com/viewarticle/721647.

177. The Final Guidance encourages mobile medical app developers to affirmatively contact the FDA to seek clarification on applicable regulatory requirements. *See* FINAL GUIDANCE, *supra* note 25, at 12.

178. *See supra* Sections III, IV.

FDA's limited budget and ever-growing plate of responsibilities,[179] requiring full premarket approval for every new mobile medical app would clog the application pipeline to the point where releasing new mobile medical apps would be cost-and-time prohibitive.

Even more, most smartphone apps communicate with their creators when problems arise, allowing developers to react within hours or days to correct the glitch and publish a new update. Compare that responsive system to a traditional device manufacturer with a defective standalone product: the manufacturer learns of a defective device by injured parties filing lawsuits or directly from the FDA long after the malfunction has occurred, and then must expend a great deal of money to repair, replace, or recall each device.[180] Thereafter, the manufacturer must recoup the cost of its mistake by raising prices of future products, further increasing the costs of healthcare for doctors, consumers, and insurers. Allowing for a faster-acting system of recall-and-replace app updating tied to automated glitch reporting without the 510(k) substantial change application requirement would reduce the cost of recall and dramatically shorten the timetable for avoiding harm to the consumer.

The mobile medical app manufacturers are also best situated to mitigate many of the inherent risks of relying on a mobile platform, since they also bear the burden of liability to the end user. For instance, the Final Guidance exempts mobile platform manufacturers (Apple and its iPhone platform, e.g.) from "Quality Systems" requirements to which mobile medical app manufacturers must adhere.[181] This makes sense from a jurisdictional standpoint, since the platform itself is not a medical device[182] and is instead regulated by the Federal Communications Commission (FCC).[183] However, this exemption raises the question of who is responsible for unforeseen defects within the platform that substantially interfere with the reliability, accuracy, and functionality of the FDA-regulated mobile medical apps.

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179. *Food and Drug Administration FY 2014 Congressional Budget Request*, FOOD & DRUG ADMIN. (May 7, 2013), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM347422.pdf.

180. The FDA regulations for recalls account for voluntary recalls as well as mandatory ones. *See Recalls, Corrections and Removals (Devices)*, FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/ (last updated Nov. 16, 2010); 21 C.F.R. § 7 (1977); 21 C.F.R. § 810 (1996).

181. FINAL GUIDANCE, *supra* note 25, at 10-11.

182. *See id.* at 7, 10.

183. The FCC's Wireless Telecommunications Bureau regulates smartphones and other wireless devices, including licensing and bandwidth issues. *See Wireless Telecommunications Bureau*, FED. COMM'N COMM., http://www.fcc.gov/wireless-telecommunications-bureau (last visited Feb. 23, 2013).

Since the manufacturer has the regulatory obligation to implement Quality Systems and Design Controls, it is responsible for ensuring the quality of the components it purchases and uses in creating the device.[184] Additionally, it has the power to choose its own suppliers and the power to influence its suppliers to implement quality standards consistent with the device manufacturer's own Quality Systems protocol. This can be accomplished by contract, or by simple market competition.[185] But considerations for bandwidth and connectivity outages are primarily the concern of the FCC and the wireless network providers themselves, not the app developers.[186] Ultimately, the mobile medical industry is best equipped to assign responsibility to its members and to those capable of bearing the risk, and it will reap the benefits of more flexibility in innovation as a result.

V. FINAL GUIDANCE: NOT THE FINAL FRONTIER

The Final Guidance itself contains problems with terminology and scope. While it is impossible to know the future of mobile technology, even the base definition of "mobile platform" contains problematic phrases like "handheld in nature" and "typically used as smartphones" that might inadvertently exclude new technologies on the near horizon, since some new platforms capable of hosting mobile medical apps are currently in development and testing that are not handheld and are not even typically used as smartphones. For example, Google expects its "Project Glass" research and development project for "wearable computing" — glasses lenses that display computerized images — to be sold publicly in 2014.[187] Microsoft recently obtained its own patent on similar "augmented reality" wearable computer glasses.[188] Both the Google and Microsoft prototypes could potentially utilize any number of mobile medical device accessories and apps to monitor and interpret the wearer's bio-data, achieving the exact functional definition of the "mobile platform," yet both fall outside of the limited handheld platforms typically used as smartphones. Even more, Ford Motor Company is developing integrated sensors embedded in the steering wheel and driver seatbelt of its new vehicles to monitor the driver's facial

184. THOMPSON, *supra* note 118, at 9.

185. *Id.* at 26.

186. *See Wireless Telecommunications Bureau*, FED. COMM'N COMM., http://www.fcc.gov/what-we-do (last visited Nov. 16, 2013).

187. James Rivington, *Google Glass: What You Need to Know*, TECH RADAR, http://www.techradar.com/us/news/video/project-glass-what-you-need-to-know-1078114 (last updated Feb. 15, 2012).

188. Charles Arthur, *Microsoft Gets Patent on Augmented Reality Glasses as "AR Wars" Start*, THE GUARDIAN (Nov. 27, 2012), http://www.guardian.co.uk/technology/2012/nov/27/microsoft-augmented-reality-glass-google-apple.

temperature and compare it with the ambient temperature in the cabin, as well as conductive heart rate monitors and piezoelectric sensors in the lap belt to detect changes in heart rate and breathing, respectively.[189] These sensors are designed to interpret the vital driver data and alert the driver when physiological and biological signals indicate driver distraction.[190]

To extrapolate the "handheld" dilemma, under the proposed Final Guidance definitions, would an app running on Google's "Project Glass" that is designed to detect cataracts fall outside the definition of a "mobile medical app" because it does not technically operate on a "mobile platform"? What about the Ford car that monitors driver vitals? It is (equivocally) a *mobile* medical device, after all. While the steering wheel is "handheld" to an extent, the lap belt is akin to the "wearable computer" glasses. Yet all these are platforms upon which mobile medical apps could be executed. Substitute "portable" or "wireless" for "handheld," and the problem might be solved. This may be yet another complication that will result in more FDA guidance down the road, indicating that this Final Guidance is not so final after all. In fact, the FDA quite clearly dodged offering any guidance whatsoever concerning app software that "performs patient-specific analysis to aid or support clinical decision-making" and "accessories to medical devices" and apps.[191]

Not only should the FDA encourage or require developers and manufacturers to integrate self-monitoring features for apps and devices, but it should also require mobile app manufacturers to program their apps to report adverse event data compatible with the FDA's *own* adverse event reporting system, the Sentinel Initiative.[192] Apps designed for smartphones and tablets already collect many different types of information as a background process to be sent back to the app developer, tracking each and every "click" or action within the app, when the app is in use, the location of the user during use, and the duration of that use.[193] Some apps even collect data when they (or the phone itself) are not in use.[194] So an FDA requirement for mobile app manufacturers to compile that data and pass it along to the Sentinel Initiative system is not particularly burdensome.

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189. Doug Newcomb, *How Ford Calculates Driver Workload to Dial Back Distractions*, WIRED (Jun. 27, 2012, 12:06 PM), http://www.wired.com/autopia/2012/06/ford-workload/.

190. *Id.*

191. FINAL GUIDANCE, *supra* note 25, at 12.

192. *See FDA's Sentinel Initiative – Background*, FOOD & DRUG ADMIN., http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm149340.htm (last updated Jan. 9, 2010).

193. *See* Abby Abazorius, *CSAIL Research Examines How Smartphone Apps Track Users*, MIT NEWS (Sept. 17, 2012), http://web.mit.edu/newsoffice/2012/csail-research-examines-how-smartphone-apps-track-users-0917.html.

194. *Id.*

Since the system is already in place, this would not require an unreasonable resource allocation.

All things considered, the FDA faces numerous financial and logistical hurdles in its office with respect to processing applications and overseeing compliance and safety. For example, the FDA must prepare itself for the potential deluge of adverse event reports under its Medical Device Reporting (MDR) structure[195] as the number of mobile medical app manufacturers is expected to increase exponentially now that the final guidance has been issued.[196] Because the rate of innovation vastly surpasses the timeline and barriers accompanied by current regulation and oversight structures,[197] one solution proposed by the U.S. House of Representatives would create a new FDA "Office of Mobile Health" and other offices in a bill called the Health Information Marketplace Technologies Act (HIMTA).[198] Creating an Office of Mobile Health would establish a branch of the agency sensitive to the dynamic changes in mobile medical technology that could provide a quicker turnaround scheme for premarket approval that is not time and cost prohibitive. Granted, the solution to every problem in government may not always be to create a new office, committee, or position, but given the overall benefits to the health care profession that mobile medical device technology — including the economic savings of low-cost devices — a new office might be worth the extra funding.

VI. CONCLUSION

As technology advances and becomes even more widely used, the learning curve for mobilechondriacs and health care providers will flatten out, resulting in a shift from responsive care to individualized preventative care and an improvement in patient outcomes. Because mobile medical apps could be much cheaper to produce and to purchase than stand-alone devices, the cost savings of "going mobile" would be passed down to the health care consumer, consistent with the goals of the Affordable Care Act to improve patient outcomes and lower the cost of health care in our nation. Nonetheless, the risks associated with mobile medical devices remain, and

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195. *See* FINAL GUIDANCE, *supra* note 25, at 25-26.

196. The mobile medical app market was projected to reach $1.4 Billion by the end of 2012 and is predicted to grow by 23% by 2017. Ryan Minarovich, *A Coming Storm: FDA Regulation of Mobile Medical Applications*, THE HEALTH CARE BLOG (Oct. 24, 2010), http://the healthcareblog.com/blog/2012/10/24/a-coming-storm-fda-regulation-of-mobile-medical-ap plications/.

197. *See* Jenny Gold*, supra* note 49.

198. Health Care Innovation and Marketplace Technologies Act of 2012 (HIMTA), H.R. 6626, 112th Cong. (2012). *See also* Jenny Gold, *supra* note 49. In addition to establishing the new office, if passed, HIMTA would also provide for coordinating developer assistance offices to open in conjunction with Health and Human Services (HHS). *Id.*

despite possible liability apportionment in common law remedies, the FDA must balance its new mobile medical app regulations to simultaneously protect the consumer and also encourage innovation. Even so, the mobile medical app industry will provide the most substantial oversight where FDA's budget and infrastructure are lacking. With more resources, and the right political backing, creating the Office of Mobile Health could shift some of that burden away from the manufacturers as regulation may require. Ultimately, whether or not the FDA's final guidance addresses these enumerated concerns, the bulk of the Final Guidance places a necessary level of responsibility on the mobile medical app manufacturer.

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