The Mobile Health Revolution?

Nathan Cortez

Rarely does a class of technologies excite physicians, patients, financeers, gadgeteers, and policymakers alike. But mobile health — the use of mobile devices like smartphones and tablets for health or medical purposes — has captured our collective imagination. Observers predict that mobile health, also known as “mHealth” or by products called “medical apps,” can save millions of lives, billions in spending, and democratize access to health care. Proponents argue that mobile health technologies will transform the ways in which we deliver, consume, measure, and pay for care, disrupting our sclerotic health care system.

This Article evaluates mobile health and its many ambitions. Given the significant hype surrounding mobile health, I try to provide a more sober review of the many claims here. I begin by surveying the universe of mobile health technologies, offering a typology of products based on their functions, many of which have regulatory significance.

The Article then considers the federal government’s posture towards mobile health. To date, Congress and over half a dozen federal agencies have addressed these technologies. Contrary to the prevailing wisdom, federal regulators are sympathetic, not hostile, to mobile

---

* Copyright © 2014 Nathan Cortez. Associate Professor and Associate Dean for Research, Southern Methodist University (SMU), Dedman School of Law. J.D. Stanford Law School, B.A. University of Pennsylvania. Many thanks to Nicholas Bagley, Jeffrey Bellin, Glenn Cohen, Nancy Leveson, Lars Noah, Jordan Paradise, Frank Pasquale, Nicolas Terry, Bradley Merrill Thompson, and David Zaring for commenting on earlier drafts. This Article no doubt benefited from the comments and questions I received from fellow participants at: the American Society of Law, Medicine, and Ethics annual meeting; the SMU Law School Faculty Forum; and the Harvard Law School Petrie-Flom Center’s conference on “The Food and Drug Administration in the 21st Century.” I also thank Courtney Eudy, Banee Pachuca, and Robert Thetford for characteristically excellent research assistance. This paper was selected for the New Voices in Administrative Law panel at the 2013 AALS Annual Meeting. This research was supported by generous funding from the A.J. and Ann Van Wynen Thomas Memorial Endowed Research Award, as well as a grant from the Radcliffe Institute for Advanced Study at Harvard University, supporting an Exploratory Seminar on Mobile Health.

1173
health products. However, I demonstrate how one agency, the U.S. Food and Drug Administration (“FDA”), is repeating the same mistakes that it made when it first confronted medical device software twenty-five years ago, relying on nonbinding guidance documents that are largely weak and unenforceable. I argue that, somewhat counterintuitively, mobile health will only reach its immense potential if regulators like the FDA provide meaningful oversight. Otherwise, users will be flooded with mobile technologies that are ineffective, or worse, unsafe.

TABLE OF CONTENTS

INTRODUCTION ................................................................................. 1175
I. A TYPOLOジー OF MOBILE HEALTH ........................................... 1181
   A. Connectors ............................................................................. 1182
   B. Replicators ............................................................................ 1184
   C. Automators and Customizers ............................................. 1186
   D. Informers and Educators....................................................... 1188
   E. Administrators ....................................................................... 1189
   F. Loggers and Trackers .............................................................. 1189
II. THE PROMISE OF MOBILE HEALTH .......................................... 1190
   A. Improve Quality ................................................................. 1192
   B. Reduce Spending ............................................................... 1195
   C. Democratize Medicine ......................................................... 1197
III. THE GOVERNMENT’S POSTURE ................................................ 1200
   A. The Food and Drug Administration .................................... 1200
   B. Other Agencies ...................................................................... 1211
IV. ENTERING THE REGULATORY FEEDBACK LOOP ................. 1217
   A. A Quarter-Century of Computerized Medicine .................. 1218
   B. “The Wonders and Brutality” of Innovation ....................... 1224
   C. “To Really Screw Things Up, You Need a Computer” ....... 1226
CONCLUSION..................................................................................... 1230
INTRODUCTION

The video begins with the deep, familiar drum of a heartbeat, overlaid with piano staccato and flashes of internal organs observable only through modern machinery. The narrator begins: “Technology has given us an unprecedented view into the human body. But on a day-to-day basis, we’re still in the dark about our own health.” Staccato gives way to more buoyant notes. “We are changing that.”

The video continues with three vignettes — all concerned parents with young children. In the first, a father uses a smartphone to scan his son’s rash, which the phone matches against a database of archetypes. The phone advises, “Roseola rash. Recommended action: Rest at home.” The father turns to his wife, relieved, “Rest at home. It’s okay.”

In the second vignette, a mother relaxes on her couch with a tablet computer, when an alert warns, “Whooping Cough in your area.” The tablet recommends a DTaP vaccination for her daughter, which the mother schedules with a few taps on the screen.

In the third vignette, two worried parents use a smartphone to measure a 103.8 degree fever in their young daughter. The phone prompts for additional symptoms. In response, it recommends a urinalysis, which the father performs with peripherals that plug into his phone. The software advises “Urinary Tract Infection. Visit Urgent Care Now,” displaying a route to the nearest hospital.

The narrator closes: “We’re building a way for people to check their bodies as often as they check their email. It’s all possible. And it’s only the beginning.”

The video is by Scanadu, a medical technology company that resides at NASA’s Ames Research Center in Silicon Valley. Since 2010, the company has been trying to create a real life version of the Tricorder, the mythical, universal diagnostic device used by Dr. McCoy on Star Trek. Three years later, Scanadu claims to have done

3 Indeed, Scanadu has become almost synonymous in the media with efforts to develop the Tricorder. See, e.g., Press Mentions, Scanadu, http://www.scanadu.com/press_mentions/ (last visited June 24, 2013) (citing various news article headlines likening Scanadu to the Tricorder); see also Mark P. Mills, Tricorder Update: Social Medicine Is the Next Big Thing After Social Media, FORBES (May 21, 2012), http://www.forbes.com/sites/markpmills/2012/05/21/tricorder-update-social-medicine-is-the-next-big-thing-after-social-media/ (calling Scanadu’s innovation a “protean medical
so with its first product, the Scout — a small, puck-shaped device that measures vital signs like temperature, heart rate, blood oxygenation, blood pressure, and what it calls “emotional stress,” when held against the forehead. The Scout uses various algorithms and sensors, some of which derive from NASA’s Mars Curiosity Rover mission. Scanadu broke fundraising records when it launched a campaign on the crowdfunding site Indiegogo. It is now soliciting participants for usability studies that the company hopes will lead to marketing clearance by the U.S. Food & Drug Administration (“FDA”). Scanadu’s marketing line is “Sapere Aude” (“Dare to Know”). And its website invites users to “[i]magine the tools of an emergency room from the comfort of your living room.” If successful, the company could win a $10 million award from the X Prize Foundation, which in 2011 created a competition for the first group to create a medical Tricorder.

In many ways, Scanadu embodies the nascent mobile health industry and its boundless ambitions. “Mobile health,” or “mHealth,” is the use of mobile communications devices like smartphones and tablet computers for health or medical purposes, usually for diagnosis, treatment, or simply well-being and maintenance. Most mobile health technologies interface with users through applications (“apps”) downloaded onto iPhones, iPads, or Android or Windows devices, for example.


See INDIEGOGO, supra note 4.

See Ki Mae Heussner, Scanadu’s Medical ‘Tricorder’ Sets Record for Fastest Funding Velocity on Indiegogo, GIGAOM (May 24, 2013), http://gigaom.com/2013/05/24/scanadus-medical-tricorder-sets-record-for-fastest-funding-velocity-on-indiegogo/.

See INDIEGOGO, supra note 4.

See id.

See id.

In addition to the Scout, we now have technologies that allow us to use smartphones to control FDA-regulated devices like blood pressure cuffs, ultrasound machines, and insulin pumps. Other mobile health apps can link smartphones to hundreds of hospital monitors, allowing physicians to track patient vital signs remotely. Some apps allow physicians and patients to view CT scans, MRIs, PET scans, and other medical images remotely.\textsuperscript{11} Others allow patients to listen to abnormal heart, lung, and bowel sounds, or track their blood-glucose levels using their phones. And still others try to turn smartphones into all-in-one diagnostic tools like the Scout.\textsuperscript{12}

Some mobile health applications target patient users. Some target health care professionals. Many do not discriminate.

Mobile health applications often take advantage of a smartphone’s built-in features, like touch screens, cameras, gyroscopes, lights, sounds, and wireless connectivity — as well as software that processes interactive questionnaires, algorithms, formulae, calculators, clinical decision support tools, and other parameters. Used in combination, mobile health applications can generate customized diagnoses and treatment recommendations by comparing user-specific data to vast bodies of clinical research and accumulated medical knowledge. Mobile apps are turning phones into medical devices.

Mobile health might digitize the ways in which we deliver, consume, measure, and pay for health care. Some believe mobile health will reduce medical errors, improve quality care, and save millions of lives. Others posit that it will save us billions in health spending by preventing more serious, acute episodes of illness. Mobile health may also decentralize and demystify medicine by shifting the locus of care away from expensive medical facilities and professionals, and towards digitally-empowered patients.

Mobile health could provide a much needed shock to the U.S. health care system. Smartphones already are replacing stethoscopes and pagers as the most ubiquitous physician accessory.\textsuperscript{13} The number of

\begin{footnotesize}
\textsuperscript{11} “CT” is “computed tomography.” “MRI” is “magnetic resonance imaging.” And “PET” is “positron emission tomography.” Each uses different methods to view internal organs, structures, and tissues. \textit{Stedman’s Concise Medical Dictionary for the Health Professions} 236, 636, 751 (4th ed. 2001).

\textsuperscript{12} For a brief snapshot of the history of mobile health devices that connect to other medical devices, including many described in this paragraph, see Aditi Pai, Jonah Comstock & Brian Dolan, \textit{Timeline: Smartphone-Enabled Health Devices}, MobiHealthNews (June 7, 2013), http://mobihealthnews.com/22674/timeline-smartphone-enabled-health-devices/.

\textsuperscript{13} For a physician’s perspective on this phenomenon, see William Hanson, \textit{Smart Medicine: How the Changing Role of Doctors Will Revolutionize Health Care}
smartphone users downloading health applications roughly doubles every year, and is expected to hit 500 million by 2015. Today, Apple offers around 13,000 different health applications for consumers in its App Store, not counting the many more targeted at doctors and nurses, or yet more offered on other device platforms. The $10 million Tricorder X Prize is but an emblem of the excitement. Even policymakers see the potential, hoping that mobile health can accomplish what has eluded them for decades: the Holy Trinity of reducing costs, improving quality, and expanding access to care.

The mobile health revolution is in many ways the convergence of several panoramic trends, including evidence-based medicine, personalized medicine, consumer-driven health care, coordinated care, pay-for-performance, the “quantified self” movement, and even broader evolutions in science, technology, and society. In short, mobile health sits at the intersection of several converging phenomena, and our collective response to it is worth studying.

This Article evaluates mobile health and its many possibilities. I argue that for mobile health to reach its immense potential, regulators must not only try to facilitate these technologies, but also ensure that

---


16 See Torie Bosch, Inspired by Star Trek, $10 Million X-Prize Searches for Real-Life Tricorder, SLATE (Jan. 10, 2012), http://slate.me/xukOY5 (hoping that the winner’s device will “allow a user to diagnose themselves without having to visit a doctor or hospital”). For the final guidelines, see Competition Guidelines, QUALCOMM TRICORDER X PRIZE (July 1, 2013), http://www.qualcommtricorderxprize.org/competition-details/competition-guidelines.

17 For example, there is a rich literature in the Science, Technology, and Society discipline that examines problems related to scientific and technological innovation. The scholarship ranges from Thomas Kuhn’s famous 1962 book, The Structure of Scientific Revolutions, to work by modern founders like Sheila Jasanoff. Although these debates are beyond the scope of this Article, the legal questions I address no doubt benefit from their perspectives.

18 See Kenneth W. Goodman, Ethical and Legal Issues in Decision Support, in CLINICAL DECISION SUPPORT SYSTEMS: THEORY AND PRACTICE 137 (Ela S. Berner ed., 2d ed. 2007) (“[T]he debate over medical software regulation represents one of the most important controversies of the Computer Age. The balancing of risks and benefits, as well as public safety and technological progress, means that scientists, clinicians, and policymakers have one of civilization’s most interesting — and challenging — tasks.”).
they are safe and effective. To date, Congress and over half a dozen federal agencies, including the FDA, the Federal Communications Commission ("FCC"), the Federal Trade Commission ("FTC"), the Department of Commerce, the Department of Defense, and various subagencies of the Department of Health and Human Services ("HHS"), have addressed mobile health.19

The tenor of their responses, with some exceptions, has been optimistic and aspirational. I argue, somewhat counterintuitively, that the mobile health market will flourish long-term only if it is subjected to a healthy dose of skepticism from federal regulators, particularly the FDA. The FDA, and perhaps also the FTC, is in the best position to prevent U.S. health policy (and spending) from being dictated by "technological solutionism," the idea that technology can solve any and all of our problems, no matter how complicated or persistent.20

Without meaningful regulatory oversight, users might be flooded with mobile technologies that are ineffective, or worse, unsafe.

I begin in Part I by surveying the universe of mobile health technologies and offering a typology of products based on their functions. For example, some mobile health apps connect to FDA-regulated medical devices, amplifying their capabilities. Others replicate the functionality of traditional devices. Some automate and customize diagnoses or treatment recommendations based on patient-specific inputs. And others do more. These functions have regulatory significance and present discrete benefits and risks.

Part II then evaluates the many ambitions of mobile health. I examine claims that mobile health can save millions of lives, billions in spending, and democratize access to medicine. Given the significant hype surrounding mobile health, I try to offer a relatively sober, dispassionate review of the many claims here.21

Given these claims, Part III considers the federal government’s posture towards mobile health. As noted above, both Congress and over half a dozen federal agencies are actively monitoring mobile

---

19 See infra Part III.

20 See Evgeny Morozov, To Save Everything, Click Here: The Folly of Technological Solutionism 5-6 (2013). For a critical review by a legal scholar, see Tim Wu, Book Review: ‘To Save Everything, Click Here,’ by Evgeny Morozov, WASH. POST (Apr. 12, 2013), http://www.washingtonpost.com/opinions/book-review-to-save-everything-click-here-by-evgeny-morozov/2013/04/12/0e82400a-9ac9-11e2-9a79-e6b28d0e163_ story.html (describing “solutionism” as “the idea that deep and serious problems can be solved with a few cute apps”).

21 The need for more detached, critical evaluations of new Internet technologies and their social implications is highlighted, in rather scathing terms, by Morozov, supra note 20, at 18-20.
health technologies. I pay particular attention to the FDA, the agency responsible for ensuring that new medical devices are safe and effective. I demonstrate that, contrary to the prevailing wisdom, federal regulators are sympathetic, not hostile, to mobile health. To most observers, this is entirely reasonable.

However, as I demonstrate in Part IV, the FDA is repeating some of the same mistakes that it made when first confronting medical device software twenty-five years ago. In 1987, the FDA published a draft software guidance, partly in response to several deaths caused by the first radiation machines operated by software. The FDA then relied on the draft guidance for the next eighteen years, withdrawing the policy unceremoniously in 2005, leaving nothing in its place. The FDA never promulgated comprehensive software regulations and never even finalized the draft policy. All of this happened during a profound computer revolution, no less, when software became increasingly ubiquitous and critical to patient safety.

Likewise, the FDA now relies on nonbinding guidance to explain its tentative approach to mobile health, specifying the types of apps that it may and may not regulate. The agency is thus adopting the same posture it did when first confronting medical device software twenty-five years ago, building on a scaffolding of nonbinding guidance documents that are largely unenforceable. I show how recent tragedies caused by the latest generation of radiation software echo the same problems that first prompted FDA involvement in the mid-1980s. Given this evidence, I argue that the FDA should confront its past regulatory failures and push itself into a regulatory “feedback loop,” in which the agency can identify past shortcomings and correct them.


going forward. For example, if draft guidances become obsolete, the agency should update them. And if the FDA declares enforceable principles via guidance or elsewhere, it should enforce them.

For the mobile health revolution to succeed, regulators will need to provide genuine oversight, not just cheerleading.

I. A TYPOLOGY OF MOBILE HEALTH

The mobile health revolution began on June 29, 2007. On that day, Apple released the first iPhone, perhaps “the most anticipated gadget of all time.” Twenty months later, on stage in front of thousands at the World Wide Developer’s Conference, an Apple executive connected an iPhone to a blood pressure monitor, and an executive from the Johnson & Johnson subsidiary LifeScan connected an iPhone to a blood glucose meter. The Apple executive observed, “We think this is profound.” Although mobile health can trace its roots back further, to personal digital assistants (“PDAs”), websites like WebMD, and even early electronic medical records, the first iPhone introduced an era of torrential creativity with mobile communications devices.

Barely five years later, and the mobile health revolution is well underway. Physicians, nurses, entrepreneurs, financeers, gadgeteers, futurists, and even policymakers can barely contain their excitement. Media stories feature breathless quotes about the transformation of medicine. Part II, below, evaluates these claims.

But before doing so, Part I introduces mobile health technologies, evaluating the first generation of mobile applications and previewing later generations that may do much more. I present a typology of

25 Brian X. Chen, June 29, 2007: iPhone, You Phone, We All Wanna iPhone, WIRED (June 29, 2009), http://www.wired.com/thisdayintech/2009/06/dayintech_0629/.
26 See Pai et al., supra note 12.
27 Id.
28 See generally Nicolas P. Terry, Information Technology’s Failure to Disrupt Health Care, 13 Nev. L.J. 722 (2013) (tracing the recent history of health information technology (“HIT”), beginning with the Institute of Medicine’s call for HIT in 2001 and continuing on to medical apps).
29 See infra Part II.
mobile health applications, categorized largely by their functionality. Of course, with an estimated 97,000 mobile health apps on the market in 2013, any typology will necessarily oversimplify. But the typology largely reflects how regulators like the FDA divide the market. Finally, to truly appreciate these technologies, one must see them in action, and for that reason I cite to such sources infra.

A. Connectors

The first category of applications connects smartphones and tablets to FDA-regulated devices, thus amplifying the devices’ functionalities. For example, applications now enable clinicians to use their smartphones to view and manipulate medical images, analyze electroencephalograms (“EEGs”) or electrocardiograms (“ECGs”), connect to bedside monitors, screen blood samples, or act as wireless remote controls for medical devices.

In this latter category, several applications allow users to control FDA-regulated devices. Examples include apps that allow users to inflate and deflate blood pressure cuffs, perform portable ultrasounds, operate insulin pumps, and visually track whether wounds heal or regress. Other apps also display, analyze, or transmit

---


32 See FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 18-20.

33 See id. at 18 (listing examples).


Yet another allows cardiologists to review and manipulate ECG results and histories. See The Impact of Airstrip ONE Mobility Across the Cardiology Care Continuum, AIRSTRIP TECHS., http://www.airstriptech.com/cardiology/pre-hospital (last visited June 24, 2013).

Perhaps the most well-known of these is Mobile MIM, which allows physicians to view CT scans, MRIs, PET scans, and other diagnostic tests on mobile devices. Mobile MIM was the first imaging app cleared by the FDA, in 2011. While physicians use Mobile MIM to diagnose patients, its patient version, VueMe, shares the same images. The apps themselves are free, but the company charges one dollar each time the user (again, a physician or patient) uploads or sends an image. Mobile MIM was available for download from iTunes before the FDA had cleared it, but the agency directed the company to remove it pending regulatory review. The company then


43 See Eisenberg, supra note 42.

44 See id. (noting the charge is $2 for iPad users).

45 See Vernessa T. Pollard & Chandra Branham, FDA MEDICAL DEVICE REQUIREMENTS:
spent two and a half years and roughly $150,000 obtaining the FDA's blessing. The FDA initially was concerned that physicians would struggle to make accurate diagnoses while viewing images in bright environments (particularly outdoors), as opposed to the traditional approach of viewing images on large dedicated screens in dimly-lit rooms. In response, Mobile MIM developed a feature to automatically detect subpar lighting conditions. The Mobile MIM story is both a cautionary tale and a success story for app developers.

B. Replicators

A second class of apps turns the smartphone or tablet itself into a medical device by replicating the functionality of an FDA-regulated device. For example, several apps use attachments or sensors to send data directly to the smartphone, which then processes and displays the results, and perhaps even recommends diagnoses or treatment options. These apps allow users to connect, for example, to blood glucose monitors, stethoscopes, or ECG or EEG machines. Others might use the phone's built-in microphone "to amplify heart, lung, blood vessel, enteral, and other body sounds." Still others might use built-in features like accelerometers to measure a patient's body movement or heart rate. More and more apps are engaging stock features like lights, vibrations, and cameras for medical uses.

Within this class, several cardiology apps replicate traditional device functions and demonstrate the possibilities (and perils) here. For example, iStethoscope Expert uses the iPhone's built-in microphone to record sounds emanating from the heart, lungs, and bowels. It includes a Heart Murmur Interpreter, a Lung Sounds Interpreter, and a Bowel Sounds Interpreter. The Heart Murmur Interpreter, for

---


47 See Eisenberg, supra note 42.

48 See id.

49 See FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 19 (listing examples).

50 Id.

51 See id.

52 See id.

example, instructs the user to place the microphone against the chest, then answer a series of questions like, “Where is the murmur the loudest on the chest?” “Is the murmur a systolic murmur?” and “Is the murmur a diasystolic [sic] murmur?” It then generates what it calls a “diagnosis.” For a test run, selecting the first answer in response to each of the five questions generates a diagnosis of hypertrophic cardiomyopathy, which, the app explains, can cause sudden cardiac death in younger patients during exertion.54

A similar app by AliveCor made waves when videos went viral of a doctor turning an iPhone into a cardiac event monitor.55 AliveCor uses a slim iPhone case with two silver electrodes on the outside, which users hold in their hand or press against the chest. The iPhone’s screen then displays the familiar peaks and valleys of a heartbeat. The video proclaims that the app “turns the iPhone 4 into a wireless, clinical quality cardiac event monitor.”56 The video also claims that the app can offer “an immediate diagnosis.”57 In 2012, the company was preparing to submit clinical trial results to the FDA.58

Other cardiac apps rely on more traditional recorders. For example, in 2011, the FDA cleared the Reka E100 app, which transmits events recorded by a peripheral cardiac event recording device.59 The app sends recordings from the event monitor to a monitoring center, which is then evaluated by a cardiologist. The company’s submission to the FDA carefully noted that the Reka E100 is not a “conventional diagnostic tool.”60

Similar apps appear in the diabetes field. The iBGStar Diabetes Manager app connects iPhones directly to a separate blood glucose

---

56 See AliveCor, Inc., supra note 55.  
57 See id.  
60 Id. at 2.
monitoring system. Together, the app and the monitor allow patients to track their blood glucose levels and send results to physicians. iBGStar presents data in multiple formats and even alerts users when their blood sugar levels are too high or too low. An iBGStar meter was associated with two adverse events reported to the FDA in March 2012, although it was unclear if users were also using the app.

Some replicator apps are even more ambitious. For example, the BioZen app claims it can receive real-time feedback from several biosensor devices, like EEGs, ECGs, electromyographies (“EMGs”), galvanic skin responses (“GSRs”), respirators, and thermometers. BioZen is unique in that it has been endorsed by the U.S. Department of Defense for improving the mental health of military personnel. Notably, the BioZen web-site says, “These devices and BioZen are not designed or intended for psychological therapy or medical treatments.” Nevertheless, many apps are now trying to replicate the functions of conventional medical devices.

C. Automators and Customizers

Notwithstanding its disclaimers, BioZen blurs the line between apps that replicate medical device functions and apps that also use patient data to generate custom diagnoses or treatment recommendations. This third category of apps uses questionnaires, algorithms, formulae, medical calculators, or other software parameters to aid clinical decisions. As such, these apps are part of a broader universe of clinical

---

65 See id.
The Mobile Health Revolution?

decision support software.67 The apps can, for example, automate tasks for physicians, such as calculating an Apgar Score for newborns, or determining the precise dose of blood thinner, anesthesia, or chemotherapy for patients based on their age, weight, and other inputs.68 As noted above, iStethoscope Expert features this functionality via its questionnaire, demonstrating how the categorical lines blur. Another example is Depression Journal, an iPhone app that allows users to track when they are depressed and identify potential triggers.69 It once claimed that the app is “a valuable tool for Depression Trends Analysis to get additional insights about triggers and how to avoid them.”70

A related species of apps that may hold the most promise of decentralizing and demystifying medicine is the all-in-one diagnostic tool, like Pocket Doctor, Caracal Diagnosis, Diagnosis Pro, and WebMD’s Symptom Checker. These apps are proliferating. A search for “diagnosis” in the App Store generates 275 iPad apps and 509 iPhone apps.71 These programs typically allow users to key in symptoms and even laboratory values, which feed into an algorithm that generates potential diagnoses, usually ordered by probability. For example, entering “chest pain” and “lightheadedness” into Caracal generates 119 possible diagnoses and 15 “high probabilities.” Caracal differentiates high-probability from low-probability diagnoses by color (red to green).

Many apps simultaneously promise great things and then disclaim their accuracy, urging users to seek advice from medical professionals.72 Notably, many customizer apps generally target

67 Clinical decision support software is drawing increased attention from scholars. See, e.g., Amanda Swanson & Fazal Khan, The Legal Challenge of Incorporating Artificial Intelligence into Medical Practice, 6 J. HEALTH & LIFE SCI. L. 90 (2012) (discussing how health providers have increasingly turned to such technology as it has become more affordable and reliable).

68 See FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 19-20.


70 Id. (note that the description has since changed).

71 Search conducted on January 26, 2014.

72 For example, the Caracal app disclaims that: “Caracal is a clinical decision support system. It cannot guarantee the accuracy of the diagnoses and please note that you are solely responsible for any decisions you take based on the information contained in it.” Husam Salhab, Caracal Diagnosis: Smart Medical Diseases Search Engine, iTUNES PREVIEW, https://itunes.apple.com/us/app/caracal-diagnosis-smart-medical/id329633939?mt=8 (accessed on Aug. 9, 2013) (note that as of December 9, 2013, the disclaimer was updated to read, “Please note that Caracal is only a differential diagnosis tool and isn’t supposed to give you any further information
medical professionals and students, though nothing prevents lay users from downloading them. Like other medical innovations, the message is often “caveat emptor.”73 Yet, these all-in-one tools may represent the primordial beginnings of the Tricorder.

D. Informers and Educators

A broad fourth category includes medical reference texts and educational apps that primarily aim to inform and educate. For example, hundreds of apps replicate medical textbooks, references, or teaching aids. Trusted sources like the Physician’s Desk Reference, the Merck Manual, and Gray’s Anatomy have been converted into app format.74 Many medical journals now present themselves in app format as well, including the New England Journal of Medicine (“NEJM”), the Journal of the American Medical Association (“JAMA”), the Journal of Clinical Oncology, and The Lancet.75 As a godsend to medical students, hundreds of apps replicate flash cards, quizzes, and other exam review materials, enhanced by touch controls and other interactive features on modern smartphones and tablets.76


73 See Nathan Cortez, Recalibrating the Legal Risks of Cross-Border Health Care, 10 Yale J. Health Pol’y L. & Ethics 1, 18-19 (2010).


These apps largely represent digital versions of print sources — or sources that otherwise might have been printed in bygone eras. They do not concern the FDA or other regulators much, as their print counterparts would fall outside of FDA jurisdiction.\footnote{See FDA DRAFT SOFTWARE POLICY, supra note 22, at *1.} Still, informer and educator apps are worth noting, as they seem to comprise a robust portion of the reported 97,000 mobile health apps on the market in 2013.\footnote{See RESEARCH2GUIDANCE, Report 2013–2017, supra note 31, at 7.}

\section*{E. Administrators}

Other, more mundane apps automate office functions, like identifying appropriate insurance billing codes or scheduling patient appointments.\footnote{For example, a search conducted on December 29, 2013 for “ICD” in the App Store (short for International Classification of Diseases, the World Health Organization’s coding system commonly used by insurers) generates 135 iPad apps and 194 iPhone apps.} These represent the mobile evolution of practice management software. Such apps are “medical” insofar as they are used by medical providers, not because they perform any medical functions per se. Yet, at some point these apps might become more ambitious. For example, a scheduling app logically might administer pre-appointment patient questionnaires, then flag certain patients for specific diagnostic tests based on their answers. Such a feature would bring administrative apps closer to clinical decision support software, which I categorize above as automators or customizers. Again, these categories will be transient for apps that evolve.

\section*{F. Loggers and Trackers}

A final, more interesting cluster of apps allows users to log, record, and make decisions about their general health and wellness. This group includes diet trackers, calorie counters, exercise regimens, and the like. They may integrate alarms, timers, reminders, and other interactive features. Others try to “gamify” health care by using game-like rewards systems, point-tracking, and challenges to encourage healthier behavior.\footnote{In fact, there is a new academic journal dedicated to studying the “gamification” of health care, the Games for Health Journal. See Brian Edwards, Gamification of Healthcare Gets Its Due Recognition from Academic Elite, iMEDICALAPPS (Aug. 19, 2011), http://www.imedicalapps.com/2011/08/gamification-healthcare-due-recognition-academic-elite/; Games for Health Journal, LIEBERT OPEN ACCESS, http://online.liebertpub.com/loi/G4H (last visited June 24, 2013).} These apps represent another innovative frontier.
for health care, even though they generally do not concern the FDA — as long as they do not try to diagnose, cure, treat, mitigate, or prevent specific, identifiable diseases or conditions.81

But herein lays the gray area. Many health and wellness apps do address themselves to specific diseases or conditions. An important subset of these includes apps offered by FDA-regulated firms, like pharmaceutical, biotech, and medical device companies.82 Loggers and trackers may also automate knowledge contained in medical literature and clinical studies to educate users and guide their decisions. The FDA notes that such apps could meet the statutory definition of medical “devices,” but intends to monitor these apps without regulating them at the moment.83 European regulators are also debating whether pharmaceutical apps qualify as medical devices under EU law.84 In both jurisdictions, such apps are proliferating.

***

A final observation worth emphasizing is that any taxonomy of mobile health technologies will be suggestive rather than definitive. Apps that today inform and educate may add logging or tracking features. Loggers and trackers may evolve into customizers, replicators, or connectors. These apps are subject to frequent updates. Indeed, part of the appeal of software is that it is easy to change. But it also marks a significant departure from more traditional medical devices.

II. THE PROMISE OF MOBILE HEALTH

These first-generation apps should evolve into more sophisticated, capable iterations that might change how we deliver, consume,
measure, and pay for health care. As the mobile health market begins to mature, it is worth pausing to evaluate these possibilities.

As an initial matter, both the trajectory of mobile health users and the value of the market are impressive. For example, the number of medical apps created for Apple devices more than doubled in just one year, jumping from roughly 800 in 2010 to 2,000 in 2011 — not even counting apps for other platforms, like Android and Blackberry. The number of people accessing health data on their phones increased 125% between 2010 and 2012, to roughly 17 million. The number of users that downloaded mobile health apps nearly doubled in just one year, from 124 million in 2011 to 247 million in 2012. By 2015, industry observers predict that 500 million smartphone users will use mobile health apps.

The value of the medical app market has risen correspondingly, from $718 million in 2011 to an estimated $1.3 billion in 2012. The broader mobile health industry may be worth anywhere from $2 billion to $6 billion by 2015. Another estimate predicts that by 2018, the market will generate $26 billion in revenues.

On a broader scale, there has been a rapid diffusion of smartphones, tablets, and other mobile devices, which seems to be accelerating rather than abating. By 2018, there may be 3.4 billion unique smartphones and tablets capable of downloading mobile health apps, about half of which are predicted to do so. Today, more people worldwide have access to mobile phone service (5.7 billion) than to

88 See Orr, supra note 14, at 2.
89 See Jahns, supra note 87.
90 See FCC, CHAIRMAN PROPOSAL, supra note 86, at 2 (citing Healthcare Information and Management Systems Society).
basic sanitation (4.4 billion). Mobile phones are creating new possibilities in developing countries in particular for mobile banking and mobile health.

If we are truly on the cusp of a mobile health revolution, several groups are trying to accelerate it. In 2011, the X Prize Foundation and Qualcomm announced a $10 million prize for the first group to create a real-life Tricorder — the futuristic, all-purpose, handheld medical diagnostic tool used by Dr. McCoy in Star Trek. According to the contest guidelines, the winning device must “allow a user to diagnose themselves without having to visit a doctor or hospital.” The guidelines encapsulate the aspirations for mobile health, which is nothing short of “major disruption to global health care systems.”

The following sections evaluate the three major ambitions of mobile health: to improve the quality of health care and reduce medical errors; to reduce the cost of health care; and to increase access to care by democratizing and demystifying medicine.

A. Improve Quality

A primary aspiration of mobile health is to reduce medical errors, improve quality care, and save lives. One idea is that mobile monitoring will allow us to gather more granular health data on patients, and in shorter, more frequent intervals. Patients and

---

93 See FDA Public Workshop, supra note 85 (statement of Robert Jarrin, Qualcomm, Inc.).
94 See, e.g., Marc J. Epstein & Eric G. Bing, Delivering Health Care to the Global Poor: Solving the Accessibility Problem, 6 INNOVATIONS: TECH., GOVERNANCE, GLOBALIZATION 117 (2011) (discussing how technology, including the use of mobile phones, has revolutionized health care in the developing world); James G. Kahn, Joshua S. Yang & James S. Kahn, Mobile Health Needs and Opportunities in Developing Countries, 29 HEALTH AFF. 254 (2010) (analyzing various mhealth applications in developing countries at the large geographic area level, community level, and individual level); Terje Aksel Sanner, Lars Kristian Roland & Kristin Braa, From Pilot to Scale: Towards an mHealth Typology for Low-Resource Contexts, 1 HEALTH POLY & TECH. 155 (2012) (providing an analysis of the use of mobile phones in the Health Information System in low-resource settings); Symposium, Mobile Money in Developing Countries: Financial Inclusion and Financial Integrity, 8 WASH. J.L. TECH. & ARTS 155 (2013) (presenting articles about the use of mobile phones in developing countries for banking and the creation of financial institutions).
95 See Bosch, supra note 16.
96 See id. (citing tweet by Dr. Peter Diamandis, Chairman and CEO of X Prize Foundation). Final guidelines for this competition were published in September 2012, but have been updated in 2013. See generally Competition Guidelines, supra note 16 (containing the full details about the Competition).
97 Competition Guidelines, supra note 16, at 61.
providers can then use this data to better tailor care, to better coordinate care, and to avoid duplicative or unnecessary care. For example, hospitals can use networked devices to monitor inpatients or even discharged patients, particularly those managing chronic conditions. Mobile technologies might then process this data to alert patients and physicians of sudden (or even gradual) changes for the worse. Constant monitoring might give providers more lead-time to respond to life-threatening conditions, or even predict them ahead of time, and could reduce hospital readmission rates.

The intuitive appeal of mobile technologies is that they might leverage massive amounts of clinical research data and experience, embodying the ideals of empirical, "evidence-based medicine." Data-driven technologies could help physicians and hospitals better coordinate care, and empower patients to better manage their own health, particularly chronic conditions. Medical apps could, in theory, improve the quality of all types of care — preventative and primary, acute and tertiary.

Yet, despite the ambition to reduce medical errors and improve quality, a recent study found that many medical apps “do not follow established medical guidelines.” For example, a 2011 study of forty-seven different smoking cessation apps found that they followed very few of the evidence-based clinical practice guidelines for smoking cessation programs, like combining pharmacotherapy and counseling. A review of 137 diabetes apps found “obvious gaps between the evidence-based recommendations and the

98 For a description of the possibilities with Medical Body Area Networks (MBANs), see FCC, CHAIRMAN PROPOSAL, supra note 86.
99 See id. at 1.
100 “Evidence-based medicine (EBM) is the process of basing clinical decisionmaking on the best available objective and unbiased medical research, which generally means information gained from randomized controlled clinical trials or systematic reviews of data from multiple trials.” Swanson & Khan, supra note 67, at 110; see also Arnold J. Rosoff, The Role of Clinical Practice Guidelines in Healthcare Reform: An Update, 21 ANNALS HEALTH L. 21, 21 (2012). For a historical evaluation of the ambitions of evidence-based medicine and clinical practice guidelines, as related to legal battles over physician standards of care, including its recent resurgence, see Maxwell J. Mehlman, Professional Power and the Standard of Care in Medicine, 44 ARIZ. ST. L.J. 1165 (2012).
functionality . . . found in online markets." In fact, various reviews find that many mobile health apps either ignore or contradict evidence-based guidelines, are not supported by scientific research, or are not even developed with the input of a medical professional.

A Boston University study examined 1,500 mobile health apps, and found that over 20% (331) "claim[] to treat or cure medical problems." Almost half of these rely on a smartphone's stock features (like lights, sound, or vibration) to produce a therapeutic effect. Yet, the study found a near consensus among scientific and medical experts that smartphones cannot deliver lights or sounds in therapeutic doses, particularly for the conditions being targeted. For example, the iSAD app claims to treat seasonal affective disorder ("SAD") and depression, instructing customers to use the app for 15 to 45 minutes each day with the iPhone screen adjusted for maximum brightness. But the iPhone emits a maximum of only 200 lux, while light therapy to treat SAD requires ten times that amount (2,000 lux) during a two-hour session. The app is careful to disclaim, "The iSAD Lamp is meant for entertainment purposes."

Similarly, the Boston University study found that sound therapy apps have very little scientific or medical research to support their claims. For example, the A.G.Method app, which sells for $9.99,
claims to use “sonic induction” to treat pain. In the company’s words: “This Application helps you to quickly and easily relieve everyday pain such as insomnia, headache, toothache, minor muscle aches and other general pains. A.G.Method App has been completely tested and verified as safe, efficacious, and effective.” Again, experts reacted with deep skepticism about these claims. In one reviewer’s opinion: “There is no plausible, physiologic way in which something like this would help.”

Thus, in these early, evolutionary phases of mobile health, some aspire to harness evidence-based medicine to enable higher quality, better tailored, and better coordinated care, with fewer mistakes. But at the other end of the spectrum, many apps are the equivalent of “digital snake oil.” The problem is that consumers (both patients and professionals alike) may have trouble distinguishing the two.

B. Reduce Spending

A second aspiration for mobile health is to reduce our profligate spending. A recurrent theme in the writing on mobile health — be it academic, business, government, media, or medical — is that mobile technologies can economize in a number of ways, typically by preventing more acute, expensive episodes of care. For example, mobile technologies could reduce the number of hospital visits, physician visits, and other expensive face-to-face consultations. Mobile apps might also enable us to better manage chronic diseases, which account for roughly 75% of all U.S. health spending.

---

113 A.G. Method, supra note 112.
114 Sharpe, supra note 101 (quoting Satish Misra, physician and managing editor of the website iMedicalApps).
Several estimates predict concrete savings through mobile health. For example, one estimate predicts that using disposable wireless sensors to detect hospital-acquired infections early could save up to $12,000 per patient, or $11 billion per year. Another calculates $10 billion in annual savings from using mobile technologies to remotely monitor patients with congestive heart failure. And a 2008 study suggested that using mobile technologies to monitor just four common chronic conditions could save us $197 billion over twenty-five years. Studies even predict that mobile technologies can help cut our health care system’s considerable administrative costs.

The vast majority of medical apps are either free or very inexpensive (in the one to five dollar range). And anything that shifts the locus of care away from expensive professionals, facilities, and insurance systems could save us significant money. Although we have long suspected that indiscriminately adopting new technologies (many with marginal benefits over the old) contributes to higher health care spending, mobile health could buck this trend.

Policymakers have also been quick to jump on the cost-saving bandwagon. For example, FCC chairman Julius Genachowski has made repeated public remarks that mobile technologies can save billions in health care spending. Members of Congress repeat this refrain, noting blithely that “innovative wireless medical devices play...
a vital role in addressing our nation's unsustainable health care costs."  

Of course, for all this to be true, these technologies must work. Apps of the “digital snake oil” variety will squander rather than save money. The likely outcome is that some mobile technologies will economize while others either have no affect or even raise spending. The question, then, is what net economic effect mobile health care will have on overall spending.

C. Democratize Medicine

A third, related aspiration for mobile health is to decentralize, demystify, and democratize medicine. Many mobile health technologies allow patients to closely monitor their own health, which should increase patient engagement. Patients thus equipped might be less reliant on the bottleneck of information and advice generated by medical professionals, facilities, and even payors. Mobile health aspires to shift the locus of care away from these more established, expensive institutions, and towards individual patients. Indeed, decentralizing and democratizing access to health information and self-diagnostic tools is a core theme of the “disruption” literature, which sees medical apps and other health information technologies fundamentally transforming health care in the near future.

When viewed more broadly, mobile health is part of broader cultural and technological evolutions, including the march towards more personalized medicine, the “quantified self” movement, the

---


128 For a description of the futuristic ambitions of personalized medicine and related trends, see Melanie Swan, Health 2050: The Realization of Personalized Medicine through Crowdsourcing, the Quantified Self, and the Participatory Biocitizen, 2 J. PERSONALIZED MED. 93 (2012).

129 The “quantified self” movement, founded by two Wired magazine editors, seeks
“lifelogging” phenomenon, and the rising era of “big data.” These trends converge in mobile health. Mobile apps that allow consumers to collect more granular health data about themselves, and in more frequent intervals, might lead to better-tailored diagnoses and treatments. This data collection effort is made possible through wearable sensors, ingestible diagnostic devices, and advances in bioinformatics that inspired, in part, the “quantified self” and “lifelogging” phenomena. And the “big data” era promises to use advances in large-scale data crunching to engage this flood of data in more and more surprising ways. A byproduct of these phenomena is the “deskilling” of medicine — demystifying medical practice that for decades has been based on idiosyncratic professional judgments and intuitions rather than hard data and evidence-based medicine. To
advocates, mobile health provides a logical, efficient vehicle for achieving these ideals.\textsuperscript{135}

Still, other innovations have fallen short of similar promises, such as the consumer-driven health care movement,\textsuperscript{136} and (so far) the electronic medical record, as embodied in the well-documented failures of Google Health, and before it, Healtheon.\textsuperscript{137} But some substrata of mobile health technologies, like telemedicine, have already made care more accessible in rural and other underserved areas.\textsuperscript{138} And given the trajectory of mobile phone users and health apps, this technology might succeed where its predecessors failed.

***

Improving health care quality, lowering costs, and increasing access has long been the Holy Trinity of health care — a triad that has eluded U.S. policymakers for decades.\textsuperscript{139} It would be extraordinary if smartphones and tablet computers could accomplish what federal and state policymakers have not. Is mobile health too good to be true? As desperate as the U.S. health care system is for genuine transformation,

\textsuperscript{135} See, e.g., ERIC TOPOL, THE CREATIVE DESTRUCTION OF MEDICINE: HOW THE DIGITAL REVOLUTION WILL CREATE BETTER HEALTH CARE (2012) (discussing how the digital revolution will improve health care).

\textsuperscript{136} For a devastating critique of consumer-driven health insurance, see TIMOTHY STOLTZFUS JOST, HEALTH CARE AT RISK: A CRITIQUE OF THE CONSUMER-DRIVEN MOVEMENT (2007).

\textsuperscript{137} See Terry, supra note 28, at 724-25. For the story of Healtheon, the precursor to ventures like Google Health, see MICHAEL LEWIS, THE NEW NEW THING: A SILICON VALLEY STORY (1999).


\textsuperscript{139} See, e.g., Nathan Cortez, The Elusive Ideal of Market Competition in United States’ Health Care, in HEALTH CARE AND EU LAW 359 (J.W. van de Gronden et al. eds., 2011) (arguing that the implementation of market-based techniques in the United States have failed to lower cost, increase quality, or increase access); Timothy Stolzfus Jost, Why Can’t We Do What They Do? National Health Reform Abroad, 32 J.L. MED. & ETHICS 433 (2004) [hereinafter Why Can't We Do What They Do?] (citing U.S. political institutions, U.S. social culture, the political power of providers, and the strength of path dependency as forces preventing healthcare reform).
many hope that mobile technologies can be the panacea. We cling to
the notion that we can innovate our way to a better health care system,
even though decades of innovation have not produced better
outcomes or more efficiency relative to our peer countries. There are
valid reasons for excitement. But there are equally valid reasons for
healthy skepticism. The last quarter-century demonstrates that
medical software quickly evolves to become more ubiquitous and
more critical to patient safety. Given the wide range of outcomes here
— including the possibility of core transformations to health care
delivery, consumption, and financing — how are policymakers
responding?

III. THE GOVERNMENT’S POSTURE

The revolutionary potential of mobile health has not gone
unnoticed. Mobile health is on the radars of Congress and over half a
dozen federal agencies, including the FDA, FCC, and FTC. In Part III,
I demonstrate that contrary to prevailing sentiment, Congress and
federal regulators are facilitating rather than stifling mobile health
technologies. I argue that this posture is admirable, so long as it does
not preclude meaningful oversight.

A. The Food and Drug Administration

The FDA has clear jurisdiction to regulate most of the mobile health
technologies described above, though it is unclear how prepared the
agency is. To understand the FDA’s approach to mobile health, and
why mobile health will test the agency, one must first understand FDA
jurisdiction.

The FDA has always been burdened by its steadily expanding
dominion. Every year, more companies introduce more products that
fit within the FDA’s jurisdiction under the federal Food, Drug, and
Cosmetic Act. The Act grants the FDA jurisdiction over medical
“devices,” which it defines very broadly as any product intended to
diagnose, cure, mitigate, treat, or prevent disease, or any product intended to affect the structure or function of the body (and that is not a drug). As Part I demonstrates, many mobile health technologies intend to perform one or more of these functions. “Intended use” is a key element in defining “devices,” and thus in defining the outer bounds of FDA jurisdiction. The agency, by regulation, has defined “intended use” as the objective intent of how those responsible for marketing the product intend it to be used. The agency can determine objective intent by looking at the product itself, at the manufacturer’s claims about it, and at other oral and written statements by those marketing it. Moreover, the FDA can consider the “circumstances surrounding distribution of the article,” including widespread consumer use. Again, the typology of mobile health technologies in Part I demonstrates that the FDA has clear jurisdiction over most of these products.

Thus, FDA jurisdiction depends in large part on a product’s intended functionality. As a result, FDA-regulated devices range from toothbrushes and Band-Aids to pacemakers and MRI machines. Because devices are so numerous and varied, Congress and the FDA have prioritized which devices deserve more regulatory attention based on the risks they present. A mobile application thus might qualify as a Class I device (low risk), a Class II device (moderate risk), or a Class III device (high risk). The higher the classification, the more scrutiny the device receives. For example, to get to the market,

---

143 See 21 U.S.C. § 321(h) (2012) (defining “device” as “an instrument, apparatus, implement, machine, contrivance . . . or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes”). The FDA considers device accessories to be finished devices themselves. See 21 C.F.R. § 820.3(l) (2013).

144 See 21 C.F.R. § 801.4 (2013).

145 See id.


147 See Pollard & Branham, supra note 45, at *3.

Class III devices generally must undergo premarket approval by the FDA, which typically requires clinical trials. In contrast, Class II devices must provide relatively cursory premarket notification, known as a 510(k) notice, which the FDA generally accepts. Finally, most of the lowest-risk Class I devices typically require no premarket notification at all. Thus, the FDA will impose very different gatekeeping requirements on mobile health products depending on the risks each one poses.

The problem with device software in general, and mobile health apps in particular, is that they evolve quickly and frequently. FDA device classifications are not nearly as fluid as software products, particularly this latest generation of software apps. Like many new technologies, medical apps can complicate existing regulatory frameworks.

The FDA addressed these ambiguities in July 2011, when it published a Draft Guidance on Mobile Medical Applications, announcing a 90-day public comment period. The Draft Guidance followed months of speculation about how the FDA might confront medical apps. Indeed, days before the FDA published it, an industry coalition proposed its own competing framework. And, months earlier, the FDA issued a joint statement with the FCC explaining that the agencies wanted to facilitate wireless medical technologies.

The FDA finalized the guidance just two years later, in September 2013 (a quick turnaround by FDA standards, but an eternity by Silicon Valley standards). The guidance enunciates a tentative approach to medical apps, including the types of apps that it might...
regulate, the types of apps that it might not, what rules might apply to regulated apps, and areas of lingering uncertainty that would benefit from further public comment. For example, who among the constellation of smartphone manufacturers, wireless providers, app store portals, and app developers may have to answer to the U.S. Food and Drug Administration? The guidance reassures these industries that the FDA generally will withhold exercising jurisdiction over all but the last group (app developers), thus absolving the Apples, Googles, and Samsungs of the world that manufacture smartphones, tablets, and the platforms on which they operate. Instead, the FDA will train its eyes on those who create, design, label, or initiate specifications for a mobile medical app.

Second, the FDA’s guidance tries to delineate the types of apps that it will and will not regulate. In fairness to the FDA, this is not at all easy. As noted above, the statutory definition of “device” is a functional one, and depends on whether the manufacturer intends certain specified functionality. The FDA’s guidance clarifies that the agency will assert jurisdiction over “mobile medical apps,” which it defines as those apps that are intended to diagnose, cure, mitigate, treat, or prevent diseases or other conditions, or affect the structure or any function of the body. Again, many apps clearly qualify. Many clearly do not. And many are entirely unclear.

The FDA’s guidance does an admirable job trying to translate the technical definition of “device” and explain the opaque intended use doctrine. But the app industry understandably remains confused, calling for more clarity. To that end, the FDA introduced a pyramid of jurisdiction. The pyramid itself represents the entire universe of

---

157 See id. at 4.

158 See id. at 9-10.

159 See id. at 9.

160 The Food, Drug, and Cosmetic Act lists the things that can be “devices,” including “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent,” or similar such objects that perform one of the listed functions. See 21 U.S.C. § 321(h) (2012). This includes components, parts, or accessories. Id.


162 See FDA FINAL GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 7-8.

163 See id. at 7-8. Several commenters at the Public Workshop noted that the Draft Guidance is clearly aimed at smaller companies inexperienced with FDA regulations. See, e.g., FDA Public Workshop, supra note 85 (presenting statements of Bernie Liebler, AdvaMed, and Scott Thiel, who noted that this was the first FDA guidance document that he could remember that listed specific regulations in the C.F.R. that companies should recognize).

164 See FDA Public Workshop, supra note 85.

165 See BAKUL PATEL, U.S. FOOD & DRUG ADMIN., PUBLIC WORKSHOP — MOBILE
health-related apps. It then divides into three tiers: (i) the top tier representing “mobile medical apps” that meet the definition of “device” and are either accessories to separate FDA-regulated devices (such as a blood glucose monitor that plugs into an iPhone) or turn the smartphone or tablet itself into a regulated device; (ii) the middle tier representing apps that meet the technical definition of “device,” but not the FDA’s narrower conception of “mobile medical apps,” over which the FDA will exercise enforcement discretion; and (iii) a bottom tier of health apps that do not meet the definition of “device” and are thus beyond FDA jurisdiction.

The middle and bottom tiers are worth understanding. At the bottom, the Draft Guidance identifies a few species of non-regulated apps. For example, the FDA is not concerned with apps that replicate medical textbooks, reference materials, or teaching aids. The FDA is also not concerned with apps that allow users to log and track their general health or well-being, even if the app also suggests a course of action. The classic examples (inasmuch as apps can be “classics” already) are calorie trackers, appointment reminders, and exercise regimens. Finally, the FDA says it is not concerned with apps that replicate or automate office functions, like billing, reimbursement, and the like. The one proviso, however, is that if any of these apps use patient-specific data to generate customized diagnoses or treatment recommendations, FDA jurisdiction would apply.

But therein lies the gray area. Many medical apps apply a vast body of accumulated medical knowledge to patient-specific inputs, generating more granular diagnoses and treatments. All-in-one diagnostic apps like Pocket Doctor and WebMD’s Symptom Checker are the Precambrian ancestors of Tricorder-like devices. But the FDA punts these for later guidance. The Draft Guidance, for example, says that the FDA would continue to monitor apps that either


166 See id.
167 See id. at 8; FDA FINAL GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 12, 20-25.
168 See FDA FINAL GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 18, 20.
169 See id. at 16.
170 See id. at 25.
171 See id. at 16.
172 See id. at 15.
173 The guidance also emphasizes that it does not address safety concerns with wireless devices, and that it will issue separate guidances on related topics, including apps that analyze data from multiple medical devices. See id. at 12, 16-18.
“automate common medical knowledge available in the medical literature,” “allow individuals to self-manage their disease or condition,” or “automate common clinician’s diagnostic and treatment tasks.”174 Thus, the FDA’s guidance does not even confront some of the most provocative products.

At the same time, the FDA’s guidance states that it will regulate apps that combine algorithms or formulae with patient information to generate a patient-specific diagnosis or treatment recommendation to be used in clinical practice.175 The line between this category and the previous one is not very clear, and promises to blur even further as developers envision new products with new functionalities. For example, will the FDA regulate all-in-one diagnostic apps intended for patient use? These apps might tell a parent whether to take a child to the emergency room or not, or recommend other important actions (or inaction), as the Scanadu example demonstrates.176 Part IV, below, emphasizes the dangers of relying blindly on medical software.

Thus, the FDA says that it will regulate apps that obviously are medical devices; that it will not regulate apps that obviously are not; and that it will defer on the provocative middle tier of apps, over which the agency will exercise enforcement discretion.177 Yet, at the same time, the FDA “strongly recommends” that app manufacturers in this gray area follow the FDA’s extensive Quality Systems regulations,178 which require manufacturers to design and manufacture their products in accordance with certain standards.179 Thus, in the same breath, the FDA is telling certain mobile health products that they may not fall within FDA jurisdiction, but that they should follow FDA rules anyway.

This language pushes the FDA’s guidance well beyond its disclaimers. The FDA makes clear that the guidance is a nonbinding draft, intended only to solicit public comments.180 This caution is by

174 FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 12 n.13.
175 See id. at 14 (“[E]xamples include mobile apps that provide a questionnaire for collecting patient-specific lab results and compute the prognosis of a particular condition or disease, perform calculations that result in an index or score, calculate dosage for a specific medication or radiation treatment, or provide recommendations that aid a clinician in making a diagnosis or selecting a specific treatment for a patient.”).
176 For a video vividly demonstrating the possibilities, and the certainty with which apps promise to provide actionable advice, see SCANADU, supra note 1.
177 See FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 12.
179 See FDA FINAL GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 13.
180 See FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 4.
design. More than other agencies, the FDA must be explicit that its guidance documents are not legally binding.\footnote{See 21 U.S.C. § 371(h) (2012); 21 C.F.R. § 10.115 3(iv) (2013).} Thus, as with most FDA guidances, it features a sort of black box warning emphasizing that the guidance, when finalized, will represent the FDA’s current thinking on the topic and nothing more.\footnote{See FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 4.} Regulated firms are free to take alternative approaches, as long as they comply with the underlying statute and regulations.\footnote{See id. The entire blurb reads: This draft guidance when finalized will represent the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance. Id.} Of course, notwithstanding this boilerplate, few people understand FDA guidance documents as being so impotent.\footnote{See infra Part IV.B.}

Shortly after it published the Draft Guidance, the FDA held a two-day public workshop to ventilate this framework.\footnote{See FDA Public Workshop, supra note 85. FDA announced the public workshop in August. Mobile Medical Applications Draft Guidance; Public Workshop, 76 Fed. Reg. 50,231 (Aug. 12, 2011); see Mobile Medical Applications Draft Guidance; Public Workshop; Correction, 76 Fed. Reg. 55,068 (Sept. 6, 2011).} Some clear themes emerged.

First, the FDA is well aware that it lacks technical expertise on mobile technologies. Agency staff made several overtures expressing technical deference to the app industry.\footnote{See FDA Public Workshop, supra note 85.} In fact, anyone concerned with the FDA’s tentative approach towards device software over the last twenty-five years would view the agency’s comments as being over-solicitous of those it is supposed to regulate.

Second, the app industry is relatively naïve to any kind of regulation, not to mention the uniquely technical requirements imposed by the FDA.\footnote{See id.} Several comments by industry representatives betrayed ignorance of even basic FDA rules, as well as profound confusion with more advanced concepts like intended use.\footnote{See, e.g., id. (pointing out that Kerry McDermott, the Senior Policy Director of
Third, the industry understandably wants the FDA to clarify which apps it will and will not regulate. 189 There were several suggestions that the FDA should regulate apps based on the risks they present, rather than their intended uses. 190 This recommendation confuses the first-order question of FDA jurisdiction with the second-order question of how the FDA will regulate devices that fall under its jurisdiction. 191

Finally, the workshop revealed a near-consensus that mobile health represents a genuine paradigm shift for our health care system. Commenters observed that the real benefits of medical apps might accrue to the next aging generation, not the current one. 192 But this was viewed as a matter of when, not if.

The comments also reflected a near-consensus that the FDA's regulatory authority might not map very well onto this technology. For example, should the FDA require evidence that apps are safe and effective before they are cleared for marketing? 193 Would the user reviews that typically appear at the point of sale (in app stores) be a good indicator of whether the app is safe and effective? 194 Will low-quality apps undermine the entire industry by eroding user confidence? 195 Would alternatives like private certification standards be superior to centralized government oversight? 196 Will consumers trust apps just because they are cleared by the FDA? 197 Will one-size-fits-all regulation work for such interactive, customized applications that are frequently updated? 198 Is it feasible to regulate medical apps at all, given the sheer number of similar health applications already on the Internet (for example, one commenter noted that a Google search

---

189 See id. (statement of Dave Eichler).
190 See id. (statement of Grant Elliott).
191 The FDA classifies devices based on risk, which determines how each device may enter the market and the requirements that apply once it does. See 21 U.S.C. § 360c 2(c) (2012).
192 See FDA Public Workshop, supra note 85 (statement of Donna Tillman).
193 See id. (statement of John LaLonde).
194 See id. (providing the statement of Grant Elliott, which argues that users will gravitate to apps that work and delete from their phones ones that do not).
195 See id.
196 Since the 2011 FDA workshop, private certification has spawned. For example, Happtique offers perhaps the most well-known private sector certification program for mobile health apps. See App Certification, HAPPTIQUE, http://www.happtique.com/app-certification/.
197 See FDA Public Workshop, supra note 85 (statement of Grant Elliott).
198 See id. (statement of Bernie Liebler).
for “BMI calculator” generated 9,000 hits).\textsuperscript{199} Does the FDA need to regulate at all if medical malpractice liability will encourage physicians not to misuse or over-rely on apps?\textsuperscript{200}

Of course, even the FDA’s relatively friendly Draft Guidance, which bends over backwards to accommodate the industry, is criticized by the industry for simultaneously being too burdensome and too vague. For example, an industry group called the mHealth Regulatory Commission submitted a 220-page comment to the FDA in response to the Draft Guidance, in which it urged the agency to promote innovation in the mobile health industry and reduce unnecessary regulation.\textsuperscript{201}

The FDA’s approach to mobile health also has been a frequent topic in Congress. In May 2012, Senators Michael Bennet (D-CO) and Orrin Hatch (R-UT) proposed an amendment to a pending FDA appropriations bill that would have prohibited the FDA from finalizing the Draft Guidance until September 2013,\textsuperscript{202} a proposal that some industry groups opposed as introducing even more regulatory uncertainty for the industry.\textsuperscript{203} Another proposed bill by Representative Mike Honda (D-CA) took a different tack, by recommending that the FDA create an entirely new center to facilitate mobile health technologies.\textsuperscript{204} One bill that did become law simply requires the FDA to coordinate with the FCC and the Office of the National Coordinator for Health Information Technology to recommend “an appropriate, risk-based regulatory framework

\textsuperscript{199} See id. (statement of Grant Elliott).

\textsuperscript{200} See id. (statement of Leslie Kelly Hall).


\textsuperscript{204} The bill would have created an Office of Wireless Health at the FDA, among other things. See Health Care Innovation and Marketplace Techs. Act of 2012, H.R. 6626, 112th Cong. (2d Sess. 2012). The bill died in committee.
pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.\textsuperscript{205}

Then, in March 2013, the House Energy & Commerce Committee held an unusual three days of hearings on the regulation of mobile health technologies, which warned the FDA to provide regulatory clarity without overregulating the industry.\textsuperscript{206} Again, the hearings demonstrate the great faith policymakers have in mobile health and its capacity to solve our health care system’s most pressing problems. The message is clear — the FDA is not to stifle innovation in one of our economy’s only bright spots.

In the meantime, the FDA continues to address mobile medical apps as they arise. As noted above, the FDA has cleared the Reka E100 app, which transmits data about cardiac events from an external event recorder.\textsuperscript{207} The FDA cleared the iBGStar Diabetes Manager app, which connects with a blood glucose meter.\textsuperscript{208} And it has cleared the Mobile MIM app, which displays medical images for physicians, radiologists, and technicians.\textsuperscript{209} Other companies are also seeking the FDA’s blessing.\textsuperscript{210} As of March 2013, FDA officials report that the agency has reviewed around 100 discrete medical apps,\textsuperscript{211} averaging roughly 110

\textsuperscript{205} FDASIA § 618(a). The FDASIA Working Group’s report is expected in 2013.


\textsuperscript{207} These are Class II medical devices per 21 C.F.R. § 870.2340 (2014). FDA approved the REKA E100 by Reka Ltd., in September 2011.

\textsuperscript{208} Sanofi-Aventis received FDA clearance for the iBGStar Diabetes Manager Application (510(k) k103544). The document suggests that this is a Class I device under 21 C.F.R. § 862.2100 (2014) (data processing module for clinical use).


days with each review. \(^{212}\) And the agency finalized its Draft Guidance in September 2013. \(^{213}\)

Similarly, the FDA is tracking adverse events related to medical apps, some of which portend future problems that might arise. For example, in 2011 the FDA received a report that a neurostimulator had malfunctioned because the patient had spent hours with an iPhone near the head while the phone was in GPS (global positioning system) mode. \(^{214}\) The neurostimulator thus turned off, but the patient suffered no injury. \(^{215}\) Also in 2011, Pfizer alerted physicians in a “Dear Doctor” letter that its popular Rheumatology Calculator app was computing incorrectly, recalling it from the market. \(^{216}\) And in 2012, Sanofi Aventis recalled a medical app for diabetics because the software “could miscalculate an insulin dose potentially resulting in dangerously low or high blood glucose levels in diabetic patients.” \(^{217}\) Both recalls were voluntary.

In May 2013, the FDA sent its first regulatory letter to a mobile health company. \(^{218}\) The letter was directed to Biosense, maker of the uCheck Urine analyzer app, used as an automated reader and urinalysis program for reagent strips marketed by Bayer and Siemens. \(^{219}\) The letter explained that the product qualifies as a medical device and must be precleared by the FDA. \(^{220}\) The agency’s letter was


\(^{212}\) See Mital Letter, supra note 146, at 3.

\(^{213}\) See FDA FINAL GUIDANCE ON MOBILE MEDICAL APPS, supra note 24.


\(^{215}\) See id.


\(^{219}\) See id.

\(^{220}\) See id.
titled, awkwardly, as an “It Has Come To Our Attention Letter,” which
lacks the punch and publicity of the more traditional FDA Warning
Letters.\textsuperscript{221} Apparently, these letters are intended for private
consumption by well-meaning novices — although the Biosense letter
was widely disseminated as the FDA’s first foray into medical app
enforcement.\textsuperscript{222}

Thus, the FDA marches forward, but timidly. The agency faces
distinct pressure from both Congress and the mobile health industry
to facilitate rather than regulate these new products. Patient safety and
consumer protection have not been the overriding concerns thus far.
Certainly, the first generation of medical apps does not seem overly
dangerous, particularly compared to the many drugs and devices
under the FDA’s jurisdiction. But, as Part IV demonstrates below, the
risks may be latent.

B. Other Agencies

As with many new technologies, multiple regulators have an interest
in mobile health. These agencies too have adopted a posture of
facilitating rather than regulating mobile health, with some
exceptions.

One exception is the Federal Trade Commission. Although the FTC
primarily is concerned that medical apps will compromise privacy and
data security,\textsuperscript{223} the agency also polices unsubstantiated product
claims, a charge it shares with the FDA. In 2011, the FTC brought two
maiden cases against medical apps that claimed to treat acne. The apps
(Acne Pwner and Acne App) flashed alternating colored lights from a
smartphone screen, which users were instructed to hold near their
faces.\textsuperscript{224} The FTC charged both with making unsubstantiated

\textsuperscript{221} See id.; see also Alexander Gaffney, FDA Sends Unusual Letter to Maker of iPhone-
Based Testing Product, REGULATORY FOCUS (May 22, 2013), available at
\textsuperscript{222} See Gaffney, supra note 221.
\textsuperscript{223} See generally Overview of Federal Role in Mobile Health, HEALTHIT.GOV,
http://www.healthit.gov/policy-researchers-implementers/overview-federal-role-
mobile-health (last visited June 24, 2013) (explaining the role of the FCC in mobile
health). Risks to patient privacy and data security are significant with mobile health
applications, but I do not address them here. Even apps that track sensitive health
information are not necessarily covered by federal privacy laws like HIPAA. Media
stories observe quite astutely that cell phones are “increasingly becoming a portable
medical record.” See Nancy Shute, Apps Can Help You Take a Pill, but Privacy’s a Big
01/143005028/apps-can-help-you-take-a-pill-but-privacy’s-a-big-question.
\textsuperscript{224} See Ann Carrns, F.T.C.: No App to Cure Acne, N.Y. TIMES (Nov. 1, 2011),
marketing claims, including one claim that a medical journal article supported the treatment, when it did not. Acne Pwner was downloaded 3,300 times for 99 cents each, and AcneApp was downloaded 11,600 times at $1.99 each. Although the FTC’s fines were modest (just $1,700 for Acne Pwner and $14,924 for AcneApp), they demonstrated that the FTC would scrutinize health claims made by apps. Still, it remains unclear how the FTC will police less objectionable claims, or those supported by more credible evidence. The FTC traditionally has been more lenient on therapeutic claims than the FDA. In the meantime, the FTC has created a Mobile Technology Unit to develop expertise on mobile apps and to coordinate the agency’s mobile enforcement efforts.

Outside the FDA and FTC, the third major agency that can claim jurisdiction over medical apps is the Federal Communications Commission, which regulates the radio frequencies used by mobile devices. As such, the FCC already shares jurisdiction over wireless medical devices like pacemakers. Perhaps for this reason, medical apps have been on the FCC’s radar longer than other agencies, despite the FCC’s relatively narrow charge here.


226 See Carrns, supra note 224.

227 See id.

228 Note, however, that in 2012, an Administrative Law Judge for the FTC required a lesser than usual standard of scientific proof for POM Wonderful, which claimed that its products, derived from pomegranates, could address heart disease, prostate cancer, or erectile dysfunction. In re POM Wonderful LLC, No. 9344, 2012 WL 2340406, at *1 (F.T.C. May 17, 2012), available at http://www.ftc.gov/sites/default/files/documents/cases/2012/05/120521pomdecision.pdf (initial decision).


231 See Pollard & Branham, supra note 45, at *6 (citing the Federal Communications Act, 47 U.S.C. § 151 et seq. (2012)).

232 See Overview of Federal Role in Mobile Health, supra note 223.
In July 2010, the FCC and FDA jointly announced that they would simultaneously try to promote wireless medical devices and ensure that they are “safe, reliable and secure.”233 The agencies memorialized this announcement in a Memorandum of Understanding.234 They then hosted a public meeting, during which the FDA Commissioner and FCC Chairman shared remarks about the tremendous potential of wireless medical devices, followed by several industry panels.235 The tone of the meeting was aspirational, preliminary, and introductory — the speakers addressed how wireless medical devices work and how they might be regulated.236

Since then, the FCC has remained engaged in mobile health. In 2012, the FCC announced that it would reserve additional spectrum space for wireless medical body area networks (“MBANs”), which devices and apps can use to constantly monitor patients.237 Indeed, the FCC chairman’s remarks read like an industry brochure, suggesting that wireless devices may save millions of lives and billions in health spending.238 The FCC followed this announcement by hosting an mHealth Summit, during which representatives from industry, academia, and government (including the Centers for Medicare and Medicaid Services, the FDA, the HHS, the National Institutes of Health, and the Department of Veterans Affairs) discussed mobile health devices.239 The FCC Chairman reiterated that “mHealth” is a transformative, disruptive technology that may improve quality care, lower costs, and save lives.240

236 See generally FCC/FDA Joint Meeting, supra note 235 (providing a transcript of Day 1 and Day 2 of the Joint Meeting).
237 See FCC, CHAIRMAN PROPOSAL, supra note 86, at 1.
238 See id. at 1-2.
239 See FCC, CHAIRMAN GENACHOWSKI, supra note 117, at 1.
240 See FCC CHAIRMAN JULIUS GENACHOWSKI, PREPARED REMARKS ON MED. BODY AREA NETWORKS, GEORGE WASHINGTON UNIV. HOSP. 1 (May 17, 2012), available at
In addition to the FDA, FTC, and FCC, several other agencies also have medical apps on their radars. For example, the Department of Commerce’s National Institute of Standards and Technology has led discussions about privacy and data security standards for medical apps. The Centers for Medicare and Medicaid Services and its parent agency HHS have created several programs to encourage physicians, hospitals, and insurers to use health information technologies (known as “health IT” or just “HIT”) to deliver safer, higher quality, and more efficient care to patients. These programs encourage the industry to use electronic records, prescribe medicines, coordinate patient care, and measure quality outcomes electronically.

Many of these efforts are superintended by the Office of the National Coordinator for Health Information Technology, situated within HHS by the 2008 stimulus bill, whose charge is to promote a national health IT infrastructure. In recent testimony, the National Coordinator told Congress that health information technologies will help transform “how care is paid for and delivered and how patients engage in their own health.”

Thus, contrary to regulatory alarmists who claim a federal assault on mobile health technologies, the federal government is actively promoting them, or at the very least is creating a very sympathetic regulatory environment. To wit, some federal agencies have entire programs dedicated to developing and promoting medical apps. The


241 See Pollard & Branham, supra note 45, at *2.

242 See Overview of Federal Role in Mobile Health, supra note 223.

243 See Pollard & Branham, supra note 45, at *7-8 (surveying programs).


246 Health Info. Admin. Perspectives Hearing, supra note 211, at *25 (statement of Farzad Mostashari).

most prominent is the U.S. Department of Defense, which created a National Center for Telehealth and Technology to evaluate mental health technologies for military personnel. The program features several apps, including: an app that helps physicians diagnose and treat traumatic brain injuries and mental disorders; an app that allows users to assess themselves for post-traumatic stress disorder ("PTSD"); an app that uses clinical guidelines to help providers treat mild traumatic brain injuries; and even an app that connects to EEG devices, EMG devices, ECG/EKG devices, respirators, and other biometric monitors. The U.S. Army runs a similar program, the Telemedicine and Advanced Technology Research Center, which researches health informatics, mobile health, telemedicine, and computational biology, among other things. The Center proclaims that it is focused on “putting research findings into the hands of warfighters while looking toward wider civilian utility.” As in decades past, the U.S. military is at the forefront of medical advancement.

Other federal agencies are also studying and promoting mobile health. The National Institutes of Health ("NIH") and the National Science Foundation recently convened an mHealth Evidence Workshop to discuss how to gather scientific evidence to support mobile health technologies. This is part of a larger program at HHS

---

250 This app was developed by the Department of Defense's National Center of Telehealth and Technology (T2) program, in collaboration with the Department of Veteran Affairs' National Center for PTSD. Notably, the app's website says that: "The assessment does not formally diagnose PTSD." The app won the 2011 FCC Chairman's Awards for Advancement in Accessibility. See PTSD Coach, NAT'L CTR. FOR TELEHEALTH & TECH., http://www.t2health.org/apps/ptsd-coach (last visited June 24, 2013).
251 This app was developed by the Defense Centers of Excellence for Psychologic Health and Traumatic Brain Injury. See mTBI Pocket Guide, NAT'L CTR. FOR TELEHEALTH & TECH., http://www.t2health.org/apps/mtbi (last visited June 24, 2013).
252 See BioZen, supra note 64 (disclaiming that “[t]hese devices and BioZen are not designed or intended for psychological therapy or medical treatments”).
254 Id.
and the NIH to subsidize research on mobile health applications.\textsuperscript{256} In fact, the NIH itself offers several health-related apps.\textsuperscript{257}

In short, federal agencies are assisting rather than assaulting mobile health technologies. Even international bodies like the World Health Organization ("WHO") are examining the vast potential of mobile health.\textsuperscript{258}

Congress usually is the last to respond, and is so here. Although a few congressional committees have considered medical apps, they usually do so in passing.\textsuperscript{259} Only one statute has addressed them directly,\textsuperscript{260} and that was to preserve the FDA’s Draft Guidance from being frozen in carbonite by congressmen concerned with premature regulation.\textsuperscript{261} Indeed, would-be regulators like the FDA and FCC have


\textsuperscript{261} In The Empire Strikes Back, Han Solo is frozen in carbonite, until he was rescued in Return of the Jedi. Star Wars Episode V: The Empire Strikes Back (20th Century Fox 1980); Star Wars Episode VI: Return of the Jedi (20th Century Fox 1983). The FDA’s Draft Guidance on Mobile Medical Apps faced a similar fate. As Congress considered the 2012 FDA user fee bill, Senators Michael Bennett (D-CO) and Orrin Hatch (R-UT) proposed an amendment that would have prohibited the FDA from finalizing its Draft Guidance until September 30, 2013. See Bennett-Hatch
been upbraided by skeptical members of Congress for daring to regulate some of these products.262

Thus, contrary to the prevailing wisdom, federal regulators are sympathetic, not hostile, to mobile health. Again, this in itself is not problematic, so long as this sympathetic posture does not sacrifice meaningful oversight. Mobile health will only fulfill its immense promise if federal regulators help ensure that the technologies are safe and effective, and function as they claim.

IV. ENTERING THE REGULATORY FEEDBACK LOOP

The FDA’s response to mobile health is the continuation of a longer narrative. The FDA, our country’s oldest consumer protection agency, has long been oriented towards traditional food, drug, and device products.263 But over the last twenty-five years, the FDA has had to confront “laser age” products like computer software.264 Part IV, then, tells the broader story of the FDA’s experience regulating computer hardware and software over the last quarter-century, dating back to the mid-1980s. I argue that the FDA risks repeating the same mistakes it made when first addressing device software twenty-five years ago. Mobile health, after all, simply represents the latest incarnation of device software.

I argue that for the FDA to provide meaningful oversight of mobile health, it must confront its longstanding posture towards medical device software more generally, which has relied on nonbinding guidance documents and spotty case-by-case enforcement. Confronting past regulatory failures will push the FDA into a regulatory “feedback loop,” in which the agency can identify past shortcomings and initiate corrective and preventive actions in response.265 History need not be doomed to repeat itself.


262 See, e.g., Letter from Marsha Blackburn et al. to Margaret Hamburg and Julius Genachowski, supra note 125 (expressing concerns about the regulation process).

263 For a nice retrospective of the agency at its centennial, see FDA: A CENTURY OF CONSUMER PROTECTION (Wayne L. Pines ed., 1st ed. 2006).


265 For another example of how the spigot of information can be adjusted to affect
A. A Quarter-Century of Computerized Medicine

As with many regulatory interventions, the FDA's foray into software was prompted by tragedy.\footnote{266} Between 1985 and 1987, a radiation machine called the Therac-25 massively overdosed patients in the United States and Canada, administering up to 100 times the prescribed dose, sometimes burning literal holes in patients' bodies.\footnote{267} The Therac-25 (an abbreviation for therapeutic radiation computer) was notable for being the first radiation machine controlled primarily by software.\footnote{268} The manufacturer, Atomic Energy of Canada Limited, designed the Therac-25 to rely on software, and thus chose to remove the hardware failsafes from previous versions.\footnote{269}

The result was a cascade of errors. For example, the Therac-25's user interface displayed cryptic error alerts like “MALFUNCTION 54,” which user manuals neglected to interpret.\footnote{270} Persistent, daily malfunctions eventually numbed users, making them impervious to error alerts.\footnote{271} In one episode, a patient died from a substantial radiation overdose five months after the operator ignored repeated error messages, some of which incorrectly warned of a substantial


\footnote{268} See id. at 3.

\footnote{269} See id.

\footnote{270} See id. at 17.

\footnote{271} See id. at 7.

underdose. The manufacturer was overconfident in patching software errors, even though it could not identify their root causes when pressed to do so. Users developed a false sense of security that the Therac-25’s software would make it “virtually impossible to overdose a patient.” Indeed, the complacency was so entrenched that the initial reaction by radiation technicians, hospital physicists, and the manufacturer to patient complaints (“You burned me!”) was widespread disbelief (“That’s impossible.”). The manufacturer’s first safety review of the Therac-25 did not even cover its software. Subsequent investigations and lawsuits revealed all types of bugs — including, astoundingly, typing too fast, and moving the cursor up, both of which caused crashes and errors — as well as fundamental software design flaws.

When the FDA investigated these incidents, it required Atomic Energy to make several corrections, which were not fully implemented until after a recall two years later. The Therac-25 had entered the U.S. market via a 510(k) notification, by which the FDA cleared the device as being “substantially equivalent” to a predicate already on the market, despite its unprecedented reliance on software. The Therac-25, like many software-driven devices today, was not subject to meaningful premarket review.

The Therac-25 episode has since become a standard university case study in software failure. The authoritative report on it concluded that “[t]here seems to be a feeling among nonsoftware professionals that software will not or cannot fail, which leads to complacency and overreliance on computer functions.” At the time, the FDA’s response was considered “impressive,” given that it had no policy for medical software.

That began to change as a direct result of the Therac-25. In 1986, the FDA Commissioner Frank Young first announced in a speech that

---

272 See id. at 17-18.
273 See id. at 13, 16, 19.
274 Id. at 8.
275 See id. at 9, 15, 18.
276 See id. at 8.
277 See id. at 20-28.
278 See id. at 29, 40.
279 Id. at 29.
281 LEVESON, supra note 267, at 44.
282 Id. at 48.
the agency would approach software with the “least regulation consistent with the requirements of public health and safety.” 283 Shortly thereafter, in 1987, the FDA published its first draft policy on software.284 In 1989, the FDA updated the document, which became known as the “Draft Software Policy.”285 The policy confirmed that the FDA’s “basic philosophy for computer products is to apply the least degree of regulatory control necessary to provide reasonable assurance of safety and effectiveness.”286 Since then, the FDA’s approach to computerized devices has been the archetype of regulatory minimalism.

Like the 2011 Draft Guidance on Mobile Medical Applications, the 1989 policy delineated which computer products the agency would and would not regulate.287 Both guidances tried to clarify how new technologies might fit into the statutory definition of “device,” written by Congress in 1976 when no one could have imagined today’s versions.288

A key idea introduced in 1987 was that of “competent human intervention.”289 The FDA explained that it would exempt from regulation artificial intelligence and clinical decision support software as long as it allowed ample time for competent human intervention by the user.290 For example, the FDA would be more concerned with a computer program that alerted nurses to “Inject Dose Now!” than one recommending well ahead of time that nurses administer the dose at certain intervals, with opportunity for the nurse to consider those instructions. The distinction is whether “clinical judgment and experience can be used to check and interpret a system’s output”
before “any impact on human health.”201 As discussed below, this distinction is neat but facile.

The FDA never finalized the 1989 Draft Software Policy, and ultimately withdrew it in 2005.292 Nevertheless, during the past twenty-five years, lawyers have advised clients largely based on the 1989 policy (even after being withdrawn), largely because this was the only concrete guidance available. Ironically, after the FDA withdrew the 1989 guidance, the agency explained that “it would be impractical to prepare an overarching software policy to address all of the issues related to the regulation of all medical devices containing software” because “the use of computer and software products as medical devices grew exponentially and the types of products diversified and grew more complex.”293 Thus, rather than providing more firm guidance as medical technology matured — during a profound computer revolution, no less — the FDA provided less.

Although the FDA avoided announcing an overarching approach to software, it has exercised jurisdiction over various software devices on a case-by-case basis.294 For example, the FDA has created dozens of regulatory categories for devices that incorporate software, including medical calculators, cameras, lights, magnifiers, microscopes, monitors, recorders, reminders, scales, surgical tools, transmitters, and a host of data systems that store, display, and manipulate information.295 Many mobile applications will fall into one of these preexisting categories.296 But many will fit uneasily, or not at all. And in such cases, the FDA might have to create entirely new categories,
adding to the roughly 1,700 different device categories in the Code of Federal Regulations.\textsuperscript{297}

But by and large, the FDA has avoided proceeding by rule here. It has promulgated very few prospective regulations governing software, and what little it has done addresses relatively low-risk devices.\textsuperscript{298} For example, in 2011, the FDA finalized a regulation governing medical device data systems (“MDDS”),\textsuperscript{299} a narrow slice of products that simply transfer, store, display, or convert medical device data without doing much else, like analyzing the data or even charting it visually.\textsuperscript{300} Indeed, to qualify as an MDDS, a product may not feature alarms or actively monitor patient data that a health care practitioner might use to make immediate treatment decisions.\textsuperscript{301} Undoubtedly, many mobile applications will qualify as MDDSs because they do nothing more than store, display, and transfer data. But these devices should not concern us much.

Periodically, in the preambles to final rules, the FDA will acknowledge computer products. For example, when finalizing its Quality System regulation (“QSR”) for devices in 1996, the FDA observed that software design flaws and the failure to validate software after maintenance were the most common sources of software errors.\textsuperscript{302} The QSR, which establishes good manufacturing practices for devices,\textsuperscript{303} has been perhaps the one area in which the FDA has provided firm standards for device software. But the QSR is notable for giving manufacturers significant flexibility to design and manufacture devices according to customized specifications.\textsuperscript{304} This is both a

\textsuperscript{297} See 21 C.F.R. pts. 862-892 (2013).

\textsuperscript{298} For example, in 2011, the agency promulgated a rule classifying devices that electronically display, store, transfer, or convert medical device data, known as Medical Device Data Systems (“MDDS”). Medical Devices; Medical Device Data Systems, 76 Fed. Reg. 8637 (Feb. 15, 2011) (codified at 21 C.F.R. pt. 880.6310 (2013)).

\textsuperscript{299} See id.

\textsuperscript{300} See id. at 8637-44 (codified at 21 C.F.R. pt. 880.6310(a)).

\textsuperscript{301} See id. at 8644.


\textsuperscript{304} See U.S. FOOD & DRUG ADMIN., MEDICAL DEVICES, QUALITY SYSTEM (QS) REGULATION/MEDICAL DEVICE GOOD MANUFACTURING PRACTICES (2011), available at
strength and a weakness— a strength in recognizing the diversity of medical devices and the implausibility of generating one-size-fits-all standards, but a weakness in decentralizing standards and delegating significant discretion to regulated firms. Of course, the FDA relies on guidance to explain how the QSR applies to software.305

By and large, FDA oversight of software relies on guidance. Agency documents that summarize the FDA’s approach to software generally cite to the same cluster of five guidances.306 Following this tradition, the Draft Guidance on Mobile Medical Applications cites to the same five guidances, as well as four others discussing basic device regulations.307 The Draft Guidance also cites to over a dozen international standards published by groups like the International Electrotechnical Commission, the Institute for Electrical and Electronics Engineers, and the International Organization for Standardization.308

Together, these documents form a cascade of quasi-regulation, recommendations, and “current thinking,” but few firm rules. Software does not stand on terra firma with the FDA. Looking back, the 1987 document was like a gateway drug that led to guidance after guidance for the next quarter-century. But the FDA’s response to software has not been commensurate with how ubiquitous and critical software has become.


307 See FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, supra note 24, at 16 (citing guidelines on overall regulation of devices and marketing devices); id. at 24 (citing guidance on scheduling meetings with the FDA to discuss device classifications); id. at 26 (citing guidelines on how to report adverse events); id. at 27 (citing guidelines for recalls and removals); id. at 28-29 (citing nine FDA guidances and fourteen international ones).

308 These generally govern the use of software and electrical equipment, particularly in medical devices. See id.
B. “The Wonders and Brutality” of Innovation

The Therac-25 saga not only prompted the FDA’s attention to software, but also presaged the next quarter-century of torrential innovation in computerized medicine. An agency long oriented towards more traditional products responded impressively in the absence of an overarching policy for software.309 Yet, after twenty-five years with such a policy, history repeats itself. Between 2009 and 2011, the New York Times documented several hundred catastrophic injuries caused by software and user errors related to the newest generation of radiation machines.310 The incidents bear striking resemblance to the Therac-25 saga two decades earlier, demonstrating the “wonders and the brutality”311 of medical innovation.

In one case, St. Vincent’s Hospital in Manhattan exposed a 41 year-old tongue cancer patient to fatal doses of radiation for three consecutive days after the software repeatedly crashed.312 The medical physicist operating the machine had calibrated it to target cancerous tissue at the base of the patient’s tongue, without damaging surrounding healthy tissue — precisely the allure of new intensity modulated radiation therapy devices, which use complex software to beam radiation at cancerous tissue and little else.313 But after repeated error messages and software crashes, the machine erased the coordinates that would have shaped the beam; instead, it administered unmodulated radiation to his entire neck and the base of his skull, including the brain stem.314 The overdose “left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe.”315 He died roughly two years after the mistake.316

309 See LEVESON, supra note 267, at 48.


312 See id.

313 See id. at 3, 4.

314 See id. at 4.

315 Id.

316 See id. at 3.
In another case, a 32 year-old breast cancer patient at the State University of New York’s Downstate Medical Center in Brooklyn was administered three and a half times the prescribed dose of radiation each session for 27 days. She was the victim of “a baffling series of missteps,” again eerily reminiscent of the Therac-25. A radiation therapist had misprogrammed the device, which in turn omitted a metallic wedge that would have shaped the beam. Other therapists and staff then failed to catch the mistake, both when reviewing the patient’s treatment records, and more disturbingly, when an alert (“wedge OUT”) was displayed on the computer screen during her treatment. The N.Y. Department of Public Health observed, “[t]he fact that therapists failed to notice ‘wedge OUT’ on 27 occasions is disturbing.” The radiation seared a hole in her chest, which grew until her rib bones were openly visible.

The Times reporters documented hundreds of similar mistakes: 90 prostate cancer patients at a hospital in Philadelphia misdosed with radiation; 77 brain cancer patients at a hospital in Florida overdosed; 36 cancer patients at a veterans hospital in New Jersey overdosed; 260 patients at a hospital in Los Angeles who received eight times more radiation than designed. The reporters comprehensively studied just one state (New York), and found 621 documented mistakes between 2001 and 2008, including 133 incidents of incorrectly shaped beams, 284 incidents in which “radiation missed all or part of its intended target or treated the wrong body part entirely,” and 50 incidents in which “patients received radiation intended for someone else.” These spot reports align with nationwide estimates that one in twenty radiation patients will suffer injury.

A hospital official at St. Vincent’s said the incident above “occurred as a result of a unique and unanticipated combination of issues.” But

317 See id.
318 Id. at 5.
319 See id.
320 Id. at 6.
322 Bogdanich, Radiation Offers New Cures, supra note 311, at 2.
323 See id. at 1 (quoting Dr. John J. Feldmeier).
324 Id. at 4. As Nancy Leveson’s work emphasizes, these types of events are indeed often unanticipated, but far from unanticipatable. See, e.g., NANCY G. LEVESON, ENGINEERING A SAFER WORLD: SYSTEMS THINKING APPLIED TO SAFETY (2011) (using systems theory to discuss software engineering in increasingly complex environments).
it was neither unique nor unanticipated. These incidents, dating back to the Therac-25, largely germinate from two related sources: software failures and user errors.

C. “To Really Screw Things Up, You Need a Computer”

Old medical software problems still persist — serial system crashes, user impatience that leads to quick bypasses, user fatigue with error alerts, misplaced trust in the software, and utter disbelief that these technologically advanced, highly calibrated machines could err so badly. And as radiation technology becomes increasingly powerful, it requires more sophisticated software that itself requires more sophisticated users. The problems will compound.

Hospitals and specialty practices can be quick to adopt new technologies. But they often do so without a corresponding increase in the personnel and resources required to use them properly. American medicine has long embraced unproven new technologies that are later shown to be ineffective, or worse, unsafe. But health providers are not solely to blame. As Einer Elhauge notes, technology excites us, and “[c]onsumers often irrationally demand new technologies that have no demonstrable benefit.” In short, health providers seem particularly susceptible to novelty, consumer demand, and manufacturer claims. We see glimpses of this in the exuberance over mobile health.


The one thing they have in common is overlooking the interaction between software and humans. Manufacturers often design software that is confusing or downright hostile to users. Software users do not always operate in ideal conditions. They might be harried, distracted,

325 On this latter point, St. Vincent's Hospital in Manhattan was so dismissive that when the wife of the tongue cancer patient reported serious problems with her husband, it sent a psychiatrist to see her. See Bogdanich, Radiation Offers New Cures, supra note 311, at 4.

326 See id. at 1 (“[L]inear accelerators and treatment planning are enormously more complex than 20 years ago,” quoting Dr. Howard I. Amols, chief of clinical physics at Memorial Sloan-Kettering Cancer Center).


328 Elhauge, supra note 327, at 1592.

329 See id.
or frustrated, or some combination of the three. Regulators focus myopically on their own narrow sphere of jurisdiction — either the device itself or the licensed user — but rarely both. As the Institute of Medicine reminded us: “To Err Is Human.” But, as a federal official quipped during the FDA’s public workshop on medical apps, the subtitle to the Institute’s report should have been “To Really Screw Things up, You Need a Computer.” Another physician researcher testified at the workshop that errors and “never events” associated with software technologies are generally caused by design flaws, defective coding, interoperability conflicts, and user errors.

Some skeptics are sounding the alarm, requesting real data that mobile health applications actually do what they claim. As the researcher testified, “Like a lot of things in medicine, when you actually test it in a randomized controlled trial, you may find out it doesn’t work . . . Optimism is not a substitute for rigorous trials.” This is precisely the FDA’s charge, and it is particularly important with new software technologies.

We are dangerously predisposed to believe computers. We believe they are error-resistant, even infallible. And this mindset, known as “automation bias,” disarms us from critically evaluating potential errors. In fact, research demonstrates that we trust automation even when we suspect errors or malfunctions, a reality made crystalline by the radiation examples above.

The allure of automation is that it represents rule-bounded, binary-coded clarity. Automation has a reductionist allure — software at its core is ones and zeroes and nothing in between. But automated
systems are usually inaccessible and opaque to the non-programmer, which often “shields them from scrutiny.”\textsuperscript{338} Such scrutiny should come from the FDA.

Indeed, the agency seems to be well aware of the dangers posed by computerized devices. In February 2010, the FDA revealed during a public meeting that it had received voluntary reports of 260 malfunctions, 44 injuries, and six deaths related to health information technologies.\textsuperscript{339} Errors included mixing different patients’ data, accessing incorrect data, losing or corrupting data, errors in computing and analyzing data (like calculating wildly incorrect medication dosages), and compatibility errors between different types of software and computer systems.\textsuperscript{340} Because these were voluntary reports, and because even the FDA’s mandatory reporting requirements suffer from dramatic under-reporting,\textsuperscript{341} the real numbers are no doubt much higher.

Unfortunately, the FDA’s posture towards software is reactive rather than proactive. To wit, FDA and local regulators confronted by the New York Times series on radiation mistakes opened subsequent investigations.\textsuperscript{342}

Mobile health applications, of course, are not yet capable of inflicting the “unspeakable pain” that radiation machines can.\textsuperscript{343} But as history demonstrates, medical software gradually becomes more ubiquitous and critical to patient safety, not less.

Consider that device software currently struggles at even basic things, like keeping accurate time. A surprisingly large number of clocks used by medical devices and hospitals are wrong, sometimes by thirty minutes or more.\textsuperscript{344} A study by Julian Goldman reviewed the

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{338} See id. at 1254.
\item \textsuperscript{339} See Pollard & Branham, supra note 45, at *6; Testimony of Jeffrey Shuren, Director of FDA’s Center for Devices and Radiological Health, ADOPTION/CERTIFICATION WORKGROUP, HEALTH INFO. TECH. POLY COMM. (Feb. 25, 2010), available at http://www.cchfreedom.org/pdfs/Health%20IT%20Deaths%20-%20FDA%20Shuren.pdf.
\item \textsuperscript{340} See sources cited supra note 339.
\item \textsuperscript{342} See Bogdanich, As Technology Surges, supra note 321.
\item \textsuperscript{343} See Bogdanich, Radiation Offers New Cures, supra note 311, at 1.
\item \textsuperscript{344} See M.H., Medical Devices: A Ticking Time-Bomb, ECONOMIST (May 23, 2012) [hereinafter A Ticking Time-Bomb], http://www.economist.com/blogs/babbage/2012/05/medical-devices.
\end{itemize}
\end{footnotesize}
clocks used by 1,700 medical devices. He found that only three percent of the clocks were within three seconds of actual time, and 20 percent deviated by more than 30 minutes, with the average clock 24 minutes off. The devices he studied were located in four prestigious east coast hospitals.

These types of time-keeping errors may seem trivial, but evidence suggests that they are both common and costly. In 2007, a researcher in Vienna studied 113 intensive care units in 27 countries, and found that almost half of all mistakes in administering intravenous drugs were timing errors. A simple solution has existed since 1985 — using a Network Time Protocol that cell phones use to synchronize time to atomic clocks. But the FDA has never required devices to use this technology. HHS has proposed regulations that would require it for electronic medical records, but they would not phase in until 2014.

As alluring as medical innovation is, it is not an unmitigated good. The role of regulators is to facilitate the benefits of new technologies and manage their risks. Doing so should support long-term markets for the technology, preserve consumer trust, and level the playing field among competitors. One goal of this Article is to push the FDA towards a regulatory feedback loop, in which the agency confronts broader, longstanding problems with software oversight and corrects them going forward, particularly as it oversees emerging technologies like mobile health.

346 See M.H., A Ticking Time-Bomb, supra note 344.
347 Massachusetts General in Boston and Brigham and Women’s in Boston, both teaching affiliates of Harvard Medical School, the Hospital of the University of Pennsylvania in Philadelphia, and Johns Hopkins in Baltimore. See id.
348 See id.
349 See id.
350 See id.
CONCLUSION

Rarely does a class of technologies excite physicians, patients, financiers, gadgeteers, and policymakers alike. But for mobile health to begin to reach its immense potential — saving millions of lives, cutting billions in spending, and democratizing medicine — federal regulators will have to provide meaningful oversight, ensuring that these technologies are safe and effective. For this to happen, the FDA will first have to confront its long history of piecemeal oversight of medical device software. If the FDA does so, it can enter a regulatory feedback loop, through which the agency can begin to craft enforceable policies that not only ensure the safety and efficacy of mobile health technologies, but also facilitate the long-term health of this promising market.352

This Article tries to draw attention to the major legal and regulatory challenges presented by mobile health. Obviously, there are many more avenues of inquiry. For example, in the health policy literature alone, there are looming questions about how mobile health might disturb existing legal and regulatory frameworks governing how we finance, deliver, and measure the quality of care. There are also troubling questions, largely untouched here, about the lack of privacy and data security in mobile health applications, their integration with electronic health records, and the dangers of “big data” in the health care sphere.353 If the mobile health revolution has really begun, we must now grapple with it.

352 See, e.g., Daniel Carpenter, Confidence Games: How Does Regulation Constitute Markets?, in Government and Markets: Toward a New Theory of Regulation 164, 164-90 (Edward J. Balleisen & David A. Moss eds., 2010) (arguing that the FDA’s gatekeeping authority facilitates more than it burdens certain markets by giving consumers a baseline confidence that they would otherwise lack). FDA oversight of mobile health could play a similar “market-constituting” role.

353 See, e.g., Pasquale, supra note 131 (discussing the need for “grand bargains” between providers, patients, and administrative agencies if health information technology will be able to save lives).