The Mobile Health Revolution?

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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

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.

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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,[1] a medical technology company that resides at NASA's Ames Research Center in Silicon Valley.[2] 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*.[3] Three years later, Scanadu claims to have done

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[1] SCANADU, http://www.scanadu.com (last visited Feb. 3, 2014); *see* Ivo Clarysse, *Scanadu Trailer*, YOUTUBE (Oct. 11, 2011), http://youtu.be/KSwMauCno6o.

[2] *NASA Research Park: Partners: Scanadu*, NAT'L AERONAUTICS & SPACE ADMIN., http://www.nasa.gov/centers/ames/researchpark/partners/industry/scanadu.html (last visited June 24, 2013).

[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.[4] The Scout uses various algorithms and sensors, some of which derive from NASA's Mars Curiosity Rover mission.[5] Scanadu broke fundraising records when it launched a campaign on the crowdfunding site Indiegogo.[6] 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").[7] Scanadu's marketing line is "Sapere Aude" ("Dare to Know").[8] And its website invites users to "[i]magine the tools of an emergency room from the comfort of your living room."[9] 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.[10]

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.

Tricorder"). *See generally* Harry McCracken, *Scanadu Aims to Turn Smartphones into Healthcare Helpers*, TIME (Nov. 29, 2012), http://techland.time.com/2012/11/29/scanadu-aims-to-turn-smartphones-into-healthcare-helpers/ (describing Scanadu's features).

   [4] *Scanadu Scout, the First Medical Tricorder*, INDIEGOGO, http://www.indiegogo.com/projects/scanadu-scout-the-first-medical-tricorder?website_name=scanaduscout   (last visited June 24, 2013) (using the term "emotional stress"); *see also* Matt Peckham, *A Star Trek Tricorder? 'Scanadu Scout' Health Monitor Surges Past Indiegogo Funding Goal*, TIME (May 24, 2013), http://ti.me/14Z2QGE; *Scanadu Scout*, SCANADU, http://www.scanadu.com/scout.

   [5] *See* INDIEGOGO, *supra* note 4.

   [6] *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/.

   [7] *See* INDIEGOGO, *supra* note 4.

   [8] *See id.*

   [9] SCANADU, *supra* note 1.

   [10] *See* Jesse Sunenblick, *X Prize: Making the Tricorder a Reality*, WIRED (Feb. 17, 2013), http://www.wired.co.uk/magazine/archive/2013/02/features/tricorder; QUALCOMM TRICORDER X PRIZE, http://www.qualcommtricorderxprize.org/ (last visited June 24, 2013).

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.[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.[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.[13] The number of

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[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. STEDMAN'S CONCISE MEDICAL DICTIONARY FOR THE HEALTH PROFESSIONS 236, 636, 751 (4th ed. 2001).

[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, *Timeline: Smartphone-Enabled Health Devices*, MOBIHEALTHNEWS (June 7, 2013), http://mobihealthnews.com/22674/timeline-smartphone-enabled-health-devices/.

[13] For a physician's perspective on this phenomenon, see WILLIAM HANSON, 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.[14] 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,[15] or yet more offered on other device platforms. The $10 million Tricorder X Prize is but an emblem of the excitement.[16] 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.[17] In short, mobile health sits at the intersection of several converging phenomena, and our collective response to it is worth studying.[18]

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

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19-22 (2011).

[14] *See* Elizabeth Orr, *2011 in Review: MDUFA, 510(k) Debate Made List of Top News*, *in* DEVICES & DIAGNOSTICS LETTER 2 (Jan. 2, 2012) (citing a study by research2guidance).

[15] *See* Brian Dolan, *Report: 13K iPhone Consumer Health Apps in 2012*, MOBIHEALTHNEWS (Sept. 22, 2011), http://mobihealthnews.com/13368/report-13k-iphone-consumer-health-apps-in-2012/.

[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 (Eta 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 policy makers 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

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[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-eb5280c81c63_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,[22] 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,[23] 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.[24] 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

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[22] Draft Policy for the Regulation of Computer Products, 52 Fed. Reg. 36,104 (Sept. 25, 1987); U.S. FOOD & DRUG ADMIN., DRAFT POLICY FOR THE REGULATION OF COMPUTER PRODUCTS (Nov. 13, 1989), *available at* 1989 WL 1178702 [hereinafter FDA DRAFT SOFTWARE POLICY].

[23] Annual Comprehensive List of Guidance Documents at the Food and Drug Administration, 70 Fed. Reg. 824, 890 (Jan. 5, 2005).

[24] In July 2011, the FDA published a Draft Guidance on Mobile Medical Apps. U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: MOBILE MEDICAL APPLICATIONS (July 21, 2011) [hereinafter FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS], http://www.genomicslawreport.com/wp-content/uploads/2013/03/FDA-mHealth-Draft-Guidance.pdf; *see also* Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications; Availability, 76 Fed. Reg. 43,689 (July 21, 2011). In September 2013, the FDA finalized the guidance. U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Sept. 25, 2013) [hereinafter FDA FINAL GUIDANCE ON MOBILE MEDICAL APPS], *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.

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."[25] 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.[26] The Apple executive observed, "We think this is profound."[27] Although mobile health can trace its roots back further, to personal digital assistants ("PDAs"), websites like WebMD, and even early electronic medical records,[28] 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.[29] Media stories feature breathless quotes about the transformation of medicine.[30] 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

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[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.

[30] *See, e.g.*, Katie Hafner, *For a Second Opinion, Consult a Computer?*, N.Y. Times (Dec. 3, 2012), http://www.nytimes.com/2012/12/04/health/quest-to-eliminate-diagnostic-lapses.html (discussing the history of computer-assisted diagnostics and how it has evolved); Katie Hafner, *Redefining Medicine with Apps and iPads*, N.Y. Times (Oct. 8, 2012), http://www.nytimes.com/2012/10/09/science/redefining-medicine-with-apps-and-ipads-the-digital-doctor.html?_r=0 (exploring how young doctors are utilizing iPhone apps in practice).

mobile health applications, categorized largely by their functionality. Of course, with an estimated 97,000 mobile health apps on the market in 2013,[31] any typology will necessarily oversimplify. But the typology largely reflects how regulators like the FDA divide the market.[32] 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.[33]

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,[34] perform portable ultrasounds,[35] operate insulin pumps,[36] and visually track whether wounds heal or regress.[37] Other apps also display, analyze, or transmit

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[31] *See Mobile Health Market Report 2013–2017: The Commercialization of mHealth Applications (Vol. 3)*, RESEARCH2GUIDANCE 7 (Mar. 4, 2013) [hereinafter *Report 2013–2017*], http://www.research2guidance.com/shop/index.php/downloadable/download/sample/sample_id/262/.

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

[33] *See id.* at 18 (listing examples).

[34] *See, e.g.*, *Blood Pressure Monitor*, WITHINGS, http://withings.com/en/bloodpressuremonitor (last visited June 24, 2013) (displaying blood pressure cuff and accompanying blood pressure monitor application); *iHealth BPM*, ITUNES PREVIEW, http://itunes.apple.com/us/app/ihealth-bpm/id391469141?mt=8 (last visited June 24, 2013) (enabling users to monitor their own blood pressure).

[35] *See* MOBISANTE, http://www.mobisante.com/ (last visited June 24, 2013) (demonstrating and describing the MobiUS SP1 ultrasound imaging system). The FDA cleared the MobiUS for marketing in January 2011. *See* MobiSante, Inc., Section 5 — 510(k) Summary (FDA Form 510(k)) 3 (Jan. 20, 2011), http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102153.pdf.

[36] *See* OMNIPOD, http://www.myomnipod.com/VPDMweb/index.html (last visited June 24, 2013).

[37] *See, e.g.*, *Silhouette Advanced Wound Assessment and Management System*, ARANZ MED., LTD., http://test.aranzmedical.com/products/silhouette-suite/ (last visited Jan. 1, 2014) (describing Silhouette, a wound assessment application); Aranz Medical Ltd., 510(k) Summary of Safety and Effectiveness (FDA Form 510(k)) (Jan. 17, 2007), http://www.accessdata.fda.gov/cdrh_docs/pdf7/K070426.pdf (document submitted by Aranz Medical Ltd. describing Silhouette's intended uses and features).

patient data from an FDA-regulated device. For example, one app allows clinicians to use their phones to track patients' vital signs remotely, pulling data "from hundreds of different types of patient monitors."[38] A related app allows obstetricians to monitor patients' contractions, fetal heartbeats, and other realtime waveform data.[39] Yet another allows cardiologists to review and manipulate ECG results and histories.[40]

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.[41] Mobile MIM was the first imaging app cleared by the FDA, in 2011.[42] While physicians use Mobile MIM to diagnose patients, its patient version, VueMe, shares the same images.[43] 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.[44] 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.[45] The company then

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[38] *AirStrip Patient Monitoring*, iTunes Preview, http://itunes.apple.com/us/app/airstrip-remote-patient-monitoring/id399665195 (last visited June 24, 2013); *see also AirStrip ONE Patient Monitoring*, AirStrip Techs., http://www.airstriptech.com (last visited June 24, 2013).

[39] *See AirStrip ONE OB*, AirStrip Techs., http://www.airstriptech.com/airstrip-one-ob (last visited June 24, 2013).

[40] *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).

[41] *See* Press Release, MIM Software, Inc., Mobile MIM, First FDA-Cleared Diagnostic Medical Imaging App, Now Available on the U.S. App Store (Feb. 15, 2011), *available at* http://www.mimsoftware.com/about/mobilemimpr.

[42] *See* Anne Eisenberg, *Those Scan Results Are Just an App Away*, N.Y. Times (Oct. 15, 2011), http://www.nytimes.com/2011/10/16/business/medical-apps-to-assist-with-diagnoses-cleared-by-fda.html; 510(k) Approval Letter from Mary S. Pastel, U.S. Food & Drug Admin., to Lynn Hanigan, MIM Software, Inc. (Dec. 2, 2011), *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf11/K112930.pdf; News Release, U.S. Food & Drug Admin., FDA Clears First Diagnostic Radiology Application for Mobile Devices (Feb. 4, 2011), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2011/ucm242295.htm. "Clearing" a device is different and less of an FDA endorsement of its safety and efficacy, than "approving" it through the Premarket Approval ("PMA") process. For a critique of the 510(k) process and the lack of scrutiny FDA gives to many medical devices, see Inst. of Med., Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years (July 29, 2011), *available at* http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx.

[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.[46] 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.[47] In response, Mobile MIM developed a feature to automatically detect subpar lighting conditions.[48] 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.[49] Others might use the phone's built-in microphone "to amplify heart, lung, blood vessel, enteral, and other body sounds."[50] Still others might use built-in features like accelerometers to measure a patient's body movement or heart rate.[51] More and more apps are engaging stock features like lights, vibrations, and cameras for medical uses.[52]

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.[53] It includes a Heart Murmur Interpreter, a Lung Sounds Interpreter, and a Bowel Sounds Interpreter. The Heart Murmur Interpreter, for

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A Legal Framework for Regulating Health Information Technology, Software, and Mobile Apps, *in* RECENT DEVELOPMENTS IN FOOD AND DRUG LAW, 2011 ED., at *9 (2011), *available at* 2011 WL 5833341.

[46] *See* Olga Kharif, *Mobile Health Apps Arrive*, BLOOMBERG BUSINESSWEEK (Sept. 29, 2011), http://www.businessweek.com/magazine/mobile-health-apps-arrive-09292011.html.

[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.*

[53] *See iStethoscope Expert*, ITUNES PREVIEW, https://itunes.apple.com/us/app/istethoscope-expert-heart/id651962198?mt=8 (last visited Jan. 1, 2014).

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

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[54] For a demonstration, see Nathan Cortez, *Medical Apps, Disruptive Innovation, and Regulatory Timing*, AM. SOC'Y OF LAW, MED., & ETHICS (2012), *available at* http://prezi.com/arr5dspyjaww/medical-apps-disruptive-innovation-and-regulatory-timing/ (last visited June 24, 2013).

[55] *See* Brian Dolan, *iPhone ECG developer AliveCor raises $3 million*, MOBIHEALTHNEWS (Aug. 2, 2011), http://mobihealthnews.com/12224/iphone-ecg-developer-alivecor-raises-3-million; AliveCor, Inc., *AliveCor — How It All Started — The Original Dr. Dave iPhone ECG Video*, YOUTUBE (May 7, 2013), http://www.youtube.com/watch?v=aDnGXzwIJBc (last visited Jan. 1, 2014).

[56] *See* AliveCor, Inc., *supra* note 55.

[57] *See id.*

[58] *See* Timothy Hay, *AliveCor Raises $10.5M as Smartphone Heart Monitor Ends Trials*, DOWJONES VENTUREWIRE (June 11, 2012), http://pevc.dowjones.com/Article?an=DJFVW00020120611e86bawgva&ReturnUrl=http%3A%2F%2Fpevc.dowjones.com%3A80%2FArticle%3Fan%3DDJFVW00020120611e86bawgva.

[59] *See* REKA Pte. Ltd., 510(k) Summary (FDA Form 510(k)) 2-3 (Sept. 12, 2011), http://www.accessdata.fda.gov/cdrh_docs/pdf11/K111438.pdf.

[60] *Id.* at 2.

monitoring system.[61] Together, the app and the monitor allow patients to track their blood glucose levels and send results to physicians.[62] 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.[63]

Some replicator apps are even more ambitious. For example, the BioZen app claims it can receive realtime feedback from several biosensor devices, like EEGs, ECGs, electromyographies ("EMGs"), galvanic skin responses ("GSRs"), respirators, and thermometers.[64] BioZen is unique in that it has been endorsed by the U.S. Department of Defense for improving the mental health of military personnel.[65] Notably, the BioZen web-site says, "These devices and BioZen are not designed or intended for psychological therapy or medical treatments."[66] 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

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[61] *See iBGStar Diabetes Manager Application*, IBGSTAR, http://www.ibgstar.us/iphone-app.aspx (last visited June 24, 2013).

[62] *See* U.S. FOOD & DRUG ADMIN., 510(K) SUBSTANTIAL EQUIVALENCE DETERMINATION, DECISION SUMMARY 2 (Dec. 7, 2011), http://www.accessdata.fda.gov/cdrh_docs/reviews/K103544.pdf; U.S. FOOD & DRUG ADMIN., 510(K) SUMMARY — AGAMATRIX, INC. 2 (Dec. 7, 2011), http://www.accessdata.fda.gov/cdrh_docs/pdf10/K103544.pdf.

[63] *See* U.S. FOOD & DRUG ADMIN., MAUDE ADVERSE EVENT REPORT: AGAMATRIX, INC., IBGSTAR BGMS BLOOD GLUCOSE METER (Mar. 10, 2012), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=2603027; U.S. FOOD & DRUG ADMIN., MAUDE ADVERSE EVENT REPORT: AGAMATRIX, INC., IBGSTAR BGMS BLOOD GLUCOSE METER (Mar. 19, 2012), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=2577874.

[64] *See BioZen*, NAT'L CTR. FOR TELEHEALTH & TECH., http://www.t2health.org/apps/biozen (last visited June 24, 2013).

[65] *See id.*

[66] *BioZen*, GOOGLE PLAY, https://play.google.com/store/apps/details?id=com.t2&hl=en (last visited Feb. 3, 2014). The FDA says that it plans to address apps that analyze, process, or interpret data from multiple medical devices in a separate guidance. FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24, at 15.

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

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[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.

[69] *See Depression Journal*, IHEALTH VENTURES, http://www.ihealthventures.com/app_details.php?aid=34824 (last visited June 24, 2013).

[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/id529633939?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]

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regarding medical conditions"). Similarly, the Pocket Doctor app disclaims, "Pocket Doctor cannot guarantee the accuracy of the diagnoses. You use it at your own risk." Pocket App Ltd., *Pocket Doctor Lite*, ITUNES PREVIEW, https://itunes.apple.com/us/app/pocket-doctor-lite/id520802051?mt=8 (accessed on Aug. 9, 2013) (note that the description has since changed).

[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).

[74] *See* AP Tech. Holdings, LLC, *The Merck Manual Professional Edition*, ITUNES PREVIEW, http://itunes.apple.com/us/app/merck-manual-professional/id331016312 (last visited June 24, 2013); Elsevier Inc., *Gray's Anatomy for Students for iPad*, ITUNES PREVIEW, http://itunes.apple.com/us/app/grays-anatomy-for-students/id429405125 (last visited June 24, 2013); Skyscape, *mobilePDR for Prescribers*, ITUNES PREVIEW, http://itunes.apple.com/us/app/mobilepdr-for-prescribers/id382594350 (last visited June 24, 2013).

[75] *See About NEJM Mobile*, NEW ENG. J. MED., http://www.nejm.org/page/about-nejm/mobile-applications (last visited Feb. 8, 2014); *About the Lancet iPad Application*, LANCET, http://www.thelancet.com/ipad (last visited June 24, 2013); HighWire Press & Stanford University, *The Journal of Clinical Oncology*, ITUNES PREVIEW, https://itunes.apple.com/gb/app/journal-of-clinical-oncology/id465016976?mt=8 (last visited June 24, 2013); *The JAMA Network*, AM. MED. ASS'N, http://mobile.jamanetwork.com/ (last visited June 24, 2013) (linking to JAMA's app, which features the Journal and nine specialty journals).

[76] *See, e.g.*, Elsevier Inc., *Netter's Anatomy Atlas Free*, ITUNES PREVIEW, http://itunes.apple.com/us/app/netters-anatomy-atlas-free/id457575880 (last visited June 24, 2013) (providing an example of an application that has quizzing and customization features).

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.[77] 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.[78]

E.   Administrators

Other, more mundane apps automate office functions, like identifying appropriate insurance billing codes or scheduling patient appointments.[79] 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.

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.[80] These apps represent another innovative frontier

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[77] *See* FDA DRAFT SOFTWARE POLICY, *supra* note 22, at *1.

[78] *See* RESEARCH2GUIDANCE, *Report 2013–2017*, *supra* note 31, at 7.

[79] 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.

[80] 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).

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.

<p style="text-align:center">***</p>

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,

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[81] *See* FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24, at 11.

[82] For example, the website Pocket.MD tracks mobile apps offered by
pharmaceutical, biotech, and medical device companies. As of January 2014, it counts
at least 1,378 such apps, including those offered by Amgen, Medtronic, Pfizer, and
other industry leaders. *All Apps*, POCKET.MD, http://www.pocket.md/applications.html
(last visited Jan. 1, 2014).

[83] *See* FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24, at 11-12 &
n.13.

[84] *See, e.g.*, James Sherwin-Smith & Rowan Pritchard-Jones, *Medical Applications:
The Future of Regulation*, 94 BULL. OF ROYAL COLL. OF SURGEONS OF ENG. 12 (2012)
(considering the legal status of medical apps under the European Union Medical
Devices Directive).

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.[85] The number of people accessing health data on their phones increased 125% between 2010 and 2012, to roughly 17 million.[86] 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.[87] By 2015, industry observers predict that 500 million smartphone users will use mobile health apps.[88]

The value of the medical app market has risen correspondingly, from $718 million in 2011 to an estimated $1.3 billion in 2012.[89] The broader mobile health industry may be worth anywhere from $2 billion to $6 billion by 2015.[90] Another estimate predicts that by 2018, the market will generate $26 billion in revenues.[91]

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.[92] Today, more people worldwide have access to mobile phone service (5.7 billion) than to

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[85] *See* U.S. Food & Drug Admin., Public Workshop — Mobile Medical Applications Draft Guidance, Transcript (Sept. 12, 2011) [hereinafter FDA Public Workshop], http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm (statement by Brian Dolan of MobiHealth News).

[86] *See* FCC, COMM'N DOC., CHAIRMAN PROPOSAL TO SPUR INNOVATION IN MEDICAL BODY AREA NETWORKS 2 (May 17, 2012) [hereinafter CHAIRMAN PROPOSAL], http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-314146A1.pdf.

[87] *See* Ralf-Gordon Jahns, *U.S. $1.3 Billion: The Market for mHealth Applications in 2012*, RESEARCH2GUIDANCE (Jan. 25, 2012), http://www.research2guidance.com/.

[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).

[91] *See* RESEARCH2GUIDANCE, *Report 2013–2017*, *supra* note 31, at 7. In 2011, a London-based research company predicted that the market would generate $11.8 billion in revenues by 2018. Brian Dolan, *Global Mobile Health Market Now Worth $11.8B by 2018*, MOBIHEALTHNEWS (Aug. 6, 2012), http://mobihealthnews.com/18159/global-mobile-health-market-now-worth-11-8b-by-2018/.

[92] *See* RESEARCH2GUIDANCE, *Report 2013–2017*, *supra* note 31, at 7.

basic sanitation (4.4 billion).[93] Mobile phones are creating new possibilities in developing countries in particular for mobile banking and mobile health.[94]

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*.[95] According to the contest guidelines, the winning device must "allow a user to diagnose themselves without having to visit a doctor or hospital."[96] The guidelines encapsulate the aspirations for mobile health, which is nothing short of "major disruption to global health care systems."[97]

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

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[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 POL'Y & 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.[98] 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.[99]

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."[100] 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."[101] 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.[102] A review of 137 diabetes apps found "obvious gaps between the evidence-based recommendations and the

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[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).

[101] Rochelle Sharpe, *Lacking Regulation, Many Medical Apps Questionable at Best*, NEW ENG. CTR. FOR INVESTIGATIVE REPORTING (Nov. 18, 2012), http://necir-bu.org/investigations/medical-apps/.

[102] *See* Lorien C. Aroms et al., *iPhone Apps for Smoking Cessation: A Content Analysis*, 40 AM. J. PREVENTATIVE MED. 279, 279-85 (2011), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3395318/.

functionality . . . found in online markets."[103] 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.[104]

A Boston University study examined 1,500 mobile health apps, and found that over 20% (331) "claim[] to treat or cure medical problems."[105] Almost half of these rely on a smartphone's stock features (like lights, sound, or vibration) to produce a therapeutic effect.[106] 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.[107] 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.[108] 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.[109] The app is careful to disclaim, "The iSAD Lamp is meant for entertainment purposes."[110]

Similarly, the Boston University study found that sound therapy apps have very little scientific or medical research to support their claims.[111] For example, the A.G.Method app, which sells for $9.99,

[103] Taridzo Chomutare et al., *Features of Mobile Diabetes Applications: Review of the Literature and Analysis of Current Applications Compared Against Evidence-Based Guidelines*, 13 J. MED. INTERNET RES. 65 (2011), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222161/.

[104] *See, e.g.*, Pamela Lewis Dolan, *What's Missing from Many Health Apps — Medical Expertise*, AM. MED. NEWS (May 13, 2013), http://www.amednews.com/article/20130513/business/130519995/6/ (citing an unpublished study of 222 pain-related smartphone apps); Benjamin A. Rosser & Christopher Eccleston, *Smartphone Applications for Pain Management*, 17 J. TELEMEDICINE & TELECARE 308 (2011), *available at* http://www.ncbi.nlm.nih.gov/pubmed/21844177 (examining 111 pain-related apps on five major platforms); Sharpe, *supra* note 101 (studying 1,500 paid apps).

[105] Sharpe, *supra* note 101. The Center investigated "apps that cost money and have been available since June 2011." The Center found a range of prices between "69 cents to $999."

[106] *See id.*

[107] *See id.*

[108] *See id.*; Comtek, *iSAD Lamp*, ITUNES PREVIEW, https://itunes.apple.com/us/app/isad-lamp/id389744890?mt=8 (last visited June 18, 2013).

[109] *See* Sharpe, *supra* note 101 (citing two leading researchers on seasonal affective disorder, including the pioneer of light therapy).

[110] *Id.*; Comtek, *supra* note 108.

[111] *See* Sharpe, *supra* note 101.

claims to use "sonic induction" to treat pain.[112] 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."[113] 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."[114]

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."[115] The problem is that consumers (both patients and professionals alike) may have trouble distinguishing the two.[116]

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.[117] Mobile apps might also enable us to better manage chronic diseases, which account for roughly 75% of all U.S. health spending.[118]

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[112] A.G. Method, *AGMethod*, ITUNES PREVIEW, https://itunes.apple.com/us/app/agmethod/id422329655?mt=8 (last visited June 18, 2013); *see* Sharpe, *supra* note 101.

[113] A.G. Method, *supra* note 112.

[114] Sharpe, *supra* note 101 (quoting Satish Misra, physician and managing editor of the website iMedicalApps).

[115] Carl Franzen, *Side Effects May Vary: The Growing Problem of Unregulated Medical Apps*, VERGE (June 3, 2013, 10:30 AM), http://www.theverge.com/2013/6/3/4380244/how-should-medical-apps-be-regulated.

[116] *See* Lex van Velsen et al., *Why Mobile Health App Overload Drives Us Crazy, and How to Restore the Sanity*, 13 BMC MED. INFORMATICS & DECISION MAKING 23 (2013), *available at* http://www.biomedcentral.com/1472-6947/13/23.

[117] *See* FCC, COMM'N DOC., CHAIRMAN GENACHOWSKI HOSTS MHEALTH SUMMIT 3 (June 6, 2012) [hereinafter CHAIRMAN GENACHOWSKI], http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-314487A1.pdf.

[118] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, CHRONIC DISEASES: THE POWER TO PREVENT, THE CALL TO CONTROL (2009), http://www.cdc.gov/chronicdisease/resources/publications/aag/chronic.htm.

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.[119] Another calculates $10 billion in annual savings from using mobile technologies to remotely monitor patients with congestive heart failure.[120] 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.[121] Studies even predict that mobile technologies can help cut our health care system's considerable administrative costs.[122]

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,[123] 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.[124] Members of Congress repeat this refrain, noting blithely that "[i]nnovative wireless medical devices play

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[119]   *See* FCC, CHAIRMAN PROPOSAL, *supra* note 86, at 2.

[120]   *See id.*

[121]   *See* Robert E. Litan, *Vital Signs via Broadband: Remote Health Monitoring Transmits Savings, Enhances Lives*, BETTER HEALTH CARE TOGETHER 1, 2 (Oct. 24, 2008), http://www.corp.att.com/healthcare/docs/litan.pdf.

[122]   *See, e.g.*, *Connected Life: The Impact of the Connected Life over the Next Five Years*, PRICEWATERHOUSECOOPERS 1, 7-8 (2013), http://www.gsma.com/connectedliving/wp-content/uploads/2013/02/GSMA-Connected-Life-PwC_Feb-2013.pdf (predicting that mHealth might cut health spending in OECD nations by $400 billion in 2017, including 20-30% savings in hospital administrative expenses); *The Socio-Economic Impact of Mobile Health*, BOSTON CONSULTING GROUP 7 (2012), http://www.telenor. com/wp-content/uploads/2012/05/BCG-Telenor-Mobile-Health-Report-May-2012.pdf (predicting administrative savings of 20-30%). In fact, a recent bill proposed in Congress would push federal health care programs to examine how wireless health information technologies could save on federal program expenses. H.R. 3577, 113th Cong. (1st Sess. 2013).

[123]   For an account almost twenty years ago, see Alan M. Garber, *Can Technology Assessment Control Health Spending?*, 13 HEALTH AFF. 115 (1994).

[124]   *See* FCC, CHAIRMAN GENACHOWSKI, *supra* note 117; FCC, CHAIRMAN PROPOSAL *supra* note 86, at 1.

a vital role in addressing our nation's unsustainable health care costs."[125]

Of course, for all this to be true, these technologies must work. Apps of the "digital snake oil" variety[126] 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.[127]

When viewed more broadly, mobile health is part of broader cultural and technological evolutions, including the march towards more personalized medicine,[128] the "quantified self" movement,[129] the

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[125] Letter from Representatives Marsha Blackburn et al., to Margaret Hamburg, FDA Comm'r, and Julius Genachowski, FCC Chairman (Apr. 3, 2012), *available at* http://blackburn.house.gov/uploadedfiles/letter_from_congress_to_fda_and_fcc_-_3apr2012.pdf.

[126] *See* Franzen, *supra* note 115. *See generally* Nathan Cortez, *The FDA Needs to Regulate "Digital Snake Oil,"* SLATE (Sept. 24, 2013, 3:59 PM), http://www.slate.com/blogs/future_tense/2013/09/24/mhealth_fda_needs_to_regulate_digital_snake_oil.html (discussing what the FDA has done to regulate health apps, and what it must do in the future to encourage high quality innovation).

[127] *See, e.g.*, CLAYTON M. CHRISTENSEN, JEROME H. GROSSMAN & JASON HWANG, THE INNOVATOR'S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTH CARE 313-20 (2009) (describing alternating waves of decentralization and centralization in the medical device and diagnostic industry). *But see* Terry, *supra* note 28, at 733-35 (explaining why health information technologies have yet to achieve such disruption).

[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,[130] and the rising era of "big data."[131] 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,[132] 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.[133] 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.[134] To

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to use various technologies, including biometric sensors and wearable devices, to collect data about ourselves and our health. It is also known as "self tracking," "body hacking," and by other labels. For popular descriptions, see Kashmir Hill, *Adventures in Self-Surveillance, a.k.a. The Quantified Self, a.k.a. Extreme Naval-Gazing*, FORBES (Apr. 7, 2011), http://www.forbes.com/sites/kashmirhill/2011/04/07/adventures-in-self-surveillance-aka-the-quantified-self-aka-extreme-navel-gazing/; *The Quantified Self: Counting Every Moment*, ECONOMIST (Mar. 3, 2012), http://www.economist.com/node/21548493.

[130] "Lifelogging," closely related to the "quantified self" movement, is the practice of using computing technologies to comprehensively archive one's existence, including but not necessarily involving one's health. *See* Anita L. Allen, *Dredging Up the Past: Lifelogging, Memory, and Surveillance*, 75 U. CHI. L. REV. 47, 48-49 (2008).

[131] "Big data" refers collectively to the practice of collecting, analyzing, and using large quantities of information. *See* Frank Pasquale, *Grand Bargains for Big Data: The Emerging Law of Health Information*, 72 MD. L. REV. 682, 683 n.1 (2013). For a dystopian, fictional glimpse of what our quantified futures might look like, see GARY SHTEYNGART, SUPER SAD TRUE LOVE STORY (2010).

[132] For example, several companies are developing "smart pill" technology, which allows patients to digest pills that transmit diagnostic data wirelessly, outside the body. In 2012, the FDA cleared for marketing an "ingestible event marker" by Proteus Biomedical, Inc., which can help track whether patients are adhering to their medication regimen. *See* Letter from Jonette Foy, Deputy Director for Science and Regulatory Policy, Ctr. for Devices & Radiological Health, to Jafar Shenasa, Senior Manager, Proteus Biomedical, Inc. (July 20, 2012), http://www.accessdata.fda.gov/cdrh_docs/pdf11/K113070.pdf. In 2013, the FDA proposed relaxing market clearance requirements for ingestible monitoring devices. *See* Medical Devices; General Hospital and Personal Use Monitoring Devices; Classification of the Ingestible Event Marker, 78 Fed. Reg. 28,733 (May 16, 2013) (codified at 21 C.F.R. pt. 880.6305) (classifying such devices as Class II and categorizing them as "ingestible event markers").

[133] *See generally* Pasquale, *supra* note 131 (arguing for a "grand bargain" between providers, administrative agencies, and patients to allow full access to data while attempting to protect personal information).

[134] For a short discussion of the pros and cons, see Stefan Timmermans & Aaron Mauck, *The Promises and Pitfalls of Evidence-Based Medicine*, 24 HEALTH AFF. 18, 20-21

advocates, mobile health provides a logical, efficient vehicle for achieving these ideals.[135]

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

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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.[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,

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(2005).

[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).

[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).

[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).

[138] *See* FCC, CHAIRMAN GENACHOWSKI, *supra* note 117, at 2 (announcing the FCC Rural Health Care Pilot). For an excellent treatment of the legal and policy issues surrounding telemedicine, see Thomas R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities*, 14 ANNALS HEALTH L. 205 (2005); *see also* Thomas R. McLean & Edward P. Richards, *Teleradiology: A Case Study of the Economic and Legal Considerations in International Trade in Telemedicine*, 25 HEALTH AFF. 1378, 1379-81 (2006).

[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 Stoltzfus 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.[140] 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.[141] 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.[142] The Act grants the FDA jurisdiction over medical "devices," which it defines very broadly as any product *intended* to

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[140] *See* Terry, *supra* note 28, at 723-24.

[141] *See* Timothy Stoltzfus Jost, *Our Broken Health Care System and How to Fix It: An Essay on Health Law and Policy*, 41 WAKE FOREST L. REV. 537, 547-48 (2006); Jost, *Why Can't We Do What They Do?*, *supra* note 139, at 436.

[142] *See* David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981, 983, 998-99 (2008). *See generally* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-99 (2012)) (giving the FDA the authority to oversee the safety of food, drugs, and cosmetics).

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).[143] 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.[144] 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.[145] Moreover, the FDA can consider the "circumstances surrounding distribution of the article," including widespread consumer use.[146] 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.[147] 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).[148] The higher the classification, the more scrutiny the device receives. For example, to get to the market,

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[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.*

[146] *Id.* Note, however, that FDA officials testified to Congress that the agency will not use actual use to determine "intended use." *See* Letter from Michele Mital, Acting Associate Commissioner for Legislation, to Hon. Tim Murphy, Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives 2 (Mar. 20, 2013) [hereinafter Mital Letter], *available at* http://www.genomicslawreport.com/wp-content/uploads/2013/03/HousemHealthLetter.pdf.

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

[148] *See* 21 U.S.C. § 360(c) (2012).

Class III devices generally must undergo premarket approval by the FDA,[149] which typically requires clinical trials. In contrast, Class II devices must provide relatively cursory premarket notification, known as a 510(k) notice,[150] which the FDA generally accepts. Finally, most of the lowest-risk Class I devices typically require no premarket notification at all.[151] 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.[152]

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.[153] 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.[154] And, months earlier, the FDA issued a joint statement with the FCC explaining that the agencies wanted to facilitate wireless medical technologies.[155]

The FDA finalized the guidance just two years later, in September 2013[156] (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

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[149]　*See* 21 C.F.R. pt. 814.1 (2013).

[150]　*See* 21 U.S.C. § 360(k); 21 C.F.R. § 860.3(c)(2) (2013).

[151]　*See* 21 C.F.R. § 860.3(c)(1).

[152]　*See generally* Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. (forthcoming 2014) (discussing the FDA's long struggle to regulate innovative medical software).

[153]　*See* Draft Guidance for Industry and Food and Drug Administration Staff, *supra* note 24, at 43,689; FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24, at 1.

[154]　For example, in December 2010, attorneys for the mHealth Regulatory Coalition, an industry group, published a white paper on FDA's potential approach to mobile medical apps. *See* Bradley Merrill Thompson et al., *A Call for Clarity: Open Questions on the Scope of FDA Regulation of mHealth*, MHEALTH REGULATORY COALITION, at i (Dec. 22, 2010), http://mhealthregulatorycoalition.org/wp-content/uploads/2010/12/mrcwhitefinal122210.pdf.

[155]　*See* U.S. FOOD & DRUG ADMIN. & FED. COMMC'N COMM'N, JOINT STATEMENT ON WIRELESS MED. DEVICES 1 (July 26, 2010) [hereinafter FDA & FCC JOINT STATEMENT], *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-300200A1.pdf.

[156]　*See* FDA FINAL GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24, at 1.

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.[157] 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.[158] Instead, the FDA will train its eyes on those who create, design, label, or initiate specifications for a mobile medical app.[159]

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,[160] and depends on whether the manufacturer *intends* certain specified functionality.[161] 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.[162] 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.[163] But the app industry understandably remains confused, calling for more clarity.[164] To that end, the FDA introduced a pyramid of jurisdiction.[165] The pyramid itself represents the entire universe of

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[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.*

[161] *See* 21 C.F.R. § 801.4 (2013).

[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.[166] 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.[167]

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.[168] 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.[169] The classic examples (inasmuch as apps can be "classics" already) are calorie trackers, appointment reminders, and exercise regimens.[170] Finally, the FDA says it is not concerned with apps that replicate or automate office functions, like billing, reimbursement, and the like.[171] 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.[172]

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.[173] The Draft Guidance, for example, says that the FDA would continue to monitor apps that either

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MEDICAL APPS DRAFT GUIDANCE 8 (Sept. 12, 2011), *available at* http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM271893.pdf.

[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

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[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.

[178] *See* 21 C.F.R. pt. 820.5 (2013).

[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.[181] 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.[182] Regulated firms are free to take alternative approaches, as long as they comply with the underlying statute and regulations.[183] Of course, notwithstanding this boilerplate, few people understand FDA guidance documents as being so impotent.[184]

Shortly after it published the Draft Guidance, the FDA held a two-day public workshop to ventilate this framework.[185] 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.[186] 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.[187] Several comments by industry representatives betrayed ignorance of even basic FDA rules, as well as profound confusion with more advanced concepts like intended use.[188]

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[181] *See* 21 U.S.C. § 371(h) (2012); 21 C.F.R. § 10.115 3(iv) (2013).

[182] *See* FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24, at 4.

[183] *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.

[184] *See infra* Part IV.B.

[185] *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).

[186] *See* FDA Public Workshop, *supra* note 85.

[187] *See id.*

[188] *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

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the West Wireless Health Institute, did not know what "intended use" was before the workshop).

[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).[199] Does the FDA need to regulate at all if medical malpractice liability will encourage physicians not to misuse or over-rely on apps?[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.[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,[202] a proposal that some industry groups opposed as introducing even more regulatory uncertainty for the industry.[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.[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

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[199] *See id.* (statement of Grant Elliott).

[200] *See id.* (statement of Leslie Kelly Hall).

[201] *See Comments to FDA's Draft Guidance on Mobile Medical Applications: Docket No. FDA-2011-D-0530*, MHEALTH REGULATORY COMM'N 3-4 (Oct. 20, 2011), *available at* http://mhealthregulatorycoalition.org/wp-content/uploads/2010/06/MRC-Comments-on-FDA-Draft-MMA-Guidance.pdf.

[202] *See* Brian Dolan, *How Congress Almost Delayed the FDA's Mobile Medical App Guidance*, MOBIHEALTHNEWS (July 5, 2012), http://mobihealthnews.com/17707/how-congress-almost-delayed-the-fdas-mobile-medical-app-guidance/.

[203] Letter from Bradley Merrill Thompson, mHealth Regulatory Coalition, to Senator Tom Harkin, Chairman, Comm. on Health, Educ., Labor, & Pensions, and Senator Michael B. Enzi, Comm. on Health, Educ., Labor & Pensions (May 17, 2012), *available at* http://mhealthregulatorycoalition.org/wp-content/uploads/2010/06/MRC-Letter-to-Senate-HELP-Committee-on-Proposed-Moratorium-FINAL.pdf. Congress passed the bill without the amendment, instead requiring FDA to report on a risk-based approach within 18 months. *See* Food and Drug Admin. Safety and Innovation Act of 2012 (FDASIA), Pub. L. No. 112-144, § 618(a), 126 Stat. 993, 1063.

[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."[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.[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.[207] The FDA cleared the iBGStar Diabetes Manager app, which connects with a blood glucose meter.[208] And it has cleared the Mobile MIM app, which displays medical images for physicians, radiologists, and technicians.[209] Other companies are also seeking the FDA's blessing.[210] As of March 2013, FDA officials report that the agency has reviewed around 100 discrete medical apps,[211] averaging roughly 110

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[205] FDASIA § 618(a). The FDASIA Working Group's report is expected in 2013.

[206] *See Health Information Technologies: Harnessing Wireless Innovation: Hearing Before the Subcomm. on Commc's & Tech. of the H. Comm. on Energy & Commerce*, 113th Cong. 2 (2013), *available at* http://energycommerce.house.gov/hearing/health-information-technologies-harnessing-wireless-innovation (statement of Robert Jarrin, Senior Director, Government Affairs, Qualcomm Inc.).

[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.

[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).

[209] These are Class II medical devices per 21 C.F.R. § 892.2050 (2014). The FDA cleared the ImageGrid Radiology Viewer app by Candelis, Inc. in October 2009, the Mobile MIM app by MIM Software, Inc. in February 2011, and the ASTRA by Candelis, Inc. in September 2011. *See* Astra, 510(k) Summary of Safety (FDA Form 510(k)) (May 17, 2011), http://www.accessdata.fda.gov/cdrh_docs/pdf11/k111694.pdf; MIM Software Inc., 510(k) Summary of Safety and Effectiveness (FDA Form 510(k)) (Sept. 30, 2011), http://www.accessdata.fda.gov/cdrh_docs/pdf11/k112930.pdf; REKA Pte. Ltd., *supra* note 59.

[210] *See* Brian Dolan, *Digital Health's Busy Summer for FDA Clearances*, MOBIHEALTHNEWS (Aug. 14, 2012), http://mobihealthnews.com/18216/digital-health-busy-summer-for-fda-clearances/.

[211] *Health Information Technologies: Administration Perspectives on Innovation and Regulation: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 113th Cong. (2013) [hereinafter *Health Info. Admin.*

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

Perspectives Hearing], *available at* http://energycommerce.house.gov/hearing/health-information-technologies-administration-perspectives-innovation-and-regulation (statement of Christy L. Foreman, Director, Office of Device Evaluation, FDA).

[212] *See* Mital Letter, *supra* note 146, at 3.

[213] *See* FDA FINAL GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24.

[214] *See* U.S. FOOD & DRUG ADMIN., MAUDE ADVERSE EVENT REPORT: MDT PUERTO RICO OPERATIONS CO., JUNCOSRESTORE ULTRASTIMULATOR, SPINAL-CORD, TOTALLY IMPLANTED FOR PAIN RELIEF (Aug. 23, 2011), *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/TextSearch.cfm (document can be found by selecting the year 2011, and searching for the keywords "Juncosrestore" and "iPhone").

[215] *See id.*

[216] *See "Pfizer Rheumatology Calculator" iPhone/Android Application — Important Information*, PFIZER 1 (Oct. 14, 2011), http://www.pharma-mkting.com/images/Pfizer_Rheum_BugLetter.pdf.

[217] Mital Letter, *supra* note 146, at 3; *see* U.S. FOOD & DRUG ADMIN., CLASS 2 RECALL, SANOFI AVENTIS DIAMIGO IPHONE APP (Dec. 22, 2012), *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=114792.

[218] *See generally* Letter from James L. Woods, Deputy Dir., Patient Safety & Prod. Quality, U.S. Food & Drug Admin., to Myshkin Ingawale, Biosense Techs. Private Ltd. (May 21, 2013), *available at* http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm (containing the full text of the letter).

[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.[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.[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,[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.[224] The FTC charged both with making unsubstantiated

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[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* http://www.raps.org/focus-online/news/news-article-view/article/3497.aspx.

[222] *See* Gaffney, *supra* note 221.

[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 Question*, NAT'L PUB. RADIO (Dec. 2, 2011), http://www.npr.org/blogs/health/2011/12/01/143005028/apps-can-help-you-take-a-pill-but-privacys-a-big-question.

[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.[225] Acne Pwner was downloaded 3,300 times for 99 cents each, and AcneApp was downloaded 11,600 times at $1.99 each.[226] Although the FTC's fines were modest (just $1,700 for Acne Pwner and $14,924 for AcneApp),[227] they demonstrated that the FTC would scrutinize health claims made by apps.[228] 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.[229] 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.[230]

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.[231] As such, the FCC already shares jurisdiction over wireless medical devices like pacemakers.[232] 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.

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http://bucks.blogs.nytimes.com/2011/11/01/f-t-c-no-app-to-cure-acne/?_r=0; Camille Sweeney, *Better Skin to the Touch?*, N.Y. TIMES (Dec. 30, 2009), http://www.nytimes.com/2009/12/31/fashion/31Skinbox.html.

[225] *See* Kobe Brown & Gregory W. Pearson, dba DERMAPPS, Analysis of Proposed Consent Order to Aid Public Comment, 76 Fed. Reg. 57,041 (Sept. 15, 2011), *available at* http://www.ftc.gov/sites/default/files/documents/cases/2011/09/110915kobebrownfrn.pdf; Andrew N. Finkel, Analysis of Proposed Consent Order to Aid Public Comment, 76 Fed. Reg. 57,043 (Sep. 15, 2011), *available at* http://www.ftc.gov/sites/default/files/documents/cases/2011/09/110915finkelanal.pdf.

[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).

[229] *See* PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 275-76 (3d ed. 2007).

[230] The Mobile Technology Unit, created by David Vladeck, resides in the Division of Financial Practices of the FTC's Bureau of Consumer Protection. *See Bureau of Consumer Prot.*, *Division of Financial Practices*, FED. TRADE COMM'N, http://www.ftc.gov/bcp/bcpfp.shtm (last visited June 24, 2013).

[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]

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[233] FDA & FCC JOINT STATEMENT, *supra* note 155; *see also* Press Release, FCC, FDA Take Steps to Promote Innovation and Investment in Wireless-Enabled Medical Devices (July 26, 2010), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-300226A1.pdf.

[234] *See* Memorandum of Understanding between the Fed. Commc'n Comm'n and the U.S. Food & Drug Admin. Ctr. for Devices and Radiological Health (2010), *available at* http:/hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-300200A2.pdf.

[235] *See FCC/FDA Joint Meeting on Life Saving Wireless Med. Tech. Day-1*, U.S. FOOD & DRUG ADMIN. (July 26, 2010) [hereinafter *FCC/FDA Joint Meeting*], http://www.fcc.gov/events/fccfda-joint-meeting-life-saving-wireless-medical-technology-day-1; *Public Meeting: Converged Commcations and Health Care Devices Impact on Regulation*, U.S. FOOD & DRUG ADMIN. (July 26–27, 2010), http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm215046.htm.

[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.[241] 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.[242] 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.[243] These programs encourage the industry to use electronic records, prescribe medicines, coordinate patient care, and measure quality outcomes electronically.[244]

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.[245] 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."[246]

Thus, contrary to regulatory alarmists who claim a federal assault on mobile health technologies,[247] 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

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http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-314145A1.pdf.

[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).

[244] *See id.* (citing, among other programs, the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494, and the American Reinvestment and Recovery Act of 2009, Pub. L. No. 111-5, 123 Stat. 115).

[245] *See generally About ONC*, OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., http://www.healthit.gov/newsroom/about-onc (last visited Feb. 8, 2014) (providing a diagram about the structure of the Office and its mission). The American Recovery and Reinvestment Act of 2009, familiarly known as the "stimulus bill," included the HITECH Act (the Health Information Technology for Economic and Clinical Health Act) at Title XIII, which created the Office of the National Coordinator within HHS. *See* American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (codified at 42 U.S.C. § 300jj-11 (2012)).

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

[247] *See, e.g.*, Joel White, *WHITE: FDA's Assault on Mobile Technologies*, WASH. TIMES (Feb. 7, 2012), http://www.washingtontimes.com/news/2012/feb/7/fdas-assault-on-mobile-technologies/ (mischaracterizing the FDA's Draft Guidance as a "proposed regulation").

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.[248] The program features several apps, including: an app that helps physicians diagnose and treat traumatic brain injuries and mental disorders;[249] an app that allows users to assess themselves for post-traumatic stress disorder ("PTSD");[250] an app that uses clinical guidelines to help providers treat mild traumatic brain injuries;[251] and even an app that connects to EEG devices, EMG devices, ECG/EKG devices, respirators, and other biometric monitors.[252] 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.[253] The Center proclaims that it is focused on "putting research findings into the hands of warfighters while looking toward wider civilian utility."[254] 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.[255] This is part of a larger program at HHS

[248] *See About T2*, NAT'L CTR. FOR TELEHEALTH & TECH., http://www.t2.health.mil/about.html (last visited Feb. 8, 2014).

[249] *See* Robyn Mincher, *New Mobile App Helps Troops to Self-Manage Behavior, Stress*, NAT'L CTR. FOR TELEHEALTH & TECH. (Nov. 21, 2011), http://www.t2.health.mil/news/new-mobile-app-helps-troops-self-manage-behavior-stress#.UsEpI7TWubF.

[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").

[253] *See Homepage*, TELEMEDICINE & ADVANCED TECH. RES. CTR., http://www.tatrc.org/ (last visited Feb. 8, 2014).

[254] *Id.*

[255] *See mHealth — Workshop on "mHealth Evidence,"* OFF. OF BEHAVIORAL & SOC. SCI. RES., NAT'L INST. OF HEALTH, U.S. DEPT. HEALTH & HUM. SERVS. (Aug. 16, 2011), *available at* http://obssr.od.nih.gov/scientific_areas/methodology/mhealth/mhealth-

and the NIH to subsidize research on mobile health applications.[256] In fact, the NIH itself offers several health-related apps.[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.[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.[259] Only one statute has addressed them directly,[260] and that was to preserve the FDA's Draft Guidance from being frozen in carbonite by congressmen concerned with premature regulation.[261] Indeed, would-be regulators like the FDA and FCC have

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workshop.aspx.

[256] *See mHealth — Mobile Health Technologies*, OFF. OF BEHAVIORAL & SOC. SCI. RES., NAT'L INST. OF HEALTH, U.S. DEPT. HEALTH & HUM. SERVS., *available at* http://obssr.od.nih.gov/scientific_areas/methodology/mhealth/index.aspx (last visited June 24, 2013).

[257] *See Gallery of Mobile Apps and Sites*, U.S. NAT'L LIBRARY OF MED., NAT'L INST. HEALTH, *available at* http://www.nlm.nih.gov/mobile/ (last visited June 24, 2013).

[258] *See Global Observatory for eHealth*, WORLD HEALTH ORG., http://www.who.int/goe/en/ (last visited Jan. 3, 2014). Note that like the FTC, the WHO's regulatory concerns focus on privacy and data security, rather than whether medical apps actually work and do what they claim to do. *See generally*, *Legal Frameworks for eHealth: Global Observatory for eHealth Series — Vol. 5*, WORLD HEALTH ORG. (2012) (focusing largely on privacy concerns, and questions regarding the extent of privacy expected), *available at* http://whqlibdoc.who.int/publications/2012/9789241503143_eng.pdf.

[259] *See The Impact of Medical Device and Drug Regulation on Innovation, Jobs, and Patients: A Local Perspective: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 112th Cong. 110-113 (2011) (statement of Rep. Brian P. Bilbray comparing FDA regulation to a "red tide" that kills a health environment for innovation); *Overcoming Rural Health Care Barriers: Use of Innovative Wireless Health Technology Solutions: Hearing Before the Subcomm. on Health of the H. Comm. on Veterans' Affairs*, 111th Cong. 20-22, 29, 56-57, 72-75, 85 (2010); *Aging in Place: The National Broadband Plan and Bringing Healthcare Technology Home: Hearing Before the S. Special Comm. on Aging*, 111th Cong. 9, 37-38, 77 (2010). The one major exception was the three-day hearing hosted by the House Energy & Commerce Committee in March 2013. *See supra* note 206.

[260] *See* Food and Drug Admin. Safety and Innovation Act of 2012, Pub. L. No. 112-144, § 618(a), 126 Stat. 993, 1063.

[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.

Amendment, 112th Cong., (2d Sess. 2012) (on file with author).

[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).

[264] I used the rather dated phrase "laser age" as a nod to President Gerald Ford, who used the phrase when he signed the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, which ushered in the modern regulatory framework for FDA oversight of devices: "The Medical Device Amendments of 1976 eliminate the deficiencies that accorded FDA 'horse and buggy' authority to deal with 'laser age' problems." Gerald R. Ford, U.S. President, Statement on Signing the Medical Device Amendments of 1976 (May 28, 1976), *available at* http://www.presidency.ucsb.edu/ ws/?pid=6069.

[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.[266] Between 1985 and 1987, a radiation machine called the Therac-25 massively overradiated patients in the United States and Canada, administering up to 100 times the prescribed dose, sometimes burning literal holes in patients' bodies.[267] The Therac-25 (an abbreviation for therapeutic radiation computer) was notable for being the first radiation machine controlled primarily by software.[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.[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.[270] Persistent, daily malfunctions eventually numbed users, making them impervious to error alerts.[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

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FDA regulation of medical devices, see Lawrence O. Gostin, *The Deregulatory Effects of Preempting Tort Litigation*, 299 JAMA 2313, 2313-15 (2008), which addresses how the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, holding that the FDCA's scheme for regulating devices preempts conflicting or additional state law tort claims, removes civil discovery as a way to uncover unsafe or ineffective devices. Ironically, the very idea of using a feedback loop to reorient the FDA's strategy towards mobile health derives in part from some of the same underlying thinking that now animates mobile health. *See, e.g.*, Thomas Goetz, *Harnessing the Power of Feedback Loops*, WIRED (June 19, 2011), http://www.wired.com/magazine/2011/06/ff_feedbackloop/5/ (discussing how advances in sensory technology enables some of the mobile health monitoring technologies discussed in Part I). I also owe this idea, in part, to the FDA's own "corrective and preventive action" (CAPA) system, which requires device manufacturers to investigate manufacturing problems, correct them, and take action to prevent their root causes. *See* Corrective and Preventative Action, 21 C.F.R. § 820.100 (2013).

[266] The tragedy over thalidomide helped prompt the 1962 Drug Amendments. J. Richard Crout, William W. Vodra & Cole P. Werble, *FDA's Role in the Pathway to Safe and Effective Drugs*, *in* FDA: A CENTURY OF CONSUMER PROTECTION, *supra* note 263, at159, 168-69; *see* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 256-60 (2010).

[267] For a comprehensive story of the Therac-25 saga, see NANCY G. LEVESON, *Medical Devices: The Therac-25*, *in* NANCY G. LEVESON, SAFEWARE: SYSTEM SAFETY AND COMPUTERS App. A (1995).

[268] *See id.* at 3.

[269] *See id.*

[270] *See id.* at 17.

[271] *See id.* at 7.

*under*dose.[272] The manufacturer was overconfident in patching software errors, even though it could not identify their root causes when pressed to do so.[273] Users developed a false sense of security that the Therac-25's software would make it "virtually impossible to overdose a patient."[274] 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.").[275] The manufacturer's first safety review of the Therac-25 did not even cover its software.[276] 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.[277]

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.[278] 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.[279] 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.[280] 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."[281] At the time, the FDA's response was considered "impressive," given that it had no policy for medical software.[282]

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

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[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.

[280] *See* Simson Garfinkel, *History's Worst Software Bugs*, WIRED (Nov. 8, 2005), http://www.wired.com/software/coolapps/news/2005/11/69355.

[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"

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[283] Suzan Onel, *Draft Revision of FDA's Medical Device Software Policy Raises Warning Flags*, MEDICAL DEVICE & DIAGNOSTIC INDUS. (Oct. 1, 1997), http://www.mddionline. com/article/draft-revision-fdas-medical-device-software-policy-raises-warning-flags.

[284] *See* Draft Policy Guidance for Regulation of Computer Products; Availability, 52 Fed. Reg. 36,104 (Sept. 25, 1987). The FDA began crafting the policy in 1985. *See* Medical Devices; Medical Software Devices; Notice of Public Workshop, 61 Fed. Reg. 36,886 (July 15, 1996); Onel, *supra* note 283.

[285] *See* FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24, at 5; FDA DRAFT SOFTWARE POLICY, *supra* note 22, at *1-3.

[286] E. Stewart Crumpler & Harvey Rudolph, *FDA Software Policy and Regulation of Medical Device Software*, 52 FOOD & DRUG L.J. 511, 513 (1997).

[287] *See* FDA DRAFT SOFTWARE POLICY, *supra* note 22, at *2-3.

[288] *See* Food, Drug, & Cosmetic Act § 201(h), 21 U.S.C. § 321 (2012); Medical Device Amendments of 1976, Pub. L. No. 94-295, § 513, 90 Stat. 539, 540-46; *see also* Ford, *supra* note 264.

[289] Draft Policy Guidance for Regulation of Computer Products, 52 Fed. Reg. 36,104.

[290] *See* FDA DRAFT SOFTWARE POLICY, *supra* note 22, at *2.

before "any impact on human health."[291] 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,

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[291]   *See id.*

[292]   *See* Annual Comprehensive List of Guidance Documents at the Food and Drug Admin., 70 Fed. Reg. 824, 890 (Jan. 5, 2005).

[293]   FDA DRAFT GUIDANCE ON MOBILE MEDICAL APPS, *supra* note 24, at 5 (referring to the 2005 withdrawal of the 1989 Draft Software Policy).

[294]   *See id.*

[295]   *See id.* app. B at 21-23 (listing 79 distinct device categories codified by the FDA).

[296]   For example, the Draft Guidance identifies several existing categories that might fit many medical apps, including 21 C.F.R. §§ 880.6310 (devices that display, store, or transmit patient-specific medical device data in its original format), 870.1875(b) (electronic stethoscope), 892.2050 (picture archiving and communications system), 862.1345 (glucose test system), 870.2300 (cardiac monitor), 870.1130 (electronic blood pressure monitor), 884.2740 (perinatal monitoring system), and 868.1890 (drug dose calculator), to name just those identified by the FDA in its Guidance. *See id.* at 14-15.

adding to the roughly 1,700 different device categories in the Code of Federal Regulations.[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.[298] For example, in 2011, the FDA finalized a regulation governing medical device data systems ("MDDS"),[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.[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.[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.[302] The QSR, which establishes good manufacturing practices for devices,[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.[304] This is both a

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[297] *See* 21 C.F.R. pts. 862-892 (2013).

[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)).

[299] *See id.*

[300] *See id.* at 8643-44 (codified at 21 C.F.R. pt. 880.6310(a)).

[301] *See id.* at 8644.

[302] *See* Medical Devices, Current Good Manufacturing Practice (CGMP) Final Rule; Quality Systems Regulation, 61 Fed. Reg. 52,602 (Oct. 7, 1996). *See* U.S. FOOD & DRUG ADMIN., CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS FOR COMBINATION PRODUCTS 31-33 (2013), *available at* http://www.fda.gov/downloads/ CombinationProducts/UCM336194.pdf (explaining how to comply with QSR requirements and noting that many comments applying the requirements focused on design controls).

[303] *See* 21 C.F.R. pt. 820 (2013).

[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.

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http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm.

[305] *See, e.g.*, U.S. FOOD & DRUG ADMIN., GENERAL PRINCIPLES OF SOFTWARE VALIDATION: FINAL GUIDANCE FOR INDUSTRY AND FDA STAFF (2002) [hereinafter FDA GENERAL PRINCIPLES OF SOFTWARE VALIDATION], *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm (containing the guidelines of how the QSR applies to software).

[306] *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR THE CONTENT OF PREMARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN MED. DEVICES (2005); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CYBERSECURITY FOR NETWORKED MED. DEVICES CONTAINING OFF-THE-SHELF SOFTWARE (2005); FDA GENERAL PRINCIPLES OF SOFTWARE VALIDATION, *supra* note 305; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, FDA REVIEWERS, AND COMPLIANCE ON OFF-THE-SHELF SOFTWARE USE IN MEDICAL DEVICES (1999); U.S. FOOD & DRUG ADMIN., DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS (1997).

[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]

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[309] *See* LEVESON, *supra* note 267, at 48.

[310] *See generally Radiation Boom*, N.Y. TIMES, http://topics.nytimes.com/top/news/us/series/radiation_boom/index.html (last visited June 24, 2013) (linking to several articles in the "Radiation Boom" series by Walt Bogdanich which examine issues arising from the increasing use of medical radiation and the new technologies that deliver it).

[311] I borrow this phrase from Walt Bogdanich, *Radiation Offers New Cures, and Ways to Do Harm*, N.Y. TIMES 1 (Jan. 23, 2010) [hereinafter *Radiation Offers New Cures*], http://www.nytimes.com/2010/01/24/health/24radiation.html.

[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.[317] She was the victim of "a baffling series of missteps,"[318] 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.[319] The N.Y. Department of Public Health observed, "[t]he fact that therapists failed to notice 'wedge OUT' on 27 occasions is disturbing."[320] 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.[321] 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."[322] These spot reports align with nationwide estimates that one in twenty radiation patients will suffer injury.[323]

A hospital official at St. Vincent's said the incident above "occurred as a result of a unique and unanticipated combination of issues."[324] But

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[317] *See id.*

[318] *Id.* at 5.

[319] *See id.*

[320] *Id.* at 6.

[321] *See id.* at 1; *see also* Walt Bogdanich, *As Technology Surges, Radiation Safeguards Lag*, N.Y. TIMES (Jan. 26, 2010) [hereinafter *As Technology Surges*], http://www.nytimes.com/2010/01/27/us/27radiation.html?pagewanted=all.

[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.[325] And as radiation technology becomes increasingly powerful, it requires more sophisticated software that itself requires more sophisticated users.[326] 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.[327] 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."[328] In short, health providers seem particularly susceptible to novelty, consumer demand, and manufacturer claims.[329] We see glimpses of this in the exuberance over mobile health.

When things do go wrong, responsibility dissipates. Providers blame manufacturers. Manufacturers blame user errors. Federal, state, and local regulators with overlapping jurisdiction remain inert.

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,

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[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).

[327] *See* Einer Elhauge, *The Limited Regulatory Potential of Medical Technology Assessment*, 82 VA. L. REV. 1525, 1596 (1996); David A. Grimes, *Technology Follies: The Uncritical Acceptance of Medical Innovation*, 269 JAMA 3030, 3031 (1993).

[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."[330] 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."[331] 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.[332]

Some skeptics are sounding the alarm, requesting real data that mobile health applications actually do what they claim.[333] 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."[334] 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.[335] And this mindset, known as "automation bias," disarms us from critically evaluating potential errors.[336] In fact, research demonstrates that we trust automation even when we suspect errors or malfunctions,[337] 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

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[330] INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (1999).

[331] FDA Public Workshop, *supra* note 85 (statement of Jon White, Agency for Healthcare Research and Quality).

[332] *See id.* (statement of Dean Kross).

[333] *See id.* (statement of Dean Kross); *see also* Scot M. Silverstein, *Contemporary Issues in Medical Informatics: Good Health IT, Bad Health IT, and Common Examples of Healthcare IT Difficulties*, DREXEL UNIV., http://www.ischool.drexel.edu/faculty/ssilverstein/cases/ (last visited June 24, 2013).

[334] FDA Public Workshop, *supra* note 85 (statement of Dean Kross).

[335] *See* Danielle Keats Citron, *Technological Due Process*, 85 WASH. U. L. REV. 1249, 1271 (2008) (citing supporting literature from the cognitive system's engineering field).

[336] *See id.* 1271-72 ("[A]utomation bias" is defined as the "use of automation as a heuristic replacement for vigilant information seeking and processing"); Linda J. Skitka et al., *Automation Bias and Errors: Are Crews Better than Individuals?*, 10 INT'L J. AVIATION PSYCHOL. 85, 86 (2000).

[337] *See* Citron, *supra* note 335, at 1271-72.

systems are usually inaccessible and opaque to the non-programmer, which often "shields them from scrutiny."[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.[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.[340] Because these were voluntary reports, and because even the FDA's mandatory reporting requirements suffer from dramatic under-reporting,[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.[342]

Mobile health applications, of course, are not yet capable of inflicting the "unspeakable pain" that radiation machines can.[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.[344] A study by Julian Goldman reviewed the

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[338] *See id.* at 1254.

[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. POL'Y COMM. (Feb. 25, 2010), *available at* http://www.cchfreedom. org/pdfs/Health%20IT%20Deaths%20-%20FDA%20jeffrey%20Shuren.pdf.

[340] *See* sources cited *supra* note 339.

[341] *See* Edward M. Basile & Beverly H. Lorell, *The Food and Drug Administration's Regulation of Risk Disclosure for Implantable Cardioverter Defibrillators: Has Technology Outpaced the Agency's Regulatory Framework?*, 61 FOOD & DRUG L.J. 251, 257-58 (2006).

[342] *See* Bogdanich, *As Technology Surges*, *supra* note 321.

[343] *See* Bogdanich, *Radiation Offers New Cures*, *supra* note 311, at 1.

[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.

clocks used by 1,700 medical devices.[345] 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.[346] The devices he studied were located in four prestigious east coast hospitals.[347]

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.[348] A simple solution has existed since 1985 — using a Network Time Protocol that cell phones use to synchronize time to atomic clocks.[349] But the FDA has never required devices to use this technology.[350] HHS has proposed regulations that would require it for electronic medical records, but they would not phase in until 2014.[351]

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.

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[345] *See generally* Julian M. Goldman, *Medical Device Interoperability Ecosystem Updates: Device Clock Time, Value Proposition, and the FDA Regulatory Pathway* (Jan. 31, 2012), *available at* http://rtg.cis.upenn.edu/MDCPS/SiteVisit/MD%20CPS% 20Meeting%20Goldman%20Jan%2031%202012.pdf (linking to the PowerPoint presentation of the study presented at the PRECISE Center at University of Pennsylvania).

[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.*

[351] *See id.*; *see also* Health Information Technology: Standards, Implementation, Specifications, and Certification Criteria for Electronic Health Record Technology, 77 Fed. Reg. 13,831, 13,840 (proposed Mar. 7, 2012) (to be codified at 45 C.F.R. pt. 170), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-03-07/html/2012-4430.htm.

CONCLUSION

Rarely does a class of technologies excite physicians, patients, financeers, 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.

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[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).