

Digital Health and Regulatory Experimentation at the FDA

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ABSTRACT

For well over a decade the U.S. Food and Drug Administration (FDA) has been told that its framework for regulating traditional medical devices is not modern or flexible enough to address increasingly novel digital health technologies. Very recently, however, the FDA introduced a series of digital health initiatives that represent important experiments in medical product regulation, departing from longstanding precedents applied to therapeutic products like drugs and devices. The FDA will experiment with shifting its scrutiny from the pre-market to the post-market phase, shifting the locus of regulation from products to firms, and shifting from centralized government review to decentralized non-government review. This Article evaluates these new regulatory approaches, explains how they depart from previous approaches, and discusses why these experiments themselves require evaluation moving forward.

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INTRODUCTION

Since the 1970s, when the U.S. Food and Drug Administration (FDA) first encountered medical software, the agency has largely regulated software devices like more traditional, tangible medical devices. In the words of one expert back in 1986, FDA staff tended to treat medical software like “some kind of new bedpan.”¹ But the FDA itself—and everyone else—has long suspected that software is *different*. For example, FDA staff in the 1980s were aware that software differed from traditional devices in terms of design, quality assurance, and user errors. The same observer above acknowledged that FDA staff, “people of immense goodwill,” were “wrestling” with these differences.²

Finally, perhaps spurred by the ongoing revolution in digital health technologies, the FDA has started to experiment with a novel regulatory framework better tailored to software that qualify as medical “devices” subject to FDA jurisdiction. Referred to collectively as “digital health,” the products include mobile applications, clinical decision support (CDS) software, artificial intelligence (AI), and machine learning programs that perform some medical device function. The agency calls its plans an “entirely new” and “comprehensive approach to the regulation of digital health tools.”³

This Article identifies and evaluates three important experiments with medical product regulation in the FDA’s new framework. First, the FDA proposes to shift its scrutiny from the pre-market phase to the post-market phase, with the idea of bringing technologies to market more quickly but giving increased scrutiny to “real world” data generated once a product is on the market. Second, the FDA proposes to shift the locus of regulation from products to firms, focusing its review on whether the firms that produce digital health devices engage in sufficient quality control, rather than its traditional product-centered approach. Third, the FDA also proposes to outsource some of these review functions to third-party certifiers, shifting from centralized government review to decentralized non-government review. This Article will evaluate these new regulatory approaches, explaining how they depart from previous approaches and why these innovations might be important.

A swirl of activity has brought us to this point—acts of Congress, guidance documents, public workshops, and inter-agency working groups and reports,

1. Information Technologies in the Health Care System: Hearing Before the Subcomm. on Investigations and Oversight of the H. Comm. on Science and Technology, 99th Cong. (1986) (statement of Vincent Brannigan).

2. *Id.*

3. Scott Gottlieb, Commissioner of Food and Drugs, *Fostering Medical Innovation: A Plan for Digital Health Devices* (Jun. 15, 2017), available at <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612019.htm>.

culminating in the FDA's 2017 Digital Health Innovation Action Plan. After years of pushing Congress and the agency to think creatively about digital health, we can now evaluate these experiments in light of the unique challenges of digital health oversight.

I. EVERYTHING'S OLD!

A. FDA's Traditional Approach to Software Regulation

For roughly 40 years, the FDA has regulated computerized medical devices under a framework established by the 1976 Medical Device Amendments.⁴ Despite Congress's longstanding interest in computerized medicine,⁵ it went decades without passing legislation to clarify the FDA's role in reviewing dramatic new advances in medical computing.⁶ Thus, during a profound computer revolution, the FDA has been both blessed and cursed with significant discretion in how to adapt the 1976 statutory framework to computer hardware and software products. Eventually, of course, the health industry introduced new technologies that few could have imagined in 1976.⁷ Of course, all statutes age with time. But rapid technological advances in both computing and the biosciences only accelerated the aging process of the 1976 Medical Device Amendments.

Despite being given wide latitude, the FDA's interest in regulating software has been reluctant, until very recently. Indeed, the agency's posture toward software has been halting and sporadic.⁸ It began in the 1970s, when the FDA approved applications for a certain computerized products, such as cardiac pacemaker programmers, patient monitors, and magnetic resonance imaging (MRI) machines.⁹ In the 1980s, FDA contemplated crafting more comprehensive rules, creating a Task Force on Computers and Software as Medical Devices in 1981, and a Program Management Committee on Software and Computerized

4. Pub. L. No. 94-295, 90 Stat. 539, 94th Cong. (1976), *codified as amended* at 21 U.S.C. §§ 301 *et seq.*

5. *See, e.g.*, Computers in Health Care: Hearing Before the Subcomm. on Domestic and International Scientific Planning, Analysis, and Cooperation of the H. Comm. on Science and Technology, 95th Cong. (1978); Health Information Systems: Hearing Before the Subcomm. on Science, Research, and Technology and Subcomm. on Natural Resources, Agricultural Research, and Environment of the H. Comm. on Science and Technology, 97th Cong. (1981); *see also* Nathan Cortez, *Analog Agency in a Digital World*, in *FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES* 438, 442-43 (2015).

6. Cortez, *Analog Agency*, *supra* note 5, at 442-43.

7. *See, e.g.*, Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173 (2014).

8. Cortez, *Analog Agency*, *supra* note 5, at 443-47.

9. Information Technologies in the Health Care System: Hearing Before the Subcomm. on Investigations and Oversight of the H. Comm. on Science and Technology, 99th Cong. (1986).

Devices in 1984.¹⁰ The decade culminated with FDA publishing a *Draft Policy for the Regulation of Computer Products* in 1987 and then an update in 1989.¹¹

In the 1990s, the FDA again hinted that it was considering comprehensive rules tailored to software devices, but never proposed them.¹² In 2005, the FDA unceremoniously withdrew its 1989 *Draft Policy* without comment.¹³ In 2011, the agency explained that it had never published an “overarching software policy” because “the use of computer and software products grew exponentially and the types of products diversified and grew more complex.”¹⁴ Thus, as the technology raced forward, the FDA moved very little—insisting that the 1976 device framework could be adapted to software devices.

This tailoring happened through the FDA’s relatively narrow, piecemeal rulemaking, product reviews, and publication of guidance. Together, these discrete acts gradually articulated the FDA’s expectations for software devices. For example, Title 21 of the *Code of Federal Regulations* includes dozens of sections that reference software, though the vast majority refer to specific device classifications;¹⁵ few establish broad rules for software devices.¹⁶ Software is given specific attention in the Quality Systems Regulation (QSR) and in rules for radiology products.¹⁷ Otherwise, FDA regulations establish almost no broadly applicable, binding rules for software devices distinct from non-software devices.¹⁸

Without decisive rules, most of the FDA’s action on software has been in individual product reviews and guidance. For example, the agency has cleared numerous software devices through its 510(k) notification process, which declares that a product is “substantially equivalent” to a predicate device already on the market.¹⁹ The agency has cleared hundreds of digital health products, but has been criticized for declaring that novel digital and mobile technologies are substantially equivalent to older devices that were introduced well before smartphones even existed.²⁰ The FDA can also clear products that are not

10. Cortez, *Analog Agency*, *supra* note 5, at 444.

11. 52 Fed. Reg. 36104 (Sep. 25, 1987); U.S. FOOD & DRUG ADMIN., DRAFT POLICY FOR THE REGULATION OF COMPUTER PRODUCTS (Nov. 13, 1989), *available at* 1989 WL 1178702.

12. Cortez, *Analog Agency*, *supra* note 5, at 443-44.

13. 70 Fed. Reg. 824, 890 (Jan. 5, 2005).

14. U.S. Food and Drug Administration (FDA), Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications, 76 Fed. Reg. 43689 (Jul. 21, 2011).

15. *See, e.g.*, 21 C.F.R. parts 862-92.

16. Cortez, *Analog Agency*, *supra* note 5, at 445.

17. *See*, 21 C.F.R. parts 1000-1050, 820.

18. Cortez, *Analog Agency*, *supra* note 5, at 445.

19. FDCA § 510(k); 21 U.S.C. § 360(k).

20. *See, e.g.*, Cortez et al., *FDA Regulation of Mobile Health Technologies*, 371 NEW. ENG. J. MED. 372, 375 (2014).

substantially equivalent to a predicate through a *de novo* classification under section 513 of the Act.²¹ For example, in September 2018 the FDA granted Apple’s request for *de novo* classification of an electrocardiogram (ECG) software application on the Apple Watch that can detect atrial fibrillation and other arrhythmias.²²

The most striking feature of the FDA’s traditional approach to software is its heavy reliance on nonbinding guidance. For example, the agency addresses premarket submissions, software design controls, cyber security, and a host of other topics on software devices through twenty-six guidance documents.²³ These guidances are supplemented by dozens more that assign “special controls” to Class II, so-called “moderate risk” devices (Class I are “low risk” while Class III are “high risk”).²⁴ Moreover, the FDA’s own guidances are built on a scaffolding of even more nonbinding guidances published by standard-setting groups like the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).²⁵

Thus, the story of the FDA’s traditional approach to software is one of the agency clarifying how a regulatory framework established in 1976 applies to devices of ever-increasing novelty, complexity, and sophistication.

B. Updating for Digital Health

The FDA began articulating regulatory expectations for digital health products in 2011, when it published a *Draft Guidance on Mobile Medical Applications*.²⁶ That same year, FDA down-classified a related but relatively mundane category of software, known as “medical device data systems,” from Class III to Class I.²⁷ (Typically, high-risk Class III devices require pre-market

21. FDCA § 513; 21 U.S.C. § 360c.

22. Letter to Donna-Bea Tillman and Apple, Inc. from Angela C. Krueger, Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Admin. (FDA) of Sep. 11, 2018, available at https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf.

23. Cortez, *Analog Agency*, *supra* note 5, at 446-47 (finding 26 separate guidance documents—including 15 original and 11 updated versions—published by FDA on software devices as of 2015). In 2018, undoubtedly, there are many more, although this author has not updated this accounting. However, the FDA does helpfully include a link to all “Guidances with digital health content.” FDA, Guidances with Digital Health Content (Mar. 8, 2018), at <https://www.fda.gov/MedicalDevices/DigitalHealth/ucm562577.htm>.

24. *Id.* at 447.

25. Cortez, *The Mobile Health Revolution?*, *supra* note 7, at 1223.

26. U.S. Food and Drug Admin. (FDA), Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications, 76 Fed. Reg. 43689 (Jul. 21, 2011) (hereinafter “MMA Draft Guidance”).

27. This down-classification focused on medical device data systems (MDDS), which transfer, store, or convert device data, or display device data, without controlling medical devices themselves. The agency re-classified such devices from Class III to Class I. See FDA, Medical

approval (PMA) applications be approved by FDA, while low-risk Class I devices can enter the market through mere 510(k) notifications, unless they are exempt.) The 2011 *MMA Draft Guidance* represented a major statement on the FDA's interest in digital health. The document was a rather rudimentary primer on which digital health products might fall under FDA jurisdiction and which ones might not.²⁸ From the beginning, the agency has declined to exercise jurisdiction over low-risk digital health products like health trackers or programs that merely provide generalized medical information. Instead, the *MMA Draft Guidance* said the FDA's risk-based approach would focus on digital health products that offered "patient-specific analysis and . . . patient-specific diagnosis, or treatment recommendations."²⁹ The *MMA Draft Guidance* received significant attention from the tech industry,³⁰ which understood the importance of a federal agency like the FDA announcing its focused attention on digital health, even if most signals pointed to a quite sympathetic regulator.³¹ In 2013, FDA finalized the guidance based on public workshops and other feedback.³²

Meanwhile, just as the FDA contemplated how to adapt its relatively old regulatory framework to relatively novel digital health technologies, Congress began pushing regulators to consider new frameworks. In 2012, Congress passed the FDA Safety and Innovation Act (FDASIA), which called for the FDA, the Federal Communications Commission (FCC), and the Office of National Coordinator for Health IT (ONC) to recommend a "risk-based regulatory framework" for health IT products, including mobile and digital devices.³³ The resulting report, published in 2014, called for the FDA to maintain its rather circumscribed approach to health IT products and regulate only a very limited subset.³⁴ Although the report recommended that the ONC create a new Health IT Safety Center focused on quality control, the Center would have functioned mostly to centralize expertise and best practices rather than serve as a traditional regulator capable of enforcing requirements.³⁵

Devices; Medical Device Data Systems, 76 Fed. Reg. 8637 (Feb. 15, 2011).

28. See *MMA Draft Guidance*, at *supra* note 26.

29. *Id.*

30. See, e.g., Brian Dolan, *FDA Drafts Mobile Medical App Regulations*, MOBIHEALTHNEWS (Jul. 19, 2011), at <https://www.mobihealthnews.com/11970/fda-drafts-mobile-medical-app-regulations>.

31. Nathan Cortez, *The FDA Needs to Regulate "Digital Snake Oil,"* SLATE.COM (Sep. 24, 2013), at <https://bit.ly/2xQo2EJ>.

32. FDA, *Mobile Medical Applications; Guidance for Industry and Food and Drug Administration Staff*, 78 Fed. Reg. 59038 (Sep. 25, 2013).

33. Pub. L. No. 112-144 § 618, 112th Cong. 2012, 126 Stat. 993, 1063.

34. FDASIA HEALTH IT REPORT (Apr. 2014), at <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>.

35. *Id.* at 14-16; Nathan G. Cortez, I. Glenn Cohen, & Aaron S. Kesselheim, *FDA Regulation*

Furthermore, between 2012 and 2014, Congress considered a series of bills that sponsors hoped would better guide both the FDA and the digital health industry.³⁶ Finally, in 2016, at the twilight of the Obama administration, Congress passed the 21st Century Cures Act,³⁷ perhaps most well-known for relaxing drug approval standards.³⁸ The Cures Act included a section titled “Clarifying Medical Software Regulation.”³⁹ But rather than modernize the FDA’s framework for regulating software devices in light of the nascent digital health revolution, Congress merely tried to clarify FDA jurisdiction over software. For example, the Cures Act added new section 360j(o) to the federal Food, Drug, and Cosmetic Act (FDCA), clarifying that “devices” subject to FDA jurisdiction would exclude “health software,” or programs used for administrative, lifestyle, or patient record purposes.⁴⁰ Such “health software” would also include some clinical decision support (CDS) software—though the line between CDS subject to FDA jurisdiction and CDS outside it remains murky, as it has for decades.⁴¹

Elsewhere, the Cures Act sent important signals to the FDA. First, notwithstanding the statutory carve-out for “health software,” the Act gives FDA discretion to regulate software that it finds to be “reasonably likely to have serious adverse health consequences.”⁴² Second, Congress reminded the FDA to impose the “least burdensome” requirements in reviewing premarket submissions,⁴³ echoing earlier calls from Congress,⁴⁴ and even the agency’s own early statements on software some 30 years earlier.⁴⁵

Despite these efforts by Congress and the FDA, observers continued to note

of Mobile Health Technologies, 371 N. ENG. J. MED. 372, 377 (2014).

36. Cortez et al., *FDA Regulation of Mobile Health Technologies*, *supra* note 20, at 375-76 (describing proposed legislation).

37. Pub. L. No. 114-255 § 3060, 130 Stat. 1033, 1130, 114th Cong. (2016).

38. Aaron S. Kesselheim & Jerry Avorn, *New “21st Century Cures” Legislation: Speed and Ease vs. Science*, 317 JAMA 581 (2017).

39. Pub. L. No. 114-255 § 3060.

40. *Id.* (codified at 21 U.S.C. § 360j(o)).

41. A long-time critic of the FDA’s unclear position on CDS is Brad Thompson from Epstein Becker Green, who created the CDS Coalition to focus on drawing the appropriate line between regulated and non-regulated CDS products. See CDS Coalition, About Us, at <http://cdscoalition.org/about-us/>.

42. Pub. L. No. 114-255 § 3060(a), *codified at* 21 U.S.C. § 360j(o)(3)(A)(i).

43. Pub. L. No. 114-255 § 3058.

44. See, e.g., Food and Drug Administration Modernization Act (FDAMA), Pub. L. No. 105-115, 105th Cong. § 513 (1997) (calling for the FDA to consider the “least burdensome” ways to evaluate device effectiveness and substantial equivalence).

45. 1986 Hearing, *supra* note 1 (promising to impose “the minimum level of regulatory control necessary” on software). See also Nathan Cortez, *Analogy Agency in a Digital World*, in *FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES* 438, 450 (2015).

the disconnect between an increasingly dated regulatory framework and the increasingly sophisticated digital health technologies being introduced to the U.S. market.⁴⁶ A collective notion began to emerge that digital health required something *new*. Indeed, Scott Gottlieb, writing before he became FDA Commissioner in 2017, critiqued the FDA’s approach to digital health products in *Forbes* (“Why Apple Dumbs Down Your Smartphone”) and *The Wall Street Journal* (“Why Your Phone Isn’t as Smart as It Could Be”), arguing that fear of, and uncertainty over, potential FDA regulation stifled innovation.⁴⁷ The FDA, in its own words, has repeated the notion that the 1976 device framework “is not well suited for software-based technologies.”⁴⁸

Meanwhile, some in the digital health industry grew frustrated with lingering confusion over the boundaries of FDA jurisdiction. Indeed, the FDA estimated that it had responded to over 900 inquiries since 2013 about its policies for digital health.⁴⁹ Some developers seemed deterred by potential FDA oversight of their products. Less scrupulous developers tried to avoid FDA oversight with disclaimers that their products were merely “recreational” or “informational” and thus did not aim to diagnose, cure, mitigate, treat, or prevent diseases or other conditions.⁵⁰ More serious developers submitted premarket notifications for FDA review, but grew impatient with what they saw as protracted FDA review cycles, particularly as compared to relatively short product life cycles.⁵¹ Meanwhile,

46. See, e.g., Cortez, *The Mobile Health Revolution?*, *supra* note 7; Cortez et al., *FDA Regulation of Mobile Health Technologies*, *supra* note 20; Nicolas P. Terry, Mobile Health: Assessing the Barriers, 147 CHEST 1429 (2015); W. Nicholson Price, *Black Box Medicine*, 28 HARV. J. L. & TECH. 419, 457-62 (2015); Fazal Khan, *The “Uberization” of Healthcare: The Forthcoming Legal Storm over Mobile Health Technology’s Impact on the Medical Profession*, 26 HEALTH MATRIX 123 (2016); W. Nicholson Price, *Regulating Black Box Medicine*, 116 MICH. L. REV. 421 (2017); Rachel E. Sachs, *Mobile Health Innovation and Interagency Coordination*, 26 ANNALS HEALTH L. 1 (2017); Nathan Cortez, *Substantiating Big Data in Health Care*, 14 I/S: A JOURNAL OF LAW AND POLICY FOR THE INFORMATION SOCIETY 61 (2017); Efthimios Parasidis, *Clinical Decision Support: Elements of a Sensible Legal Framework*, 20 J. OF HEALTH CARE L. & POL’Y 183 (2018).

47. Scott Gottlieb, *Why Apple Dumbs Down Your Smartphone*, FORBES (Dec. 4, 2015), at <https://www.forbes.com/sites/scottgottlieb/2015/12/04/why-apple-dumbs-down-your-smartphone/>; Scott Gottlieb & Coleen Klasmeier, *Why Your Phone Isn’t as Smart as It Could Be*, WALL ST. J. (Aug. 7, 2014), at <https://www.wsj.com/articles/scott-gottlieb-and-coleen-klasmeier-why-your-phone-isnt-as-smart-as-it-could-be-1407369163>.

48. Jeffrey Shuren, Bakul Patel, & Scott Gottlieb, *FDA Regulation of Mobile Medical Apps*, JAMA E1 (Jul. 2, 2018); FDA, *Developing a Software Precertification Program: A Working Model v0.1* (Apr. 2018), at <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/ucm605685.pdf>.

49. U.S. Food and Drug Administration, *Digital Health Innovation Action Plan* at 3 n.4 (June 2017), at <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf>.

50. See, e.g., Cortez, *The Mobile Health Revolution?*, *supra* note 7, at 1187-88.

51. Nathan G. Cortez, Nicolas P. Terry, & I. Glenn Cohen, *Questions About the FDA’s New*

attorneys and consultants openly advised the industry “How to Avoid FDA Regulation of Your Mobile Medical App.”⁵²

Moreover, the users of digital health—patients, physicians, and others—still lack reliable guarantees that the products on the market do what they claim. The sheer volume and variety of digital health products make it daunting for users to select reliable products from among dozens or perhaps even hundreds of options. Even physicians, nurses, and others with medical training struggle to evaluate the flood of digital health products.⁵³ Although the FDA has cleared well over 100 mobile health products through its 510(k) process as of 2016,⁵⁴ there were roughly 165,000 health-related programs available for Apple and Android devices that same year, with 1.7 billion downloads estimated for 2017.⁵⁵

The void left by lax FDA premarket oversight has been filled to various degrees. For example, the FTC has brought some high-profile enforcement actions against digital health products claiming to treat ADHD in pediatric populations, detect melanomas, measure blood pressure, or improve vision—all without sufficient scientific support.⁵⁶ Alternative methods of screening are being performed by (i) venture capital firms that are sophisticated in the biosciences, which may pass on investments without data supporting their claims, (ii) hospitals creating guidelines for users and developers, which establish ground rules for selecting reliable products, (iii) third-party app review web sites, many of which try to review the evidence base supporting a product, and (iv) health insurers establishing coverage policies, which determine the technologies that warrant reimbursement.⁵⁷ I call these “surrogate” or “proxy” forms of regulation of digital health—less centralized alternatives that have emerged in the absence of robust FDA oversight.⁵⁸ Each has obvious shortcomings. None can replace meaningful FDA premarket review.

In summary, the legal and regulatory landscape is shifting during what

Framework for Digital Health, HEALTH AFF. BLOG (Aug. 16, 2017), at <https://www.healthaffairs.org/doi/10.1377/hblog20170816.061554/full/>.

52. Keith Barritt, *How to Avoid FDA Regulation of Your Mobile Medical App*, Med. Device Online (Jul. 7, 2015).

53. Nathan Cortez, *The Evolving Law and Ethics of Digital Health*, in *DIGITAL HEALTH: SCALING HEALTHCARE TO THE WORLD* 249, 262 (Homero Rivas & Katarzyna Wac, eds. 2018)

54. See, FDA, *Examples of Pre-Market Submissions that Include MMAs Cleared or Approved by FDA*, at <https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368784.htm>.

55. Research 2 Guidance, *Global Mobile Health Market Report 2013-2017* (Mar. 2013), at <https://research2guidance.com/the-market-for-mhealth-app-services-will-reach-26-billion-by-2017/>.

56. Cortez, *Substantiating Big Data in Health Care*, *supra* note 46, at 74.

57. Nathan Cortez, *The Evolving Law and Ethics of Digital Health*, in *DIGITAL HEALTH: SCALING HEALTHCARE TO THE WORLD* 249 (Homero Rivas & Katarzyna Wac, eds. 2018).

58. *Id.* at 262.

seems to be a pivotal moment for digital health. Recent high-profile stumbles by companies like 23andMe and Theranos should remind us that medical technologies require more substantiation and evidence base than other products and services.⁵⁹ Thus, the lingering challenge remains: What evidence do we require when digital health products hit the market? And when should such evidence be due—before or after market entry? The FDA, responding to calls to create a more tailored approach, is offering some novel alternatives, which I turn to next.

II. EVERYTHING’S NEW! THREE EXPERIMENTS IN MEDICAL PRODUCT REGULATION

In 2017, the FDA announced its Digital Health Innovation Action Plan,⁶⁰ declaring that the agency was “reimagining its approach to digital health medical devices”⁶¹ and introducing an “entirely new” and “comprehensive approach.”⁶² The agency itself acknowledged that its new approach was animated by the disconnect between an aging regulatory framework and increasingly novel devices: “FDA’s traditional approach to moderate and higher risk hardware-based medical devices is not well suited for faster iterative design, development, and type of validation used for software-based medical technologies.”⁶³

The Digital Health Innovation Action Plan introduces three important experiments in medical product regulation for the FDA. First, the agency is shifting its focus from pre-market to post-market evidence gathering. Second, the agency is shifting from product-level reviews to firm-level reviews. And third, the agency is shifting from governmental to non-governmental decisionmakers as it introduces the new Software Precertification Program. Each represents a

59. See, e.g., Cortez, *Substantiating Big Data in Health Care*, *supra* note 46; JOHN CARREYROU, *BAD BLOOD: SECRETS AND LIES IN A SILICON VALLEY STARTUP* (2018) (detailing how Theranos repeatedly attempted to mislead investors, inspectors from the FDA and CMS, and even its own employees about the capabilities of its blood-testing products); Warning Letter from James L. Woods, FDA Office of In vitro Diagnostics and Radiological Health to Ann Wojcicki of 23andMe, Inc. of Nov. 22, 2013, available at <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm> (detailing how 23andMe was marketing its direct-to-consumer genetic testing products without FDA approval or clearance as medical devices).

60. U.S. Food and Drug Administration, Digital Health Innovation Action Plan (June 2017), at <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf>.

61. *Id.* at 5.

62. Scott Gottlieb, Commissioner of Food and Drugs, *Fostering Medical Innovation: A Plan for Digital Health Devices* (Jun. 15, 2017), at <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612019.htm>; Scott Gottlieb, Commissioner of Food and Drugs, *FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare* (Jul. 27, 2017), at <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612014.htm>.

63. *Id.* at 2.

significant departure from the FDA’s longstanding approach to regulating medical products, which for decades has centered on pre-market evaluation of evidence for a specific product, performed by the agency itself. Thus, the new framework is a bold departure from the FDA’s historical role as a gatekeeper for medical products.⁶⁴ And, arguably, there is not clear statutory authority for these shifts in the Food, Drug, and Cosmetic Act (FDCA), even as amended by recent bills like FDASIA and the 21st Century Cures Act.⁶⁵ Although these experiments certainly are welcome, they should be evaluated by their ability to generate reliable evidence of safety and efficacy, and their ability to facilitate high-quality innovation and deter low-quality innovation in the digital health industry.⁶⁶

A. Pre-Market to Post-Market

The FDA’s first experiment with digital health is what the agency calls a “novel” shift from pre-market to post-market oversight.⁶⁷ FDA will exempt “lower risk” digital health devices from pre-market review altogether, and then streamline reviews for “higher risk” digital health products offered by precertified firms. The FDA also has floated the idea of using “phased” or “preliminary” market authorization by which it would review some elements premarket and others post.⁶⁸ Software products offered by precertified companies either will receive streamlined FDA review or no review at all, depending on: (i) the risk presented, from non-serious, to serious, to critical; (ii) the significance of the information generated to health care decision decisionmaking, from merely informing clinical management, to driving such management, to outright treating or diagnosing directly; and (iii) the nature of the introduction, from minor changes, to major changes, to initial introduction of the product.⁶⁹ Thus, the FDA

64. See, e.g., DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 544-584 (2010) (describing this dynamic with regard to pharmaceuticals).

65. Recently, several Senators also made this argument. See Letter from Sen. Elizabeth Warren, Sen. Patty Murray, & Sen. Tina Smith to Scott Gottlieb, FDA Commissioner, and Jeffrey Shuren, Director of the FDA Center for Devices and Radiological Health of Oct. 10, 2018 (pp. 3-4).

66. Cortez et al., FDA Regulation of Mobile Health Technologies, *supra* note 20; Price, *Regulating Black Box Medicine*, *supra* note 46, at 455; Parasidis, *supra* note 46, at 193.

67. Gottlieb, *Fostering Medical Innovation*, *supra* note 62.

68. U.S. Food and Drug Administration, Challenge Questions, at <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/ucm605686.pdf>. As the Senators point out in their letter, *supra* note 65, “the FDA has stated that conditional approval—a regulatory pathway for certain animal drugs that allows these products to be legally marketed for a period of time . . . while the company continues to collect efficacy data—is not appropriate for human medical products, including SaMDs [Software as a Medical Device].”

69. FDA, *Developing a Software Precertification Program*, *supra* note 48, at 10.

proposes to shift its attention away from premarket evaluation of evidence to post-market evaluation of evidence, a marked departure for the agency.

Moreover, in line with the 21st Century Cures Act, the FDA will rely on “post-market collection of real-world data” to review new functions for digital health products already on the market. This effort will rely on data from the National Evaluation System for Health Technology (NEST), an FDA-led effort to collect “real-world evidence” across a product’s entire life cycle and evaluate it using “advanced analytics.”⁷⁰ NEST was originally envisioned as a tool for post-market surveillance, but is being utilized to support the FDA’s “pre- and postmarket regulatory decisions.”⁷¹ For example, the agency envisions that real-world evidence gathered by NEST could be used to support petitions for reclassification under section 513 of the Act.⁷² The shift from pre- to post-market oversight and evidence collection accommodates the short lifecycles and relatively low risk profiles of many digital health technologies.

Nevertheless, this is an important departure from longstanding FDA precedent and should be evaluated as an experiment. Will this new framework generate reliable data? How many products that turn out not to be as safe and effective as preliminary evidence suggested will be removed from the market? How much will the new framework change developer incentives to generate reliable data regarding safety and efficacy? Will post-market data expectations be enforced? One could imagine a world in which these questions are answered satisfactorily. But one could just as easily imagine a world in which they aren’t. What happens then?

B. Product to Firm

Second, the FDA is experimenting with firm-level review in lieu of product-level review through a new Software Precertification Pilot Program. Companies that are “pre-certified” will enjoy a quicker pathway to market for their products. The FDA explains that precertification will “provide more streamlined and efficient regulatory oversight of software-based medical devices developed by manufacturers who have demonstrated a robust culture of quality and

70. *Id.* at 5.

71. FDA, National Evaluation System for Health Technology (NEST), at <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm301912.htm>; FDA, Guidance for Industry and Food and Drug Administration Staff: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (Aug. 31, 2017), at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf>.

72. FDA, Use of Real-World Evidence, *supra* note 71, at 10.

organizational excellence, and who are committed to monitoring real-world performance of their products once they reach the U.S. market.”⁷³ The goal is to reward precertified companies by giving their products “a streamlined, less-burdensome” premarket review process or allowing them to bypass it altogether.⁷⁴ The pilot will first apply to software as a medical device (SaMD), then perhaps to software in a medical device (SiMD).⁷⁵ Precertification will be granted to companies that satisfy five criteria: patient safety, product quality, clinical responsibility, cyber security responsibility, and proactive culture.⁷⁶ In September 2017, the FDA selected nine companies for the Precertification Pilot: Apple; Fitbit; Johnson & Johnson; Pear Therapeutics; Phosphorus; Roche; Samsung; Tidepool; and Verily.⁷⁷ During the pilot, the agency is soliciting public comments on its design and performance.⁷⁸

Streamlined review for the products of precertified companies would depend on data already submitted to the agency as part of the precertification process, as well as additional information about “product performance, clinical association between [product] output and a clinical condition, and safety measures.”⁷⁹ The agency and company would then continue to collect “real-world performance data,” including user experience, software performance information, and clinical outcomes—gathered post-market.⁸⁰

Of course, at the time of this writing, important details remain in flux. An early model of the precertification program proposed by the FDA would allow even moderate- or high-risk devices offered by precertified companies to be eligible for streamlined review.⁸¹ The FDA also seems to be contemplating expanding eligibility for precertification to all companies, not just the ones with prior experience marketing medical devices in the United States, as suggested earlier by the agency.⁸² The details here are important—how *much* of a shift from product- to firm-level scrutiny will occur. And how much of a privileged or elevated position will precertified firms enjoy? Will precertification status ever be meaningfully reevaluated or revoked?

73. FDA, Digital Health Software Precertification (Pre-Cert) Program, at <https://www.fda.gov/MedicalDevices/DigitalHealth/UCM567265>.

74. FDA, Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program, 82 Fed. Reg. 35216 (Jul. 28, 2017).

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

81. FDA, Developing Software Precertification Program: A Working Model (v0.2 – June 2018), 13 (June 2018), available at <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf>.

82. Letter from Sen. Elizabeth Warren et al., *supra* note 65, at 5.

On a related front, the FDA also promises a “new approach to the review of artificial intelligence,” applying pre-certification to AI so that certain certified companies can make “minor changes to [their] devices without having to make submissions each time.” Indeed, in April 2019, FDA published its *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device*, seeking public feedback.⁸³

Again, a shift from product- to firm-level review is relatively uncharted territory for the agency. The experiment will test whether firm-level characteristics such as company culture, in-house expertise, and experience can better predict product reliability and performance than product-level characteristics that are typically the focus of FDA reviews. This is a worthwhile experiment, so long as it is evaluated critically as an experiment.

C. Government to Non-Government

Third, the FDA is experimenting with reviews by independent, non-governmental certifiers. A longstanding observation is that the FDA historically has lacked the internal expertise and resources to give in-depth reviews to sophisticated medical software.⁸⁴ An early expert on medical device software observed in 1986 that “even in the best of faith, with the best of will, the best of technology, the best of intentions,” the FDA could not adequately regulate software based on the 1976 Device Amendments.⁸⁵ Although the agency has made significant advances on this front, it is still overwhelmed by the volume and variety of digital health technologies.

In this spirit, the FDA has created a new Digital Health Unit,⁸⁶ as well as a new program called “Information Exchange and Data Transformation” (INFORMED), which will conduct regulatory science research to support the FDA’s new initiatives.⁸⁷ The program will rely on the “software as a medical device” (SaMD) framework developed through the FDA’s work with the

83. FDA, Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD), Apr. 2, 2019, at <https://www.regulations.gov/contentStreamer?documentId=FDA-2019-N-1185-0001&attachmentNumber=1&contentType=pdf>.

84. See, e.g., Kevin Fu, “Trustworthy Medical Device Software,” Institute of Medicine Workshop on the FDA’s 510(k) Clearance Process at 35 Years (2011); Cortez, Analog Agency, *supra* note 5, at 444-45.

85. 1986 Congressional Hearing, *supra* note 1 (Statement of Vincent Brannigan).

86. Zachary Brennan, *FDA to Create Digital Health Unit*, REGULATORY FOCUS (May 4, 2017), at <https://www.raps.org/regulatory-focus/news-articles/2017/5/fda-to-create-digital-health-unit>.

87. FDA, Information Exchange and Data Transformation (INFORMED), <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/oce/ucm543768.htm>

International Medical Device Regulators Forum (IMDRF), an international consortium of device regulators. Thus, even as the FDA continues to build its internal capacities on digital health, it will nevertheless experiment with outsourcing to third-party certifiers. As a result, new digital health devices could be introduced to market “without FDA ever reviewing either the medical device software developed by a company or the company itself.”⁸⁸

The use of non-FDA certifiers is a genuine innovation at the agency (although, to be fair, the FDA relies on advisory panels and the like for new drug reviews). But it is not an innovation outside the agency. Numerous other federal programs rely on third-party certifications or appraisals. A well-known example in the health industry is hospital accreditation by the Joint Commission. The Medicare statute provides that any hospital accredited by the Joint Commission is “deemed” to comply with Medicare’s extensive “conditions of participation.”⁸⁹ In early documents, the FDA describes its third-party precertification process as involving four steps: (i) an initial application; (ii) an appraisal by the third-party certifier; (iii) a determination by the FDA; and (iv) maintenance of the certification through “automated and manual analysis” of continued compliance with the standards.⁹⁰ This process roughly follows the application-appraisal-determination process used by the Joint Commission. The FDA explains that maintaining precertification status will involve automated review of “objective evidence” made available to the FDA.⁹¹ Automated review itself raises a host of questions, although again these features remain in flux during the pilot program.

IV. EVALUATING THE EXPERIMENT

The FDA’s experiments with digital health are really experiments in medical product regulation, itself a form of risk regulation. Drugs, devices, and biologics do not enter the U.S. market without a determination—direct or indirect—that their benefits outweigh their risks. For decades, the lodestar of medical product regulation has been premarket review, with the FDA serving as an expert gatekeeper evaluating clinical data to determine whether products are safe and effective for their intended uses.⁹² Even for medical devices, 99% of which are *cleared* through the 510(k) *notification* process rather than being *approved* through the premarket approval (PMA) process,⁹³ the FDA plays a gatekeeping

88. Letter from Sen. Elizabeth Warren et al., *supra* note 65, at 5.

89. 42 C.F.R. § 482.22 (2018).

90. FDA, Developing a Software Precertification Program, *supra* note 48, at 6.

91. *Id.* at 7.

92. *See generally* CARPENTER, *supra* note 64.

93. INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS (Jul. 29, 2011), <http://www.nationalacademies.org/hmd/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35->

role: determinations of “substantial equivalence” that are key to the 510(k) process often depend on subsidiary questions that touch on the product’s underlying ratio of benefits to risks.

Now, this gatekeeping function has been relaxed for digital health products. This part thus identifies a series of important questions we should consider as these experiments move forward.

A. Evidence and Incentives?

A core feature of FDA regulation of medical products is its gatekeeping authority over market entry.⁹⁴ The government’s leverage in this scheme encourages companies to produce more and better information about their products than they otherwise would absent FDA premarket review. Thus, when evaluating the FDA’s new approach to digital health, we should consider the extent to which it alters manufacturer incentives to generate reliable data regarding the safety and efficacy of their products. How will the new system compare to the existing 510(k) system (which itself has been criticized for generating insufficient data)? When should such data be generated—before market introduction or after? And what *types* of data should we expect?

Now might be the time to consider appropriate standards for demonstrating efficacy in digital health products, particularly those that rely on predictive analytics. For example, the FDA should encourage developers to identify clinically-relevant endpoints that can help demonstrate a product’s clinical benefit.⁹⁵ Although measurements like overall survival might prove difficult for digital health products, other surrogate endpoints might correspond to meaningful clinical benefits, provided they are subject to rigorous validation.⁹⁶ Moreover, the FDA should consider current clinical practices as a valid benchmark—is the digital health product inferior when compared to clinician performance?⁹⁷ We should not necessarily expect digital health products to be perfect, or even obviously superior to clinicians, but at the very least they should not be inferior.⁹⁸

Years.aspx.

94. *See, e.g.,* CARPENTER, *supra* note 64, at 544-84 (discussing how this gatekeeping authority over drugs, for example, has extended FDA’s influence over medical research itself).

95. *See, e.g.,* Ravi B. Parikh, Ziad Obermeyer, & Amol S. Navathe, *Regulation of Predictive Analytics in Medicine*, 363 *SCIENCE* 810 (2019).

96. *Id.*

97. *Id.*

98. *Id.* For example, the FDA recently cleared a convolutional neural network that is able to predict stroke more rapidly than neuroradiologists. *See* FDA, Office of the Commissioner, Press Announcements: FDA Permits Marketing of Clinical Decision Support Software for Alerting Providers of a Potential Stroke in Patients (Feb. 13, 2018), at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm596575.htm>.

Given the proposed shift from pre-market to post-market review, the users and payers that rely on digital health products introduced under the new system may still lack reliable evidence that the products work as intended. Of course, compared to the current system in which very few digital health products either seek or obtain 510(k) clearance, that is undoubtedly already the case. Nevertheless, the concern is that over the long term, the lack of reliable evidence may depress demand and thus adoption of digital health products.⁹⁹ The fact that Apple and other well-known companies introduce products may spur adoption. But what of less familiar firms?

Consumer trust—or the lack thereof—is an important question for the digital health industry.¹⁰⁰ Users can easily be overwhelmed by the sheer volume and variety of digital health tools on the market, and even licensed practitioners will find it daunting to evaluate the benefits and risks of dozens (if not hundreds) of options. Thus, the FDA posits that its new “efficient regulation” of digital health products, particularly its precertification program, “can increase consumer confidence” in these technologies and “help patients, payers, and investors better understand” the products, thereby inducing a “race to the top” among developers.¹⁰¹ In an early document describing the agency’s precertification program, FDA says the program “is intended to drive market competition to higher standards of safety and effectiveness.”¹⁰² But it is not at all clear why the FDA’s precertification program will encourage a “race to the top.” It may encourage a race to precertify, for sure. But can we call precertification “the top”?

It depends. One method that might pair well with the new post-market approach is a mandatory reevaluation period at some specified interval—such as two or three years—as some foreign jurisdictions have contemplated.¹⁰³ Mandatory post-market reviews would preserve incentives to generate data regarding product performance. Weak incentives may undermine the delicate balance between pre- and post-market oversight that the new digital health approach aspires to achieve. The new precertification process is based on the idea that the FDA should trust certain manufacturers but verify performance,¹⁰⁴

99. 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).

100. Cortez, *The FDA Should Regulate Digital Snake Oil*, *supra* note 31.

101. Jeffrey Shuren, Bakul Patel, & Scott Gottlieb, *FDA Regulation of Mobile Medical Apps*, *JAMA* (Jul. 2, 2018).

102. FDA, *Developing a Software Precertification Program*, *supra* note 48, at 2.

103. *See, e.g.*, Daniel B. Kramer et al., *Ensuring Medical Device Effectiveness and Safety: A Cross-National Comparison of Approaches to Regulation*, 69 *FOOD & DRUG L.J.* 1 (2014).

104. FDA, *Developing a Software Precertification Program: A Working Model v0.1* (Apr. 2018), at 2.

recalling President Reagan’s “trust-but-verify” approach to Soviet nuclear disarmament.¹⁰⁵ But how rigorous will the “verify” step be? And if the verification process reveals shortcomings, what then? There should be real consequences, including de-certification and market withdrawals.

B. New Governance: Theory vs. Reality?

Long ago regulatory theorists became enamored with “new governance,” a set of alternative regulatory approaches that reject traditional command-and-control regulation, particularly its reliance on formal sanctions, in favor of more cooperative, decentralized, “soft law” approaches.¹⁰⁶ Advantages are supposed to include greater flexibility, transparency, responsiveness, cost-effectiveness, and even higher levels of compliance.¹⁰⁷ The FDA’s digital health experiments all sound in new governance.

But it remains to be seen whether and how the FDA may use traditional enforcement tools to buttress its more friendly, flexible approach to digital health. The voluminous literature on “new governance” once promised that more cooperative, flexible regulation would achieve better outcomes than more traditional, centralized regulation and enforcement.¹⁰⁸ But some of the gloss has worn off. Indeed, after the recent Boeing recall of its 737 Max aircraft, critics highlighted how the Federal Aviation Administration (FAA) had allowed Boeing to self-test and self-certify its new plane design and flight software.¹⁰⁹

Thus, the experiment with third-party precertification must win over skeptics that question its effectiveness. To cite a relevant example closer to home, the federal Office of National Coordinator for Health Information Technology (ONC) used a similar third-party certification process for determining whether electronic health records (EHR) met federal “meaningful use” requirements, but it produced underwhelming results.¹¹⁰ Similarly, an early effort by a third-party certifier called “Happtique,” designed to certify that mobile health applications

105. Barton Swaim, *An Untrustworthy Political Dictum*, WASH. POST. (Mar. 13, 2016).

106. I summarize some of this literature in Nathan Cortez, *Embracing the New Geography of Health Care: A Novel Way to Cover Those Left Out of Health Reform*, 84 S. CAL. L. REV. 859, 902-06 (2011) (citing articles).

107. *Id.* at 902.

108. *Id.*

109. Brian Naylor, *Boeing’s Not Alone in Companies That Government Agencies Have Let Self-Regulate*, NPR, All Things Considered (Apr. 2, 2019), available at <https://www.npr.org/2019/04/02/709203191/boeing-not-alone-in-companies-that-government-agencies-have-let-self-regulate>.

110. Erin McCann, *Many ONC-Certified EHRs Actually Fail to Meet Certification Standards*, HEALTHCARE IT NEWS (Sep. 9, 2015), at <https://www.healthcareitnews.com/news/onc-certified-ehrs-might-not-actually-be-certified>.

met certain privacy standards, was suspended after a researcher found blatant security lapses among programs that had been certified.¹¹¹ And, of course, in the broader health care sphere, third-party accreditors like the Joint Commission, which is responsible for accrediting hospitals for the Medicare program, have been criticized for rarely denying applications for accreditation and virtually never revoking them.¹¹²

This is not to say that third-party certification is necessarily doomed. Rather, the point is that it succeeds only with meaningful monitoring and enforcement. So-called “soft law” approaches, ironically, may only work well if reinforced with more traditional “hard law” backstops.

C. Clinical Decision Support?

Another important question that remains unanswered after decades of congressional acts and FDA guidance documents is how the FDA will treat clinical decision support (CDS) software. On one hand, the Cures Act exempts from FDA regulation “health software,” including most CDS programs. On the other hand, it authorizes FDA to regulate health software if the agency finds that it “would reasonably be likely to have serious adverse health consequences.”¹¹³ In making this finding, Congress directs the FDA to consider four factors: (i) the likelihood and severity of patient harm; (ii) the extent to which the software is intended to support the clinical judgment of a health professional; (iii) whether the health professional has a “reasonable opportunity . . . to review the basis” of the recommendation; and (iv) the intended user and environment.¹¹⁴

In a 2017 guidance, FDA explained that it will evaluate the third factor—whether health professionals have a “reasonable opportunity to review the basis” of software recommendations—based on how clearly the software

111. Brian Dolan, *Happtique Suspends Mobile Health App Certification Program*, MOBIHEALTHNEWS (Dec. 13, 2013), at <https://www.mobihealthnews.com/28165/happtique-suspends-mobile-health-app-certification-program>.

112. Timothy S. Jost, *Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?*, 57 LAW & CONTEMPORARY PROBS. 15, 39-40 (1994).

113. Cures Act, section 3060(a), *codified at* 21 U.S.C. 360j(o)(3)(A).

114. *Id.* The FDA also addresses “patient decision support” (PDS) software, which is designed for use by patients or caregivers who are not health care professionals. FDA guidelines exempt PDS software if it meets three criteria: (1) it is *not* intended to acquire, process, or analyze a medical image or signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, (2) it is intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information, such as information derived from peer-reviewed clinical studies or practice guidelines, and (3) it is intended for the purpose of supporting or making recommendations to a patient, in terms that are understandable to the patient, about preventing, diagnosing, or treating diseases or other conditions. *See* FDA, Draft Guidance: Clinical and Patient Decision Support Software (Dec. 8, 2017), at 6, available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819.pdf>.

explains: (i) the purpose or intended use of the software; (ii) the intended user (e.g., ultrasound technicians, vascular surgeons); (iii) the inputs used to generate the recommendation; and (iv) the rationale or support for the recommendation.¹¹⁵ Thus, decision support software will not be regulated as medical devices if they intended user is “able to reach the same recommendation on his or her own without relying primarily on the software . . .”¹¹⁶ The sources and inputs informing the recommendation, then, must be public and understandable to the intended user.¹¹⁷

These criteria resurrect a notion from the FDA’s 1987 Draft Software Guidance regarding “competent human intervention.”¹¹⁸ The 1987 guidance explained that FDA would exempt from regulation any artificial intelligence or decision support software that allowed ample time for “competent human intervention,” meaning time during which “clinical judgment and experience can be used to check and interpret a system’s output” before “any impact on human health.”¹¹⁹ Thus, the FDA asserted jurisdiction over decision support software that is opaque and used in circumstances where there is little opportunity for independently evaluating options. So software directing a nurse to “Inject Dose Now!” would be subject to regulation, while software recommending injections at specific intervals well in advance, with the opportunity for nurses to consider the appropriateness of those intervals, would not be subject to regulation.¹²⁰

Thus, the idea of drawing lines between decisionmaking that is primarily driven by automation and driven by professional judgment is an old one. But studies of human-computer interaction (HCI) show that we are dangerously predisposed to trust automated advice, even if we have the opportunity and reasons to question it.¹²¹ So-called “automation bias” leads us to believe that automated advice is resistant to errors or infallible, even when presented with reasons to believe otherwise.¹²² Indeed, automation bias remains a problem in aviation safety, a lesson we should heed in medicine.¹²³ Thus, in practice users are likely to trust automated advice without question, even if there is time for competent human intervention. Humans are busy and fallible, and we are likely to outsource decisionmaking to automation if the option is available.

115. FDA, Draft Guidance: Clinical and Patient Decision Support Software, *supra* note 114, at 8.

116. *Id.*

117. *Id.*

118. Draft Policy Guidance for Regulation of Computer Products, 52 Fed. Reg. 36,104.

119. *Id.*

120. See Cortez, *The Mobile Health Revolution?*, *supra* note 7, at 1220.

121. *Id.* at 1227-28.

122. Danielle Keats Citron, *Technological Due Process*, 85 WASH. U. L. REV. 1249, 1271-72.

123. See, e.g., Linda J. Skitka et al., *Automation Bias and Errors: Are Crews Better than Individuals?*, 10 INT’L J. AVIATION PSYCHOL. 85, 86 (2000).

These considerations deserve much more attention than they have received in the 21st Century Cures Act or in the FDA’s many guidances to date. The FDA has taken a thoughtful approach, to be sure. And drawing the line between CDS that should and should not be regulated is a difficult task, to be sure. But important questions remain.

D. Statutory Authority?

Finally, the FDA’s bold experiments with digital health do not find clear support in the statute, even after the 21st Century Cures Act. For example, an earlier version of the Cures Act authorized the FDA to craft a new regulatory framework, but the final bill omitted the provision.¹²⁴ The Cures Act that passed included more modest provisions defining “health software” as falling outside the definition of medical “devices.”¹²⁵ In fact, Commissioner Gottlieb’s announcement itself acknowledged that the FDA might not have clear statutory authority to introduce the third-party precertification program.¹²⁶ And an October 2018 letter from three senators to the FDA questioned the FDA’s statutory authority for creating a precertification program, for using “phased” or “conditional” approvals, and for using third-party reviews.¹²⁷

On the other hand, Congress repeatedly directs the FDA to use the least burdensome approach to reviewing medical devices,¹²⁸ and these experiments would seem to be in precisely that spirit. Of course, a “least burdensome” approach would have to be within statutory bounds—which is questionable at best. In the end, if the FDA’s experiments show some success, it is not inconceivable that the agency could convince Congress to codify its practices by statute—something the agency has a track record of achieving.¹²⁹ In that case, resolving the foregoing issues will go a long way toward convincing skeptics that these experiments with medical product regulation are superior to the FDA’s longstanding (but decidedly less exciting) approach.

V. MOVING FORWARD

Instead of a traditional conclusion, let me offer some thoughts on how to

124. *See, e.g.*, 21st Century Cures Act, H.R. 6, 114th Cong. (2015-16), at <https://www.congress.gov/bill/114th-congress/house-bill/6/text>.

125. *Id.* at § 618.

126. Gottlieb, *Fostering Medical Innovation*, *supra* note 62.

127. Letter from Sen. Elizabeth Warren et al., *supra* note 65, at 3-5.

128. *See, e.g.*, Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No. 112-144, § 602 (2012); Food and Drug Administration Modernization Act § 205(a)-(b), Pub. L. No. 105-115 (1997).

129. *See, e.g.*, Richard A. Merrill, *Modernizing the FDA: An Incremental Revolution*, 18 HEALTH AFF. 96 (1999).

move forward. The FDA's new plans for digital health should be viewed as experiments with medical product regulation, and should be evaluated as such. What data and substantiation should we require of digital health products *before* they hit the market, and how do we best preserve developer incentives to generate reliable data regarding safety and efficacy *after* products are on the market? Will third-party certifiers provide meaningful review? Will firm-level characteristics be a better proxy than product-level characteristics in predicting how useful and reliable digital health products are? If shortcomings become apparent, how will the new framework adapt? And will the FDA use hard law backstops such as de-certification, product withdrawals, and traditional regulatory enforcement (such as adulteration and misbranding actions) when, inevitably, problems do occur? Finally, how does the new framework compare with the old?

The tone of this article might suggest that these experiments are not worthwhile—which could not be further from the truth. The FDA's medical device framework has yellowed with time, and the FDA is taking bold moves to adapt its old framework to very new products in the absence of genuine congressional intervention. But hopefully these bold experiments will not calcify into a weak default approach that lingers for decades, as the FDA's 1987 and 1989 draft guidances on software did.¹³⁰ There are lessons to be learned from that tentative approach,¹³¹ if we chose to heed them. Now is the time to evaluate the FDA's experiments as experiments.

130. For an evaluation of this problem, see Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 173 (2014)

131. *Id.*; Cortez, *The Mobile Health Revolution?*, *supra* note 7.