A POLICY OF TRUST: SOFTWARE DEVELOPER PRECERTIFICATION AS A VIABLE SOLUTION TO PROTECT PATIENTS AND PROMOTE INNOVATION FOR 'mHEALTH' APPLICATIONS

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The number of mobile medical applications ("mHealth apps") available on the market has more than doubled in recent years with incredible potential for expanding access to healthcare. However, it is difficult for the FDA to regulate mHealth apps under its traditional medical device regulations because these apps have rapid commercial cycles that respond to technological innovation.

The FDA has therefore chosen to employ a Software PreCertification Pilot Program ("PreCert Program"), where it plans to regulate mHealth apps by preapproving the developer rather than the product. This Note argues that the PreCert Program is an effective policy to sidestep regulatory issues for mHealth apps, so long as the FDA adopts certain measures to protect consumers and encourage innovation.

First, this Note explains how the FDA defines mHealth apps to demonstrate how the FDA has incorporated them into existing medical device regulations. Second, this Note summarizes existing medical device law to provide a baseline from which to compare the new PreCert Program, which this Note argues is better positioned to regulate mHealth apps. Third, this Note outlines safety risks that mHealth apps pose to patients. Fourth, this Note explains problems and barriers that existing medical device regulations impose on the mHealth industry. Fifth, this Note describes the PreCert Program and examines comparable approaches that Japan's Pharmaceuticals and Medical Device Agency has employed. Finally, this Note explains how the FDA can implement the PreCert Program to efficiently regulate mHealth apps while ensuring that it both promotes digital health innovation and secures patient safety.

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INTRODUCTION

On September 14, 2017, the Food and Drug Administration (FDA) approved the marketing and use of reSET, the first prescription-only smartphone application (app) to treat substance use disorders.[1] In its press release, the developer, Pear Therapeutics, touted its accomplishment as "the first time that the FDA has cleared a Prescription Digital Therapeutic with claims to improve clinical outcomes in a disease."[2] And indeed, this was a watershed moment in the mHealth industry.

Through reSET, physicians have access to a dashboard that displays patients' self-reported substance-use triggers, cravings, and outcomes, and further enables physicians to remotely provide those patients with outpatient cognitive behavioral therapy via a connected smartphone app.[3] Specifically, the app teaches patients practical skills to help them adhere to outpatient programs and

1. Press Release, Pear Therapeutics, Pear Therapeutics Obtains FDA Clearance of the First Prescription Digital Therapeutic to Treat Disease (Sept. 14, 2017) [hereinafter Pear Press Release], https://peartherapeutics.com/fda-obtains-fda-clearance-first-prescription-digital-therapeutic-treat-disease.

2. *Id.*

3. *See* Matt Hoffman, *FDA Permits Marketing of reSET Mobile App for SUD Treatment*, MD MAG. (Sept. 14, 2017), http://www.mdmag.com/medical-news/fda-permits-marketing-of-reset-mobile-app-for-sud [https://perma.cc/P5FE-HMRF]; Sy Mukherjee, *FDA Clears the First-Ever Mobile App to Treat Alcohol, Marijuana, Cocaine Addiction*, FORTUNE (Sept. 14, 2017), http://fortune.com/2017/09/14/fda-alcohol-marijuana-cocaine-mobile-app/ [https://perma.cc/ETY9-5MS9].

abstain from alcohol, marijuana, cocaine, and other stimulants, whilst they receive traditional outpatient therapies, such as face-to-face counseling.

To support its submission of reSET to the FDA, Pear Therapeutics evaluated reSET in a twelve-week clinical trial, where 399 patients received either standard face-to-face counseling coupled with a desktop version of reSET or face-to-face counseling alone.[4] The results were striking—40.3% of patients who used the standard treatments and reSET together remained abstinent, compared to only 17.6% of those who used the standard treatments alone.[5] While Pear Therapeutics did not design reSET to treat opioid addiction, reSET-O, another version of the app, is in development for this purpose.[6] Apps that treat schizophrenia (Thrive) and general anxiety disorder (reVIVE) are also in Pear Therapeutics' product pipeline.[7]

Currently, the mHealth industry is burgeoning, as the FDA predicts that 50% of the more than 3.4 billion smartphone and tablet users will have downloaded an mHealth app by 2018.[8] The number of iOS mHealth apps available in the United States have more than doubled from 2013 to 2015.[9] As of 2016, 62% of managed care organizations—that is, health care insurance organizations that contract with providers to control cost and increase the quality of health care—offer mHealth services to their members.[10]

mHealth apps can serve a range of functions. Some consumers use mHealth apps for health maintenance purposes, such as tracking exercise and diet.[11] These health maintenance apps are not the focus of this Note because they are not regulated by the FDA. When this Note references "mHealth apps," it is referring to those apps, such as reSET, that are sophisticated enough to essentially change a mobile device into a medical device. Unlike health maintenance apps, mHealth apps are regulated by the FDA.

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4. Pear Press Release, *supra* note 1.
5. Hoffman, *supra* note 3.
6. Pear Press Release, *supra* note 1.
7. *Id.*
8. *Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medicaldevices/digitalhealth/mobilemedicalapplications/default.htm [https://perma.cc/VZ24-6X8F] (last updated Oct. 8, 2018).
9. *See Number of iOS mHealth Apps Available in the U.S. in 2013 and 2015*, STATISTA, https://www.statista.com/statistics/624146/health-apps-available-ios-us/ [https://perma.cc/YC9P-LMS5] (displaying the increase of iOS mHealth apps available; 90,088 in 2015).
10. *Percentage of Managed Care Organizations (MCOs) in the U.S. Offering Mobile Health Member Services in 2016*, STATISTA, https://www.statista.com/statistics/544722/mobile-health-services-usage-by-managed-care-organizations/ [https://perma.cc/P9SU-S2HE].
11. *See Primary Reasons for U.S. Internet Users to Access Mobile Health and Fitness Apps as of March 2014*, STATISTA, https://www.statista.com/statistics/298033/us-health-and-fitness-app-usage-reasons/ [https://perma.cc/JX9K-D8N2].

The FDA has historically regulated mHealth apps using traditional medical device guidelines, which require a lengthy application process.[12] However, this approach does not adequately accommodate mHealth apps because they have rapid commercial cycles that respond to technological advancement.[13] Recently, the FDA's Software PreCertification Pilot Program (PreCert Program) proposed to regulate software that performs a medical device function (SaMD) by preapproving the developer rather than the product.[14] SaMD is a general term for software that is used for a medical purpose but is not part of a hardware medical device.[15] SaMD includes mHealth apps, and while this Note discusses the PreCert Program's implications for the mHealth industry specifically, the PreCert Program will apply to all SaMD.

This Note argues that the PreCert Program is an effective model for regulating mHealth apps so long as the FDA adopts certain measures to accomplish the goals of promoting patient safety and supporting a faster rate of innovation for mHealth apps.[16] These measures include: (1) requiring pre-certified software developers to reapply after a specified period, (2) establishing specific criteria to evaluate whether those developers demonstrate quality and organizational excellence, (3) promulgating security requirements, and (4) offering accessible avenues for patients to report safety and efficacy concerns with products.

Section I of this Note defines mHealth apps within the FDA's regulatory purview and explains how the FDA has examined them under medical device regulation. Section II of this Note summarizes pertinent medical device law, looking specifically at the Food, Drug, and Cosmetic Act's (FDCA) § 510(k) clearance and at which types of mHealth apps are expressly excluded by the 21st Century Cures Act. Section III of this Note outlines the risks that mHealth apps pose for patient safety. Section IV of this Note explains problems that existing medical device regulations pose for mHealth apps.

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12. *See* U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 6–7 (2015) [hereinafter 2015 GUIDANCE].

13. *See* JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION 5–8 (2010), http://www.medtecheurope.org/sites/default/files/resource_items/files/01112010_FDA%20impact%20on%20US%20medical%20technology%20innovation_Backgrounder.pdf [https://perma.cc/V365-YDJF] (stating that the cost for participants to bring a 510(k) product from concept to market was approximately $31 million, with $24 million spent on FDA activities).

14. U.S. FOOD & DRUG ADMIN., DEVELOPING SOFTWARE PRECERTIFICATION PROGRAM: A WORKING MODEL: VERSION 0.2, at 5–6 (2018) [hereinafter WORKING MODEL].

15. *Software as a Medical Device (SaMD)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DigitalHealth/SoftwareasaMedicalDevice/default.htm [https://perma.cc/4YCH-SEV6] (last updated Aug. 31, 2018).

16. *See* Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program, 82 Fed. Reg. 35,216 (proposed July 28, 2017) [hereinafter Precertification Pilot Program], for the FDA's approach towards spurring innovation.

Section V of this Note describes the PreCert Program, examines comparable approaches employed by Japan's Pharmaceuticals and Medical Device Agency (JMDA), and explains how medical malpractice and products liability actions may serve as an outside regulator of mHealth. Finally, that section explains how the FDA can implement the PreCert Program to efficiently regulate mHealth apps.

I. WHAT ARE mHEALTH APPS?

In conducting its oversight, the FDA covers mHealth apps under the FDCA's "device" definition.[17] Section 321(h) of the FDCA defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . ."[18]

Section 201(h) covers an mHealth app if it is intended either "to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated medical device."[19] Covered apps use "a mobile platform's built-in features such as light, vibrations, camera, or similar sources, to perform medical device functions."[20]

For example, Seattle-based Senosis Health created HemaApp, which estimates hemoglobin concentrations by harnessing the light from a phone's camera flash and shining it through the patient's finger to analyze the color of a patient's blood without drawing blood from the patient.[21] In clinical trials, the app had a 69% correlation to a patient's complete blood count test.[22] To compare, the Masimo Pronto, an FDA-approved, non-mHealth medical device, had an 81% correlation to the blood test.[23] Senosis Health was also developing SpiroSmart, an app that measures lung function by having a patient blow into a smartphone microphone.[24] Senosis Health was seeking FDA approval for these mHealth apps before the company was acquired by Google's health science arm,

17. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h) (2012).
18. *Id.*
19. 2015 GUIDANCE, *supra* note 12, at 7.
20. *Id.* at 27.
21. Jennifer Langston, *HemaApp Screens for Anemia, Blood Conditions Without Needle Sticks,* UW NEWS (Sept. 7, 2016), http://www.washington.edu/news/2016/09/07/hemaapp-screens-for-anemia-blood-conditions-without-needle-sticks/ [https://perma.cc/F4X5-LS3E].
22. *Id.*
23. *Id.*
24. Jonah Comstock, *Alphabet Acquires Senosis, a Stealthy Health App from Serial Entrepreneur Shwetak Patel*, MOBI HEALTH NEWS (Aug. 15, 2017), https://www.mobihealthnews.com/content/alphabet-acquires-senosis-stealthy-health-app-serial-entrepreneur-shwetak-patel [https://perma.cc/GVA2-BKHC].

Verily.[25] Verily is expected to continue to develop smartphone sensor-based technology.[26]

II. THE FDA REGULATES mHEALTH APPS UNDER MEDICAL DEVICE LAW

This section examines the FDA's current guidance for mHealth apps to establish context for the upcoming regulatory changes. Part (A) explains the risk categorization and how mHealth apps fit into it, including both the substantial equivalency process under FDCA § 510(k) and the Premarket Approval process under FDCA § 515. Part (B) then explains how the 21st Century Cures Act excludes certain mHealth apps from FDA oversight.

In its 2015 guidance, "Mobile Medical Applications," the FDA confirmed that it would apply the same risk categorization to mHealth apps that it uses for medical devices.[27] Though it is non-binding, the FDA prefers to use guidance in its oversight of SaMD—it is easier to modify than a binding rule and ultimately enables the FDA to better keep pace with changing technologies.[28] Manufacturers likewise prefer guidance and almost always adhere to it, both because it helps them avoid civil liability, and because it is more flexible than a set of rigid regulations.[29] Even with the PreCert Program, risk categorization will continue to be an important tool to regulate mHealth because lower risk devices will be permitted to proceed to commercial distribution, while high-risk devices can proceed after streamlined premarket review.[30]

A. FDA Risk Categorization and mHealth Apps

The FDA currently regulates mHealth apps as medical devices under three categories.[31] First, there are low-risk devices, also known as Class I, which are subject to "general controls."[32] These controls include self-registration with the FDA, reporting

25. David Meyer, *Google's Latest Acquisition Is All About App-Based Diagnosis,* FORTUNE (Aug. 14, 2017), http://fortune.com/2017/08/14/google-health-diagnosis-senosis/ [https://perma.cc/Z2XP-76TV].

26. Donovan Jones, *Google Verily Unit Acquires Senosis Health*, SEEKING ALPHA (Aug. 14, 2017), https://seekingalpha.com/article/4098698-google-verily-unit-acquires-senosis-health [https://perma.cc/WNC4-BHKL].

27. *See* 2015 GUIDANCE, *supra* note 12, at 6–7.

28. Y. Tony Yang & Ross D. Silverman, *Mobile Health Applications: The Patchwork of Legal and Liability Issues Suggests Strategies to Improve Oversight,* 33 HEALTH AFF. 222, 224 (2014).

29. *Id.*

30. U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN 5–7 (2017) [hereinafter ACTION PLAN].

31. *Regulatory Controls*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm [https://perma.cc/93UA-HQNE] (last updated Mar. 27, 2018) [hereinafter *Regulatory Controls*].

32. *Id.*

requirements, and adherence to specific good manufacturing practices, such as adequate packaging and storage.[33] These low-risk mHealth apps are not the focus of this Note because the PreCert Program does not apply to Class I devices.[34]

Second, there are medium-risk devices, also known as Class II and complex Class I, which are subject to both general controls and "special controls."[35] Special controls are device-specific and include performance standards, post-market surveillance, and special labeling requirements.[36] The FDA evaluates most medium-risk devices by determining whether a device is "substantially equivalen[t]" or similar to a previously cleared device, so that it raises no new concerns of safety and effectiveness.[37] If the device is found to be substantially equivalent, a manufacturer can proceed to commercial distribution.[38] This substantial equivalency evaluation is referred to as "510(k) clearance."[39] This test is not difficult to overcome—over 90% of medium-risk devices meet substantial equivalency without reliance on new clinical data.[40] Moreover, FDA regulation provides that 510(k) clearance is required when the device "is about to be significantly changed or modified" in a way that "could significantly affect the safety or effectiveness of the device."[41]

Accu-Chek Connect, Roche's diabetes management app, is an example of an mHealth app subject to 510(k) clearance.[42] The app is categorized as a Class II device because it calculates personalized insulin dosages.[43] Upon approving the app under 510(k) clearance, the FDA issued a summary illustrating its similarity to the already-FDA-approved Accu-Chek Aviva Combo insulin calculator.[44] That summary considered certain similarities between the apps: target

33. *See* 21 C.F.R. § 820.20 (2018); *see also id.*

34. *See* WORKING MODEL, *supra* note 14, at 9 (stating that non-device software functions are not subject to regulation and are not within the scope of the Software Precertification Program).

35. 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, 6 (2014).

36. *See* 21 C.F.R. § 820.20; 21 C.F.R. § 820.30 (referring to special controls as "design controls" in the text); *Regulatory Controls*, *supra* note 31.

37. Kramer et al., *supra* note 35.

38. *See id.* (finding substantial equivalence to an existing product raises no new safety concerns and results in no further impediments to commercial distribution).

39. *See 510(k) Clearances*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ [https://perma.cc/8EVE-H2XN] (last updated Sept. 4, 2018).

40. Kramer et al., *supra* note 35.

41. 21 C.F.R. § 807.81(a)(3)(i) (2018).

42. Letter from Tina Kiang, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Chunhong Tao, Regulatory Affairs Specialist, Roche Diagnostics Corp. (Mar. 16, 2015), https://www.accessdata.fda.gov/cdrh_docs/pdf14/K141929.pdf [https://perma.cc/4PUT-3CVE].

43. *See id.* (describing the 510(k) process and indicating that the Accu-Chek Connect app is a Class II drug dosing calculator).

44. *Id.*

patient group, intended uses, the fact that both require the same information to calculate dosages, and that both apps are prescription only.[45] Weighing these factors, the FDA determined that the app met substantial equivalency.[46] Roche is currently testing an mHealth app that is designed to complement physician-led assessments for Parkinson's disease by measuring symptom fluctuations and severity.[47] Because the device uses smartphone sensors to measure the degree of tremor caused by a certain disease, it too is classified as a Class II and will be subject to 510(k) clearance.[48]

Finally, there are high-risk, or Class III, devices which must be approved through a Premarket Approval Application.[49] Class III devices are those designed to either support or sustain human life or prevent impairments to human health.[50] These devices may also present a potential unreasonable risk of illness or injury.[51] An FDA grant of a Premarket Approval requires that the applicant have enough scientific evidence and clinical data to assure that the device is safe and effective for its intended uses.[52] A Premarket Approval operates as a private license granting the applicant permission to market the device.[53]

The table on the following page provides a simplified explanation of the FDA's risk categorizations, showing its existing regulatory approval procedures and an example of an mHealth app that would be classified in each category.

The medical device risk categorization discussed above will continue be significant for mHealth apps undergoing precertification, because the FDA will continue to evaluate apps under the risk categorization in determining what level of review to accord a pre-certified developer's product.[54] Part B will discuss certain types of mHealth apps, which the legislature has decided to exclude from the FDA's jurisdiction under the 21st Century Cures Act.

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45. *Id.*

46. *Id.*

47. *Roche Technology Measures Parkinson's Disease Fluctuations*, ROCHE, https://www.roche.com/media/store/roche_stories/roche-stories-2015-08-10.htm [https://perma.cc/466V-MFG4] [hereinafter *Parkinson's Fluctuations*].

48. *See* 21 C.F.R. § 882.1950 (2018); 2015 GUIDANCE, *supra* note 12, at 28.

49. *Regulatory Controls*, *supra* note 31.

50. *Id.*

51. *Id.*

52. *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm [https://perma.cc/JH2N-FQ82] (last updated Sept. 27, 2018) [hereinafter *Premarket Approval*].

53. *Id.*

54. *See, e.g.*, WORKING MODEL, *supra* note 14, at 20 ("The premarket review for a precertified organization's SaMD product would be informed by the organization's precertification status, precertification level, and the SaMD's risk-category.").

TABLE: FDA RISK CATEGORIZATION

	Class I – Low Risk	**Class II – Medium Risk**	**Class III – High Risk**
Regulatory Approval Procedure	General controls: includes self-registration, reporting requirements, and Good Manufacturing Practices, such as adequate packaging and storage.[55]	General Controls; Special Controls: device specific; includes performance standards, post-market surveillance, and special labeling requirements. 510(k) clearance: finding of 'substantial equivalency' to a previously cleared device.[56]	Premarket Approval Application: FDA will determine that the device is safe and effective for its intended uses, based on scientific evidence and clinical data.[57]
mHealth Example	Mobile apps that convert a smart phone camera into an Otoscope.[58]	Drug Dosing Calculators, including Accu-Chek Connect App. Tremor Transducers, including Roche's Parkinson's Disease Management App.[59]	Mobile apps that calibrate, control, or change settings of a cochlear implant.[60]

55. *Regulatory Controls*, *supra* note 31.
56. Kramer et al., *supra* note 35, at 5–7, 17–18.
57. *Premarket Approval*, *supra* note 52.
58. 2015 GUIDANCE, *supra* note 12, at 31; *see also* April Cashin-Garbutt, *Turning a Smartphone into an Otoscope*, NEWS MED. LIFE SCI. (Feb. 13, 2017), https://www.news-medical.net/news/20170213/Turning-a-smartphone-into-an-otoscope.aspx [https://perma.cc/LA93-PUBY].
59. *See Accu-Chek Connect App*, ROCHE, https://www.accu-chek.com/apps-and-software/connect-app [https://perma.cc/2K87-JD8E]; *Parkinson's Fluctuations*, *supra* note 47.
60. 2015 GUIDANCE, *supra* note 12, at 29.

B. 21st Century Cures Act Exclusions

Anticipating a growing mHealth market, Congress passed the 21st Century Cures Act to amend the FDCA and exclude certain software functions from FDA jurisdiction, including software used for (1) administrative support of a health care facility; (2) maintaining or encouraging a healthy lifestyle; and (3) electronic patient records, if they are unrelated to "the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition."[61] For example, apps like Apple's "Health" app or the "Fitbit" app, which track users' steps and exercise habits, are excluded under the amendment.[62] These excluded devices were not likely covered to begin with, because they are lower-risk devices, and electronic patient records are subject to Health Insurance Portability and Accountability Act (HIPAA) requirements.[63]

However, the 21st Century Cures Act does not exclude mHealth apps that transform a mobile platform into a regulated medical device.[64] For example, SpiroSmart—a spirometer device that measures the volume of gas that a patient takes in when they inhale—is not excluded under the 21st Century Cures Act; the FDA regulates it as a Class II device.[65] It is important to note that clinicians utilize apps such as SpiroSmart to diagnose, treat, and prevent medical conditions and disorders, which increases the risk of an adverse event.[66] Therefore, the FDA will continue to regulate moderate- and high-risk apps.

III. TYPES OF RISK TO PATIENT SAFETY POSED BY mHEALTH APPS

When this Note discusses risk, it refers to the probability of an event occurring that causes harm and the probability that that

61. 21st Century Cures Act, Pub. L. No. 114-255, § 3060, 130 Stat. 1033, 1130–31 (2016) (codified as amended at 21 U.S.C. § 360j(o) (2012)).

62. *See* 2015 GUIDANCE, *supra* note 12, at 15–18 (indicating the types of mobile apps for which the FDA does not intend to enforce requirements under the FDCA because they pose a low risk to patients).

63. *See* U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 2–3 (2016) (commenting that the FDA will not regulate general wellness products, including those that promote healthy weight, encourage healthy eating, and that promote physical fitness, such as to help log, track, or trend exercise); *id.*

64. *See* 21st Century Cures Act § 3060.

65. 21 C.F.R. § 868.1850 (2018); *see also* discussion *supra* Section II.A (explaining risk categorization and substantial equivalency).

66. *See* Thomas Lorchan Lewis & Jeremy C. Wyatt, *mHeath and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use,* 16 J. MED. INTERNET RES. 210, 210 (2014), ("[M]any app developers have little or no formal medical training and do not involve clinicians in the development process and may therefore be unaware of patient safety issues raised by inappropriate app content or functioning."); *see also* discussion *supra* Section II.A.

harm is severe.[67] In medicine, a bad outcome for the patient does not necessarily mean that the care or the medical device was deficient or at fault.[68]

The risks of mHealth apps fall into two categories: (1) those inherent to the app, and (2) those arising due to external factors, such as how the app is used.[69]

Developers are in the best position to control risks inherent to the app, which are the most easily addressed through regulation or guidance.[70] mHealth apps must be accurate and reliable, as physicians and patients often use information obtained from these apps to make important healthcare related decisions.[71] Indeed, an app that is performing a complex task or an inherently dangerous function and is inaccurate or fails to perform poses a greater danger to consumers.[72] Hence, the FDA focuses on higher-risk devices to protect consumers.[73] For example, in 2014 the FDA recalled the Accu-Chek Connect Diabetes Management App, a Class II device designed to calculate insulin doses, because of a technological glitch that caused the app to calculate the wrong doses.[74] Patients relying on this calculation could have either overdosed or taken an insufficient dose of insulin and suffered from potentially life-threatening hyperglycemia.[75]

The second category of risk includes those that arise from factors outside of the developer's control: use by the wrong person, inappropriate use, or inadequate training of users to recognize a patient safety hazard.[76] These risks are aggravated when an app's errors go undetected, when an app is used by a greater number of users, or when there is a higher number of uses per day.[77] A recent study revealed that these risks are less concerning than those in

67. As defined by Lewis & Wyatt, *supra* note 66.

68. *See* Gallardo v. United States, 752 F.3d 865, 871 (10th Cir. 2014) (finding that a medical malpractice claim requires more than proving a poor outcome; a breach of the applicable standard of care is required).

69. Lewis & Wyatt, *supra* note 66.

70. *See id.*

71. *Id.*

72. *Id.*

73. *See* discussion *supra* Section II.A.

74. *Class 2 Device Recall ACCUCHEK Connect Diabetes Management App*, U.S. FOOD & DRUG ADMIN. (Apr. 2, 2015), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=134687 [https://perma.cc/QZ2V-PS8P] (summarizing the ACCUCHEK Connect recall for an issue where turning the iPhone from a vertical orientation to a landscape orientation lead to incorrect doses).

75. *See generally* Amy Hess-Fischl, *Hyperglycemia: When Your Blood Glucose Level Goes Too High,* ENDOCRINEWEB, https://www.endocrineweb.com/conditions/hyperglycemia/hyperglycemia-when-your-blood-glucose-level-goes-too-high [https://perma.cc/96CU-5XL4] (last updated Sept. 7, 2018) (finding that people with diabetes may become hyperglycemic if they don't keep their blood glucose level under control by, for example, taking sufficient insulin before meals).

76. *See* Lewis & Wyatt, *supra* note 66.

77. *Id.*

the app's code or inherent design: only 2.6% of the apps sampled pose realistic dangers related to improper use.[78]

Though less concerning than developer-side risks, external-factor risks are more pronounced in certain situations. In particular, the risks are more acute when an app is used to provide care to vulnerable populations.[79] For example, a recent study observed twenty-six Medicare, Medicaid, or uninsured patients while using popular apps to manage three medical conditions: depression, diabetes, and geriatric care.[80] Participants expressed interest in using the apps but also expressed a lack of confidence in mobile technology and frustration in attempting to use the apps in the study.[81] Finding that the usability of the apps was suboptimal, the study suggested that there is a need for participatory design, testing, and training with patients.[82]

Against that backdrop, the FDA should continue to take steps to enhance the usability and efficacy of mHealth. The PreCert Program offers an effective framework to prevent or mitigate risks inherent to a mHealth app, because it provides the FDA with tools to scrutinize the app's developer, while leaving room for the FDA to encourage mHealth app usability.

IV. PROBLEMS WITH REGULATING mHEALTH APPS UNDER MEDICAL DEVICE LAW

Traditional approaches to regulate medical devices pose hurdles for mHealth apps and their developers by (1) delaying the innovation and introduction of novel technology, and (2) imposing market-entry hurdles that lock out smaller companies and start-ups.[83]

Because mHealth apps have commercial cycles that are more compressed than those in non-software medical devices, the lengthy FDA Premarket Approval process frustrates technological innovation.[84] Specifically, according to the FDA, the process takes

78. LINDA WILHELMINA MARIA VAN KERKHOF ET AL., CHARACTERIZATION OF APPS AND OTHER E-TOOLS FOR MEDICATION USE: INSIGHTS INTO POSSIBLE BENEFITS AND RISKS, 4 JMIR MHEALTH & UHEALTH 34, 34 (2016) (stating that only 2.6% of the 116 sampled apps were found to have realistic dangers related to inappropriate use or misuse).

79. URMIMALA SARKAR ET AL., USABILITY OF COMMERCIALLY AVAILABLE MOBILE APPLICATIONS FOR DIVERSE PATIENTS, 31 J. GEN. INTERNAL MED. 1417, 1424 (2016), (suggesting that mHealth apps have "significant usability barriers for diverse populations with chronic conditions").

80. *Id.* at 1420.

81. *Id.* at 1424.

82. *Id.* at 1417 (concluding that "[a]pp developers should employ participatory design strategies in order to have an impact on chronic conditions such as diabetes and depression that disproportionately affect vulnerable populations").

83. *See* MAKOWER ET AL., *supra* note 13, at 28.

84. *Id.* at 34.

nine months from application to filing; however, developers report that the process actually takes closer to fifty-four months from their first contact with FDA officials.[85] In this context, the Premarket Approval impedes the "release and revise" strategy that technology developers generally rely on to update software, fix bugs, and improve performance after an initial product release.[86] Although the approval process is designed to thoroughly vet medical devices and enhance patient safety, it locks developers into an early product model so that even when an improved version of an app is available it cannot be released.[87] This leads to a device lag, which hurts patients who may otherwise benefit from using a relevant mHealth app.[88]

Existing medical device regulations also exclude smaller companies and start-ups from the mHealth market because of the high costs involved in Premarket Approval. FDA guidance sets the Premarket Approval user fee at $322,147.[89] The 510(k) clearance has less expensive user fees set at $10,953.[90] Small firms can qualify for reduced user fees—$80,537 and $2,738 for Premarket Approval and 510(k) clearance, respectively—if they have gross sales of $100 million or less for the most recent tax year.[91] Small businesses with gross sales less than $30 million qualify for a one time waiver of Premarket Approval user fees.[92] However, because the pre-approval process can be difficult to navigate, applicants often must supplement their Premarket Approval application with new information to account for novel technologies.[93] In this scenario, applicants must pay the initial fee, in full, again.[94] Since the software industry necessitates constant updates, the cost of these fees is a massive hurdle to smaller developers. However, the actual costs to bring a product to market are likely higher—a Stanford University report suggests that the average cost to bring

85. *Id.* at 22.

86. Vera Gruessner, *Mobile Health Industry Faces Safety and Security Challenges,* MHEALTH INTELLIGENCE (Sept. 30, 2015), https://mhealthintelligence.com/news/mobile-health-industry-faces-security-and-safety-challenges [https://perma.cc/8VUV-ZJNA].

87. *Id.*

88. MAKOWER ET AL., *supra* note 13, at 31.

89. *FY 2019 MDUFA User Fees*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm615142.htm [https://perma.cc/EFQ6-FLVS] [hereinafter *User Fees*].

90. *Id.*

91. *Medical Device User Fees*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm540444.htm#fees [https://perma.cc/99RA-ULCX] (last updated Oct. 1, 2018).

92. *User Fees*, *supra* note 89.

93. *See PMA Supplements and Amendments*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm050467.htm [https://perma.cc/E4V8-FRY2] (last updated Sept. 27, 2018).

94. *User Fees*, *supra* note 89.

a Premarket Approval product from concept to market averages $94 million, with $75 million spent on FDA regulatory hurdles.[95] The report notes that less than one in four medical technology startups succeed and half of investment returns are less than $100 million.[96]

By requiring developers to undergo a protracted application process and to pay high user fees for both their initial application and for later supplements, the FDA's existing framework does not harmonize with the mHealth industry's innovative nature.

V. PRECERTIFICATION IS A VIABLE REGULATORY SOLUTION FOR mHEALTH APPS

In 2016, the 21st Century Cures Act mandated that the "Secretary [of Health and Human Services] . . . establish a program to expedite the development of, and provide for the priority review for, devices . . . that represent breakthrough technologies for which no approved or cleared alternatives exist."[97] On July 27, 2017, the FDA unveiled the PreCert Program to develop a new approach toward regulating mHealth by evaluating the developer rather than the product.[98]

The PreCert Program employs a firm-based approach, whereby the FDA "pre-certifies" eligible digital health developers that "have demonstrated a culture of quality and organizational excellence," based on objective demonstration of five excellence principles, as identified by the FDA: (1) patient safety, (2) product quality, (3) clinical responsibility, (4) cybersecurity responsibility, and (5) proactive culture.[99] Any organization that intends to develop or market software that performs a medical device function in the United States would fall within the scope of the PreCert Program. Companies may define the boundaries of their organization themselves to determine the business unit or center of excellence that should be considered for precertification.[100] The FDA intends to pre-certify companies in two levels in order to accommodate companies of different sizes and levels of maturity.[101] Under "Level 1," a company with demonstrated excellence in the five excellence principles with limited experience in developing products in the health care industry may develop and market lower risk products

95. *See* MAKOWER ET AL., *supra* note 13, at 7 (detailing a survey which revealed that the cost for participants to bring a 510(k) product from concept to market was approximately $31 million, with $24 million spent on FDA activities).

96. *Id.*

97. 21st Century Cures Act, Pub. L. No. 114-255, sec. 3051, § 515C, 130 Stat. 1033, 1121–22 (2016) (codified as amended at 21 U.S.C. § 360e-3(b) (2012)).

98. WORKING MODEL, *supra* note 14, at 5–6.

99. *Id.* at 10.

100. *Id.* at 13.

101. *Id.* at 18–19.

without review.[102] Level 1 further enables companies to more easily develop moderate- to high-risk products under a streamlined review process.[103] Under "Level 2," a company with demonstrated excellence in the five excellence principles and a successful track record in the health care industry may develop and market certain low- and moderate-risk products without review. Level 2 allows companies to bring high-risk products to the marketplace under a streamlined review process.[104]

On September 26, 2017, the FDA announced that it had selected nine companies from over 100 applicants to participate in the pilot PreCert Program, including Pear Therapeutics, Roche, Verily, and Apple.[105] Many of these companies are currently developing mHealth products that meet the FDCA's definition of a medical device.[106] To assess the pilot program's performance, companies have agreed to disclose measures of quality and organizational excellence real-world post-market performance data, and information regarding their quality management systems to the FDA.

The PreCert Program may ultimately replace Premarket Approval as the FDA approval process for certain pre-certified manufacturers. However, other countries are also working to streamline approval for mHealth. The Japanese government has chosen an alternative approach, where they provide conditional approval for devices based on data from early phase trials.[107] A comparison between Japan's "Conditional Early Approval" framework and the PreCert Program is instructive in identifying the PreCert Program's advantages.

A. A Cross-Cultural Comparison with Japan

Examining the approach employed in another country, Japan, buttresses this analysis of the PreCert Program, because it helps to inform the measures that this Note proposes. While no other country uses manufacturer precertification to regulate mHealth, the Pharmaceuticals and Medical Devices Agency ("JMDA") employs a comparable procedure that includes manufacturer

102. *Id.*
103. *Id.*
104. *Id.*
105. *Digital Health Software Precertification (Pre-Cert) Program*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/ucm567265.htm [https://perma.cc/9SQ3-B7X8] (last updated Sept. 27, 2018).
106. *Id.*
107. Douglas Sipp, *Conditional Approval: Japan Lowers the Bar for Regenerative Medicine Products,* 16 CELL STEM CELL 353, 353 (2015) (discussing the conditional early approval process implemented by PMDA in 2015 to facilitate early approval for regenerative medicine).

registration and facility inspections.[108] First, this section provides context for Japan's regulatory regime. Then, it will describe Japan's registration processes and quality management systems for developers' manufacturing facilities. Finally, it will discuss Japan's novel "Conditional Early Approval" program as an alternative to the PreCert Program in the United States.

Asia has seen growth comparable to the United States in the use of mHealth apps.[109] In 2015, Apple and IBM announced that they would partner with Japan Post, Japan's largest Health Insurance Company, to provide iPads with preloaded mHealth apps to senior citizens to help them lead healthier lives.[110] The iPad includes a number of vision and hearing accessible apps that are designed to help seniors with an array of tasks; they remind seniors to take medicine, connect them with physicians, and provide other family functions, such as FaceTime with loved ones.[111] The Apple-IBM-Japan Post partnership is intended to expand Japan Post's pre-existing practice of sending representatives to check on older patients at their homes.[112]

On November 25, 2014, the Japanese Government revised the Japanese Pharmaceutical Affairs Law and implemented the Pharmaceutical and Medical Device Act (PMD Act), which expressly encompasses mHealth.[113] The JMDA now regulates software that is "installed in a general-purpose PC or handheld terminal [like a smartphone]."[114] Japan regulates medical devices using a risk categorization similar to that used in the United States, except Japan uses Class IV to categorize medical devices that are potentially fatal in the event of a malfunction.[115]

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108. *Id.*

109. *E.g.*, *Mobile Health and Devices Poised for Boom*, BCC RES. (May 22, 2017), http://globenewswire.com/news-release/2017/05/22/994510/0/en/Mobile-Health-and-Devices-Poised-for-Boom.html [https://perma.cc/XE4A-AAX5] (stating that North America and Asia-Pacific predict 29% and 27.5% respective compound annual growth rate in mHealth from 2016–21).

110. Matthew Herper, *Can Apple and IBM Change Health Care? Five Big Questions*, FORBES (Apr. 30, 2015), https://www.forbes.com/sites/matthewherper/2015/04/30/five-big-questions-about-apple-and-ibms-japanese-ipad-giveaway/#593511932622 [https://perma.cc/M4WR-42N9] (stating that giving out iPads with the correct apps may help seniors, especially those with chronic conditions to lead more independent lifestyles).

111. *See* Darrell Etherington & Anthony Ha, *Apple and IBM Team with Japan Post to Address the Needs of an Aging Population,* TECHCRUNCH (Apr. 30, 2015), https://techcrunch.com/2015/04/30/apple-ibm-japan-post/ [https://perma.cc/X5EA-7778] (noting that Japan's rapidly aging population motivates this kind of move).

112. *Id.*

113. Keiichiro Ozawa, Regulatory Specialist, Fujifilm Corp., Presentation at the 4th Joint Conference of Taiwan and Japan on Medical Products Regulation: Software Regulation and Validation 4 (Dec. 7, 2016), https://www.pmda.go.jp/files/000215558.pdf [https://perma.cc/Q92A-2MEB].

114. *Id.* at 5.

115. *See id.*; *Medical Device Classification Consulting and Japan JMDN Code Research,* EMERGO, https://www.emergobyul.com/services/ japan/medical-device-

The JMDA requires high-risk mHealth manufacturers to register their production facilities—those where mHealth products are designed, assembled, sterilized, and distributed—with its agency before they can undergo Quality Management Systems (QMS) inspections.[116] Both registration and QMS inspections must occur in order for companies to apply for the JMDA's equivalent to the FDA's Premarket Certification (for Class II) or Premarket Approval (for Class III and IV).[117] During the registration process, the JMDA may examine information about the staff (including the curriculum vitae of the plant manager); the products (including product life cycle, raw materials used, and packaging, labeling, and product distribution); and the facility (including drawings, pictures, and floor plans).[118]

After registration, the JMDA conducts a QMS inspection.[119] If the manufacturer's facility has already received QMS approval for another device of an equal or greater risk class, a second inspection is not required.[120] Because the PMD Act allows for streamlined QMS inspections, if a device poses a minimal risk to patients the JMDA may conduct a QMS inspection for groups of products (rather than individual products) or it may choose a desktop inspection (rather than an on-site inspection), based on submitted documents, reported adverse events and recalls, and previous QMS inspection results.[121] This is comparable to the FDA's PreCert Program, because the agency trusts a manufacturer enough to allow it to avoid the burden of subsequent inspections when that manufacturer seeks approval of a new product. Albeit, this trust is restrained in order to protect consumers; the JMDA may conduct random inspections if quality problems are reported.[122]

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classification-jmdn-codes [https://perma.cc/GRB5-LFSR].

116. PHARM. & MED. DEVICES AGENCY, QMS REGULATION IN JAPAN 16 (2015) [hereinafter PMDA QMS], https://www.pmda.go.jp/files/000203966.pdf [https://perma.cc/EH66-UUWW].

117. *See Japan Regulatory Approval Process for Medical Devices*, EMERGO, https://www.emergogroup.com/resources/japan-process-chart [https://perma.cc/M9V8-ZQNR] (last updated June 16, 2017) (outlining regulatory process for all device classifications in Japan).

118. *See* PHARM. & MED. DEVICES AGENCY, APPLICATION FOR ACCREDITATION OF FOREIGN MANUFACTURERS 3 (n.d.), https://www.pmda.go.jp/files/000153619.pdf [https://perma.cc/TYM9-6YAH]; *id.* at 17; *see also Medical Device Registration in Japan*, PAC. BRIDGE MED., http://www.pacificbridgemedical.com/regulatory-services/medical-device/product-registration/japan/ [https://perma.cc/YCU2-XFYJ].

119. Ames Gross & John Minot, *Japanese Audits and Accreditation for Foreign Device Manufacturers,* MED. DEVICE & DIAGNOSTIC INDUSTRY (Oct. 1, 2007), https://www.mddionline.com/japanese-audits-and-accreditation-foreign-device-manufacturers [https://perma.cc/Q5WN-X6NF].

120. *Id.*

121. PMDA QMS, *supra* note 116, at 28–29 (considering factors including product complexity and past on-site inspection results).

122. *Id.*

Despite these sophisticated procedures, the JMDA has been criticized for slow approval times, which can extend years longer than those in the United States and Europe.[123] To combat these slow approval times and to accommodate the rapid growth of mHealth in Japan, the JMDA is in the process of expediting premarket review through more efficient standards.[124]

Particularly, Japan has developed a "Conditional Early Approval" process for innovative medical devices, which allows JMDA to approve medical devices for public use at an accelerated rate by minimizing the burden of clinical trials and enhancing post-market surveillance.[125] This accelerated process enables devices to attain market approval when data from early phase trials suggests that the device is safe for the public.[126] Manufacturers must (1) submit a post-market risk management plan at the time review is first sought, and (2) implement post-market risk measures after early approval is granted.[127] The process allows for a revision of the application after patients use the mHealth app in the marketplace for a period of time.[128]

While Japan might offer Conditional Early Approval as an alternative procedure to the PreCert Program, Conditional Early Approval may be ill-equipped to safeguard patients from risks and adverse events.[129] Specifically, early phase trials do not offer conclusive evidence for product safety, and it is difficult to test products in randomized clinical trials on a post-market basis.[130] Indeed, researchers criticized this method after it was employed for regenerative medicine and caused ineffective products that were not approved in other countries to enter the Japanese market.[131]

The FDA's PreCert Program is the more effective option because, like Conditional Early Approval, it facilitates approval

123. Tetsuya Tanimoto, *A Perspective on the Benefit-Risk Assessment for New and Emerging Pharmaceuticals in Japan,* 9 DRUG DESIGN, DEV. & THERAPY 1877, 1881 (2015) (discussing research indicating that drug lag is caused by uniform drug pricing in Japan).

124. Ozawa, *supra* note 113, at 17.

125. *See* Pharm. & Med. Devices Agency, Presentation at Int'l Med. Device Regulators Open Stakeholder Forum: Japan Update (Sept. 2017) [hereinafter 2017 Japan Update], http://www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-170919-canada-presentation-jurisdictional-update-japan.pdf [https://perma.cc/7GG8-XPRH] (announcing the implementation of Conditional Early Approval).

126. *See* Sipp, *supra* note 107 ("[C]linical trial sponsors now have the option to seek market approval for up to 7 years for regenerative medicine products for which data from early phase trials demonstrate safety and are 'likely to predict efficacy.'").

127. 2017 Japan Update, *supra* note 125, at 7.

128. *Id.*

129. *See* Sipp, *supra* note 107 (discussing inherent problems in Conditional Early Approval).

130. *Id.* at 354 ("The difficulties in testing products in randomized clinical trials on a post-market basis are well known.").

131. *Id.* ("This open-ended approach may leave Japan with a new set of medical products unrecognized by other countries due to efficacy concerns.").

with minimized clinical trials but only for a handful of manufacturers who have been vetted according to a preexisting standard, which, together, facilitates the commercial distribution of innovative products. Moreover, the PreCert Program's consideration of an mHealth app's risk categorization ensures that high-risk apps will continue to receive some scrutiny.[132] Nonetheless, the PreCert Program can be distinguished from Japan in three ways. First, it focuses principally on the manufacturers, who may be pre-certified if they excel in software design, development, and testing.[133] Second, it allows low- to moderate-risk devices to be marketed without additional FDA review and high-risk devices to receive streamlined Premarket Approval.[134] Finally, it enables the FDA to collect real world data about product use.[135] Ultimately, the PreCert Program is a promising avenue to regulate mHealth apps by safeguarding patient safety, while promoting the business interests of companies introducing innovative products.[136]

B. The FDA Should Adopt Four Measures to Improve the PreCert Program by Protecting Consumers and Encouraging Innovation.

Because the PreCert Program is novel and its potential for success is unknown, this Note argues that the FDA should adopt four measures to ensure that it accomplishes its goal: promoting mHealth innovation while securing patient safety.[137] Specifically, the FDA should (1) allow itself to review and revoke non-compliant manufacturers, (2) establish clear objective criteria for quality and organizational excellence, (3) enforce reporting requirements, and (4) ensure that the PreCert Program's application process is economical and efficient to promote innovation.

First, the FDA should revoke a developer's precertification under the PreCert Program if there is evidence that product quality has slipped below the initial precertification standards. The FDA's current working model of the PreCert Program states that maintaining PreCert status would be "automatic," but that "[o]rganizational leadership would track and monitor its adherence to the excellence principles, and ensure safe and effective operation of their devices by responding appropriately to postmarket indicators, including adverse events."[138] This guidance does not state whether the FDA will police compliance with these excellence

132. WORKING MODEL, *supra* note 14, at 20–24.
133. *See* ACTION PLAN, *supra* note 30, at 4–5.
134. *Id.* at 5.
135. *Id.*
136. *See* discussion *infra* Section V.B.
137. *See* Precertification Pilot Program, *supra* note 16, at 35, 216–17.
138. WORKING MODEL, *supra* note 14, at 19.

principles itself, but it does place the burden of tracking compliance on the companies themselves.[139] Enforcement frameworks that encourage compliance solely through technical and financial support, education, and other inducements do not lead to compliance in all cases; indeed, research has demonstrated that a certain degree of coercion may be necessary to prevent actors from taking advantage of a regulator's leniency.[140] Because precertification conveys a profit-saving advantage to manufacturers who can avoid costly regulatory oversight, revocation should not be an empty threat where evidence suggests that a developer has failed to meet quality standards, its precertification should be revoked.[141] While the threat of revocation will require companies to staff additional compliance professionals, this cost will be marginal in comparison to the tens of millions of dollars currently spent in application fees and clinical testing to attain traditional Premarket Approval and 510(k) approval.[142] Alternatively, the FDA could have mandatory expiration and require companies to reapply after a set time period. However, requiring continuous scrutiny through the application process defeats the purpose of promoting efficiency and lowering the costs of approval, because this would require companies to surpass regulatory hurdles and pay application fees again and again.

The proposal to revoke or expire a developer's precertification may pose constitutional problems. Under the Fifth and Fourteenth Amendments the FDA may need to provide adequate notice in order to revoke.[143] For example, in *Air North America,* the Department of Transportation revoked an airline's certificate of authority to provide air transportation because the airline was dormant and did not provide its "fitness" information in accordance with the applicable regulation.[144] The Ninth Circuit determined that the revoked certification was considered a license under the broad language of § 551(8) of the Administrative Procedure Act ("APA"),

139. *Id.*

140. *See, e.g.*, Ulrike Weske et al., *Using Regulatory Enforcement Theory to Explain Compliance with Quality and Patient Safety Regulations: The Case of Internal Audits,* 18 BMC HEALTH SERVICES RES. 62 (2018) (showing that catalytic enforcement actions based on suggestions and dialogue are insufficient, unless companies are motivated to comply, and recommending that coercive regulatory action based on punishment may be needed to motivate actors).

141. *Cf.* ACTION PLAN, *supra* note 30, at 5 (requesting that developers take further action to ensure continued quality standards; "firms that take advantage of their 'pre-cert' status could collect real-world data postmarket that might be used, for example, to affirm the regulatory status of the product").

142. *See* MAKOWER ET AL., *supra* note 13, at 28 (arguing that complying with regulatory obligations greatly impacts the total cost to bring a medical device to market).

143. U.S. CONST. amend. V ("No person shall . . . be deprived of life, liberty, or property, without due process of law . . . ."); U.S. CONST. amend. XIV, § 1 ("[No state shall] deprive any person of life, liberty, or property, without due process of law . . . .").

144. Air N. Am. v. Dep't of Transp., 937 F.2d 1427, 1431 (9th Cir. 1991).

which thus required the agency to give notice of the violation, the parameters of acceptable conduct, and a second chance to comply.[145] However, the court held that the airline was not entitled to a hearing because there were no factual issues to resolve.[146] Nonetheless, if the precertification is considered a license under § 551(8) of the APA, section 558(c) may also require notice of the violation, the parameters of acceptable conduct, and an opportunity for compliance.[147] Whether hearings are required is a case-specific inquiry.[148]

Second, the FDA should develop objective criteria that are easily accessible online, in order to address complaints that existing regulatory frameworks are "unpredictable and characterized by disruptions and delays."[149] The agency intends to review this criteria during the initial appraisal process in which precertification is awarded and to require companies to evaluate compliance during post-market monitoring.[150] The FDA has formulated five excellence principles: (1) patient safety, (2) product quality, (3) clinical responsibility, (4) cybersecurity responsibility, and (5) proactive culture.[151] Based on responses to a public docket, the FDA has included twelve tenets as elements of the excellence principles: (1) leadership and organization, (2) transparency, (3) people, (4) infrastructure and work environment, (5) risk management, (6) configuration management, (7) measurement, analysis, and continuous improvement of processes and products, (8) managing outsourced processes, activities, and products, (9) requirements management, (10) design and development, (11) verification and validation, (12) deployment and maintenance.[152] This indicates that the agency intends to be transparent in its methods of appraising companies for precertification, which will comprise of a deeper analysis of all levels of the product's life cycle.

While it is unclear how these excellence principles and their tenets will be examined to appraise developers, a PricewaterhouseCoopers Strategy and Consulting Team report provides examples of systems that promote product quality and further recommends that medical device developers adopt these tenets as they yield a quantitative commercial benefit.[153] To make

145. *Id.* at 1437–38.

146. *Id.* at 1434 ("[A]n agency need not conduct a factual hearing if there are no factual questions to resolve." (quoting Georgia-Pacific Corp. v. EPA, 671 F.2d 1235 (9th Cir. 1982))).

147. *See* 5 U.S.C. §§ 551(8), 558(c) (2012).

148. *See Air N. Am.*, 937 F.2d at 1438.

149. MAKOWER ET AL., *supra* note 13, at 6.

150. *See* WORKING MODEL, *supra* note 14, at 14–16.

151. *Id.* at 10.

152. *Id.* at 14–15.

153. *See* MARCUS EHRHARDT ET AL., MEDICAL DEVICE QUALITY: AN ESSENTIAL CAPABILITY AND COMPETITIVE EDGE FOR MANUFACTURERS (2013), https://www.

this determination, the report observes the rising incidence of product failures in the medical device industry and identifies three causes: "a siloed, reactive approach to quality; a lack of focus on continuous improvement; and the ever-increasing complexity of medical devices."[154] The report suggests that manufacturers take three actions to alleviate these quality issues.[155] First, manufacturers should implement "critical-to-quality management" systems that identify essential design features for product quality and further ensure that those features are implemented into the design and manufacturing specifications.[156] Second, forward-thinking "systems engineering" should be incorporated into manufacturing processes to ensure that "medical device components and the processes that produce them behave as anticipated when they are brought together."[157] Third, a manufacturer should adopt guided design policies so that a product reliably satisfies the most important physician and patient needs to be met by the product.[158] Requiring companies to consider the needs of diverse patient populations through actions, such as participatory design, may augment the benefits of this.[159]

These three actions appear to satisfy several of the tenets expressed in the PreCert working model with which the FDA intends to appraise companies for precertification.[160] For example, the FDA intends to evaluate a company's "risk management" or how effectively and regularly that company examines "how software works by understanding, identifying, and proactively anticipating potential issues and factors that can influence what can go wrong with the software."[161] Likewise, the FDA intends to both evaluate "measurement, analysis, and continuous improvement of processes and products" by "actively monitoring, analyzing, rapidly addressing, and implementing resulting process improvements from user feedback and product issues," and report such knowledge obtained from real world data to development teams.[162] Finally, the FDA intends to evaluate "design and development," which includes "[d]esigning software based on . . . clinical evidence [and] peer-reviewed studies . . . [i]ncorporating anticipated safety risks and mitigations throughout all lifecycle

strategyand.pwc.com/media/file/Strategyand_Medical-Device-Quality.pdf [https://perma.cc/53BU-ZQY6].

154. *Id.* at 4.
155. *Id.* at 12.
156. *Id.*
157. *Id.* at 13.
158. *Id.* at 13–14.
159. *See* SARKAR ET AL., *supra* note 79, at 1417–26.
160. *See* WORKING MODEL, *supra* note 14, at 36–41.
161. *Id.* at 38.
162. *Id.*

phases," and implementing a "[s]ecure, prompt, and agile update mechanism and process."[163] While these explanations provided in the working model are useful for defining the contours of the excellence principles, this Note recommends that the FDA adopt detailed guidance regarding their appraisal process for precertification.

Moreover, the FDA should actualize its expressed intention to evaluate a developer's organization—its infrastructure, its people, and its product development process—throughout a product's lifecycle by physically inspecting facilities where mHealth apps are designed and manufactured. Such inspection could be similar to what is required for registration and QMS inspections under JMDA's approach.[164] This inspection must include an analysis of the professional and educational backgrounds of those designing the product, to make certain that they are well qualified and to establish a public record in the event of litigation.

Third, the FDA should use the data collection, mandating, and reporting requirements as tools to correct inadequate and difficult-to-enforce post-market clinical trials, as used in Conditional Early Approval in Japan.[165] The FDA contends these requirements will occur after precertification and commercial distribution, and will comprise of three analyses: (1) real-world health analytics such as usability engineering, clinical safety, and health benefits; (2) user experience analytics such as user satisfaction, issue resolution, user feedback channels, and user engagement; and (3) product performance analytics such as product performance and cybersecurity.[166] The FDA already employs Medical Device Reporting as a tool to monitor device performance and detect device-related safety issues once that product is marketed and used by patients.[167] Medical Device Reporting both requires mandatory reporters, such as manufacturers, device user facilities, and importers, to report adverse events and other issues regarding their products to the FDA and also facilitates voluntary reports about serious adverse events associated with a medical device, use errors, product quality issues, and therapeutic failures.[168] These processes will continue to be valuable in weeding out companies failing to abide by the excellence principles. Moreover, in fulfilling their reporting requirements, PreCert Program participants should have

163. *Id.* at 40.

164. *See* PMDA QMS, *supra* note 116.

165. *See* Sipp, *supra* note 107 (discussing difficulty in testing products in clinical trials on a post-market basis).

166. *See* WORKING MODEL, *supra* note 14, at 31.

167. *Medical Device Reporting (MDR),* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm [https://perma.cc/Y597-HH4H] (last updated Sept. 25, 2018).

168. *Id.*

to describe the specific design features and manufacturing processes that lead to effective and reliable results. Because this reporting requirement will result in detailed information on a device's performance—good or bad—when used by patients, it may provide evidence to indicate whether a company is struggling to abide by the excellence principles.

Fourth, the FDA must assure that the PreCert Program's application process is faster and less expensive than the traditional Premarket Approval and 510(k) approaches, which will help remove market barriers and enable more smaller firms and start-ups to enter the marketplace.[169] Correspondingly, if smaller firms and start-ups are able to develop and market mHealth products, the increased competition may pressure companies to explore innovative ways to lower prices and improve the quality of products.[170] Lowering the administrative burden through lower application fees and less stringent clinical testing requirements will foster greater access to high quality mHealth products.[171]

C. Alternative Remedies for Patients

Because the PreCert Program is based on the FDA's trust in the engineering capabilities of app developers, opponents might express concern that the PreCert Program alone is insufficient to assure that only high-quality products are approved. These dangers are mitigated, however, by medical malpractice liability and products liability against the developer—both are an effective check to prevent poor quality mHealth products from flooding the market.[172]

Malpractice liability has and will continue to play an important role in controlling when and how physicians and other health care professionals use mHealth apps, since prescribers may be liable for failing to use an mHealth product or for prescribing or recommending an app that injures a patient.[173] Physicians play an

169. *See* MAKOWER ET AL., *supra* note 13, at 8 (arguing that fewer medical device start-ups are being launched in the U.S. and innovators and medical device companies are relocating to other countries).

170. *See* EHRHARDT ET AL., *supra* note 153, at 4; *see also* Chris Llewellyn et al., *Capturing the New 'Value' Segment in Medical Devices,* MCKINSEY & COMPANY (Jan. 2015), https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/capturing-the-new-value-segment-in-medical-devices [https://perma.cc/83NV-TC7X] (discussing innovative avenues in which medical device manufacturers can trim costs).

171. *See* EHRHARDT ET AL., *supra* note 153.

172. *See* Yang & Silverman, *supra* note 28, at 225–26.

173. *See* Nicolas P. Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS OF HEALTH L. 62 (2016) (discussing how providers may be liable for medical malpractice if they use mHealth apps incorrectly, failing to make use of data provided by mHealth apps, participating in the design of an unsafe app, or recommending an app fall beneath the standard of care).

important role in regulating mHealth products, because they understand what risks and benefits a particular product may have for an individual patient and possess knowledge and professional judgment to determine whether to use a particular app.[174] Moreover, a physician has a duty to employ the same reasonable diligence, skill, and competence as a minimally competent practitioner in the same general specialty when providing medical care to a patient; failure to do so exposes them to malpractice liability.[175] If the PreCert Program is expanded, evidence that a professional prescribed or recommended an mHealth app that fails to meet the FDA's excellence principles may be evidence of negligence in a medical malpractice action.[176] Additionally, a physician who suspects that an mHealth app has caused an adverse event has an ethical responsibility to report that product to the FDA.[177]

While many Class II devices pose only minor risks of serious injury, more patient injuries may result as innovation enables developers to create mHealth apps that perform more advanced functions. Patients may pursue legal remedies if they have suffered injuries caused by a physician's negligent actions.[178] Alternatively, a patient may claim that a physician's failure to provide informed consent led them to use a course of treatment that they would not have otherwise chosen.[179] Specifically, if a physician wants to use an mHealth app to treat a patient, that physician must obtain the patient's consent after informing them of the purpose, nature, and risks of the proposed treatment, along with viable alternatives.[180] This will mitigate risks arising from external factors, such as those related to the patient and their knowledge of the app.[181]

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174. *Id.*; *see also* MAKOWER ET. AL., *supra* note 13, at 23.

175. Nalder v. W. Park Hosp., 254 F.3d 1168, 1176 (10th Cir. 2001).

176. *See* Andrew E. Costa, *Negligence Per Se Theories in Pharmaceutical & Medical Device Litigation*, 57 ME. L. REV. 51, 77 (2005) ("Those states that regard statutory violations as negligence per se and regulatory violations as only evidence of negligence suggest the problem.").

177. *Opinion 9.032 - Reporting Adverse Drug or Device Events*, 13 AM. MED. ASS'N J. ETHICS 627–28 (2011).

178. Yang & Silverman, *supra* note 28, at 225 ("Malpractice claims require proof that a physician owed a duty of care to a patient and deviated from it, with the patient being injured as a result.").

179. *See* Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972) ("'[E]very human being of adult years and sound mind has a right to determine what shall be done with his own body. . . .' True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible." (quoting Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (1914))).

180. *Id.*

181. *See* Lewis & Wyatt, *supra* note 66.

Patients may also pursue legal remedies from manufacturers in products liability actions.[182] However, the landscape is unclear. FDA guidance defines an mHealth app manufacturer as "anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components."[183] This poses a broad range of possible defendants for aggrieved patients.[184] The FDA likely employed this wide definition to account for the difficulty in pinpointing the exact cause of defects in mHealth devices, because an array of separate pieces of equipment are connected across different wireless networks and platforms.[185] Manufacturers have expressed concern over this issue, and this may be an area for further legislation.[186]

Standing alone, medical malpractice and products liability actions are probably an insufficient means to regulate mHealth apps. However, in conjunction with the PreCert Program, these remedies perform a regulatory role by holding physicians and companies accountable for failures to exercise proper care.

CONCLUSION

This Note argues that the PreCert Program is a promising solution for mHealth, a burgeoning industry that is struggling to evolve under traditional medical device regulations. The PreCert Program has the potential to replace Premarket Approval, which delays mHealth developers for many months and costs developers hundreds of thousands (if not millions) of dollars. Consequently, the PreCert Program may promote innovation and encourage market-entry for large and small firms, and start-ups. It may also shorten the review cycle for mHealth apps and combat device lag, which harms patients who could otherwise benefit from convenient and medically advantageous mHealth apps.[187]

Nonetheless, the PreCert Program is experimental, and its level of success remains to be seen. This Note argues that the FDA should adopt proper protections, including effective review

182. Greg Ryan, *Mobile Medical Apps Invite New Breed of Product Suits,* LAW360 (Apr. 3, 2013, 8:40 PM), https://www.law360.com/articles/429830/mobile-medical-apps-Invite-new-breed-of-product-suits [https://perma.cc/FUP9-7URC].

183. 2015 GUIDANCE, *supra* note 12, at 9.

184. *See* Ryan, *supra* note 182.

185. *Id.* (noting that when separate pieces of equipment are connected over wireless networks or platforms in mHealth apps, it may be difficult to locate the exact cause of a defect).

186. *Id.*

187. Jeffrey Shapiro, *When it Comes to Software as a Medical Device, FDA Acknowledges that New Technology No Longer Fits the Old Regulatory Paradigm,* THOMSON REUTERS (Sept. 19, 2017), http://hymanphelps.info/wp-content/uploads/2017/09/WLJ_MED-2415-Shapiro.pdf [https://perma.cc/ZSG2-CJT7].

procedures, clear and objective ways to satisfy excellence principles, effective post-market and reporting requirements, and prioritizing cost and time efficiency. These protections will minimize risks to patients, while ensuring that the PreCert Program fulfills its ambition to encourage medical software innovation.

The PreCert Program will ultimately enable the FDA to trust the engineering capabilities of software developers demonstrating a culture of quality and organizational excellence. If software developers can satisfy these standards, they are rewarded with the ability to market mHealth under an accelerated process.